O'Neill Institute

for National and Global Health Law

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REVIEW OF MONTANA'S FOOD SAFETY LAWS
WHITE PAPER: ISSUES, OPTIONS AND RECOMMENDATIONS

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A. INTRODUCTION

This Paper outline the issues which need to be addressed in the reform of the parts of Montana's food safety system which are within the jurisdiction of the Department of Public Health and Human Services in Montana, and our recommendations for the reform of the laws which relate to these aspects of food safety. The Paper does not address other laws concerning food safety in Montana, such as those within the jurisdiction of Department of Livestock.

This Paper specifically addresses governance, standards, and compliance and enforcement issues for Montana's food safety system. The issues to be addressed in the Paper have been identified through our analysis of Montana's food safety statutes and administrative rules and through our discussions with Montana's Food and Consumer Safety Study Group on 29 October 2008, 3 December 2008 and 8 January 2009. During these discussions, the Study Group identified the aspects of Montana's food safety laws which function well or those which are deficient. They also identified where the laws are silent on matters which are essential to the proper operation of Montana's food safety system.

In section C below, we briefly outline each issue which needs to be addressed. We have opted to only briefly explain the issues because our document 'Using the Public Health Framework: A Detailed Analysis of the Food Safety Laws in Montana' sets out some of the issues in considerable detail. Furthermore, many of the issues are well understood by the key stakeholders in Montana and do not need extensive elaboration.

For each of the issues which are identified, we either present a single recommendation for addressing the problem in question or we present several options for resolving the problem. In some instances, we have drafted statutory language which could be used by Montana if it were to adopt our recommendation for responding to the issue in question. The statutory language is set out in a shaded box.

Our recommendations and options have been developed by using the public health framework and principles which are discussed in the document 'Public Health Framework for Reviewing the Montana Code and Administrative Rules for Food and Consumer Safety'. We presented the first draft of the document at our meeting with the Study Group on 29 October 2008. We presented a slightly revised draft of the document at the meeting with the Study Group on 3 December 2008. The Study Group endorsed the public health framework and principles as the approach to be used in reviewing and reforming Montana's food safety laws.

It should be noted that the Paper offers recommendations in accordance with the limits imposed on state regulatory authority by the current system of federal food safety regulation. There are numerous shortcomings with the federal food safety laws which, in turn, impact on what can be achieved under state law.

The recommendations and options set out in this Paper need to be scrutinized by the Study Group and other relevant stakeholders in Montana with a view to reaching a decision about the content of Montana's new food safety laws. The recommendations and options need to be considered in conjunction with Montana's other statutes and administrative rules to ensure consistency between different laws and policies. We have not reviewed our recommendations for their overall consistency with Montana's statutes and administrative rules.

B. TERMINOLOGY

In this Paper, the following terms are defined as follows:

1. *Department:* means the Montana Department of Public Health and Human Services;
2. *Local public health agency*: means an organization operated by a local government in the state, including local boards of health or local health officers, that principally acts to protect or preserve the public health (definition taken from MCA 50-1-101(9));
3. *Food safety*: means the conditions for assuring that food which is provided to the public is safe and honestly presented and is not capable of causing foodborne illness;
4. *Food safety system*: means the Montana Department of Public Health and Human Services and the local public health agencies and their public and private sector partners. It does not include aspects of food safety which are within the jurisdiction of other departments in Montana such as the Department of Livestock and Department of Environmental Quality;
5. *Food safety laws*: means the statutes and administrative rules relating to food safety which are within the jurisdiction of the Montana Department of Public Health and Human Services and the local public health agencies. It does not include aspects of food safety which are within the jurisdiction of other departments in Montana such as the Department of Livestock and Department of Environmental Quality;
6. *Administrative hearing*: means a hearing before a decision-maker appointed by the food safety agencies.
7. *Judicial hearing*: means a hearing before a court.

We have used the terminology from the current food safety laws for 'food establishments', such as 'retail food establishments', 'food service establishments' and 'wholesale food establishments'. We do propose new terminology for these establishments, but for the sake of clarity, we do not use this new terminology in the Paper.

C. ISSUES FOR DISCUSSION AND DECISION

1) Structure of the food safety laws

a) **Issue:** Should the current structure of the food safety laws be maintained? At present, there are food safety laws in, for example, the Food, Drug and Cosmetics Act ('FDCA') and rules, the Retail Food Establishments Act and rule, the Wholesale Food Establishments Act and rules, the Schools rules, the Hotels, Motels and Rooming Houses rules, the Bed and Breakfast Establishments rules etc. Should all the laws be in one statute and one set of rules? Or should they be separated out into different statutes as they are now?

b) **Recommendation:** Montana should adopt a single food safety statute. This would require repeal of the FDCA, the Retail Food Establishments Act, the Wholesale Food Establishments Act and specific food safety provisions in statutes such as those relating to B & Bs, hotels, motels etc. (Ideally, the new statute would incorporate provisions which are found in statutes not currently within the jurisdiction of the Department, such as those within the authority of Department of Livestock. However, our recommendation only related to the food safety laws within the jurisdiction of the Department.) In this single food safety statute, there would be sub-chapters for governance (including topics such as the purpose, mission, and principles of the food safety laws, the powers and duties of the food safety agencies, the requirement for collaboration between the food safety agencies and other agencies), food standards (from the FDCA), retail food establishments, wholesale food establishments, and compliance and enforcement, etc. B & Bs, hotels, motels etc could be governed by the laws relating to retail food establishments, but if there needed to be special laws to cover B & Bs, hotels, motels etc, these provisions could be in a separate sub-chapter of the statute. The advantage of this format would be to offer a single reference point for food safety laws.

2) Purpose and mission, and functions

a) **Issue:** The public health purpose and mission of the food safety system could be made clearer in the statute. This purpose and mission could then guide the drafting and implementation of all food safety laws.

b) **Recommendation:**

i) In the first sub-chapter of the food safety statute, we recommend the inclusion of a provision which states the policy and mission goal of

Montana's food safety agencies be included. A option for the provision is:

Purpose
(1) It is the policy of the state of Montana that the food safety system should promote and protect the health of the public to the greatest extent practicable.

Mission
(2) The mission of the Department and the local public health agencies is to ensure that food provided to the public is safe and honestly presented and to prevent foodborne illness by:

(a) developing and implementing an integrated food safety strategy for Montana;
(b) developing and enforcing laws which promote food safety and respond to food safety problems;
(c) developing policies, plans and programs which promote food safety and respond to food safety problems;
(d) conducting foodborne illness surveillance and investigations;
(e) informing and educating persons operating, and working in, food establishments about food safety and their responsibilities for ensuring food safety;
(f) informing and educating the public about food safety;
(g) collaborating with public sector partners at the federal, state, local and tribal levels to promote food safety and respond to food safety problems;
(h) collaborating with private sector partners in the food safety system to promote food safety and respond to food safety problems;
(i) implementing programs for effective consumer involvement in the development and improvement of the food safety system;
(j) reviewing and making changes to the food safety system to improve its effectiveness;
(k) providing a competent food safety workforce; and
(l) seeking adequate funding and other resources to increase their capacity to achieve their mission.

Principles
(3) In carrying out this mission, the Department and the local public health agencies shall observe the following principles at all times:

(a) the Department and the local public health agencies shall work to prevent the occurrence of situations of unsafe and improperly labeled food being provided to the public, and foodborne illness;
(b) all decisions made by the Department and the local public health agencies regarding food safety shall be based on the best available scientific evidence; and
(c) all decisions regarding food safety shall seek to achieve a high level of

protection of health.

ii) We note the following about the draft provision:

(1) We have sought to draft the provision to synchronize with the content and language of Montana's general public health laws in MCA 50-1-105.

(2) We have sought to incorporate the agreed guiding principles from the Public Health Framework and Guiding Principles, including the role of industry, the role of consumers, the use of the best available science, the pursuit of a high level of health protection, prevention of injury and illness, and continuous improvement.

3) Relationships between agencies in the food safety system

a) Issue: There are several aspects to this issue of the relationship between the agencies involves in food safety in Montana and outside of Montana. The different angles on this issue are set out below:

i) Relationship between the Department AND local public health agencies: You have told us that it is not always clear whether the Department or the local public health agencies have the power or the responsibility to perform a specific function. For example, should the local public health agency have the power to write food laws to apply at the local level or should this be a state function? For example, should the local public health agency have the power to interpret state food laws?

ii) Relationship between the Department/ local public health agencies AND other public sector agencies in Montana: At present, the food safety laws in Montana do not make proper reference to the power and the duty of the Department and the local public health agencies to collaborate with other public sector agencies in Montana. In relation to wholesale food establishments, MCA 50-57-104 states 'the Department may enter into cooperative agreements with other state agencies and political subdivisions of the state to carry out the provisions of this chapter.' The same provision appears in MCA 50-50-104 in relation to retail food establishments. We understand that 'other state agencies' and 'political subdivisions of the state' includes city, county and local boards of health and other departments and agencies in the state. The Department and the local public health agencies need to be empowered and required to pursue collaborative relationships with intra-state agencies. In Montana, the Department of Environmental Quality and the Department of Livestock have responsibility for some important aspects of food safety, being, respectively, water and meat/ poultry/ milk/ eggs. Cooperation with these agencies is vital to creating a safe food supply.

iii) Relationships between the Department/ local public health agencies AND federal, inter-state and tribal agencies: As noted

immediately above, the provisions in the MCA do not make unambiguous provision for relationship-building between the Department and the local public health agencies and federal, tribal, inter-state food safety agencies. Collaborations with all of these agencies is essential, particularly in order to conduct surveillance and respond to foodborne illness outbreaks

b) Recommendation:

i) We strongly recommend that Montana introduce a new provision which cross-references MCA 50-1-106 which requires that the Department and the local public health agencies to work collaboratively with each other, other public sector agencies in Montana, and federal, inter-state and tribal governments and agencies to further the food safety mission. All of these agencies are necessary for the protection and promotion of the safety of the US food supply. The interplay of these disparate agencies at the federal, state, local and tribal level can improve the operation of the food safety system, if they carry out their functions in a collaborative and complementary manner. Whilst the existence of a duty or a power in statute will not create the collaborative relationships which are necessary for a successfully integrated food safety system, it will, firstly, create an expectation that the food safety agencies at all levels pursue such relationships. To this end, we recommend that Montana consider enacting a version of the provision in MCA 50-1-106 as follows:

Collaborations and relationships for food safety

(1) In carrying out the food safety mission, the Department and the local public health agencies shall comply with their obligation in 50-1-106.

(2) The Department shall be the contact point for federal, inter-state, and tribal food safety agencies which seek to work with the Department and the local public health agencies to further the food safety mission.

(3) The Department may enter into cooperative agreements with other state agencies in Montana and political subdivisions of the state of Montana to carry out the provisions [of this chapter].

(4)The Department and the local public health agencies shall jointly determine the division of roles and responsibilities between the Department and the local public health agencies in the food safety system. In doing so, each local public health agency shall have the same role and responsibilities as every other local public health agency.

(5) Any local public health agency may enter agreements with other local public health agencies in the state to coordinate the provision of food safety services and functions consistent with Title 50, chapter 2, and this chapter. The local public health agency shall submit any agreement entered into pursuant to this section to the Department.

(6) The Department may enter an agreement with any federal agency to coordinate the provision of food safety services and functions.

(7) The Department may enter an agreement with any other state or

any agencies in any other state to coordinate the provision of food safety services and functions among the states that are parties to the agreement.

(8) A local public health agency whose jurisdiction extends to a state border may form an agreement with an adjoining state or a municipality in the other state to coordinate the provision of food safety services and functions. The local public health agency shall submit any agreement entered into pursuant to this section to the Department for prior approval.

(9) The Department or local public health agencies may form agreements with tribes and tribal food safety agencies in the state to coordinate the provision of food safety services and functions or to promote cooperation in addressing specific food safety needs of persons living on Indian reservations or Indians who reside outside the boundaries of Indian reservations.

ii) We note as follows about the relationship between **the Department and the local public health agencies** in the draft provision:

(1) There is no constitutional or statutory law which constrains the division of responsibilities between the Department and local public health agencies. This is not a legal issue but a policy issue for Montana about the respective roles of the Department and the local public health agencies. The new statute and rules can be drafted to reflect the policy decisions made about the optimal allocation of powers and duties between the Department and the local public health agencies in Montana.

(2) The Department is given the power in the draft provision to enter into cooperative agreements with, amongst others, local public health agencies in Montana.

(3) We strongly recommend that the roles and responsibilities between the Department and the local public health agencies be clearly divided and that the agreement about this division be included in the new statute and/ or the rules and/ or an agreement between the Department and the local public health agencies. There may be some allocation of roles and responsibilities which can be made permanently (and can therefore be put in the statute or the rules), whereas there may be some allocation of roles and responsibilities which needs to be revisited at annual or biennial intervals and which are linked to specific conditions such as resources or remuneration (and which would therefore be better in an agreement between the Department and the local public health agencies).

(4) We recommend that the same division of roles and responsibilities apply to the Department and *all* local public health agencies and that there are not some local public health agencies with more powers and duties than other local public health agencies. We suggest that it creates greater clarity in the food safety system for there to be consistency in the division of powers and duties.

(5) We also recommend that roles and responsibilities be divided so as to avoid both the Department and a local public health agency having a role in decision which could be competently made by one of these agencies on its own, unless there is a sound basis for both agencies being involved in a particular matter. For example, the current licensing regime involves the local public health agencies and the Department in the decision about whether to grant a license for a food establishment. This is very cumbersome and arguably a waste of scarce resources.

(6) On the substance of the division of powers between the Department and the local public health agencies, we strongly recommend that the Department be solely responsible for setting the food safety standards which should apply throughout Montana. We do not consider it appropriate that different standards for food safety apply in different parts of Montana. Uniformity across the state is very important for the protection of the public health. We also consider that if Montana were to adopt a state-wide approach to food safety standards and if Montana were to base its standards on the federally-published standards, this would contribute to some national consistency in food safety standards.

(7) On the substance of the division of powers, we also strongly recommend that the same compliance and enforcement procedures be used across Montana. This is another area in which local differences should not lead to differences in the availability of important compliance and enforcement mechanisms and procedural safeguards.

(8) We recommend that any provisions regarding the technical aspects of the relationship between the Department and the local public health agencies, such as cooperative agreements between the Department and the local public health agencies, performance standards for local public health agencies, payments to local public health agencies and the special revenue account, should be included in the rules. These matters of operational detail should not be in the statute.

iii) We note as follows about the relationship between **the Department/the local public health agencies and other public sector agencies in Montana** in the draft provision:

(1) The draft provision cross-references 50-1-106(1) that the Department, the local public health agencies and *other public sector agencies* in Montana shall establish strong working relationships with each other. The purpose of these relationships is furthering the food safety mission. This provision is intended to create a legal obligation on the part of the agencies to work together.

(2) The Department is also given the power in the draft provision to enter into cooperative agreements with, amongst others, other state agencies in Montana.

(3) The draft provision does not set down the substance of the collaborative relationship. It is open to Montana to include in the statute a more particularized provision which requires specific forms of collaboration. You have raised that you are concerned that some other

public sector agencies in Montana license establishments which sell food and that you have had some difficulties obtaining copies of the licenses for those establishments. If agreement could be reached with the other agencies about such a matter, the agreement could be recorded in the statute.

iv) We note as follows about the relationship between **the Department/the local public health agencies and federal, intra-state, tribal, collaborative food safety agencies** in the draft provision:

(1) The draft provision is, like those discussed above, intended to create an obligation and a mandate for increased coordination with the federal and other out-of-state agencies.

(2) The part of the draft provision which identifies the Department as the 'contact point' for work between the federal agencies, inter-state agencies and tribal agencies is intended to respond to criticisms of the lack of coordination between food safety agencies at the different levels. There have been suggestions made that these deficiencies in coordination could be, at least partly, ameliorated by states have a single focal point for food safety collaborations between the state and other agencies. It is not intended that the Department has to coordinate and be a party to all food safety relationships between the state and other agencies. However, having the Department as a contact point makes it easier for agencies outside the state to know the 'entry point' into the food safety system in Montana and enables Montana to have consistency and coherence in its food safety collaborations with external agencies.

4) Food safety advisory council

a) Issue: In MCA 50-50-103(3), there is a requirement that the Department use a food safety task force or an advisory council to assist in the development of administrative rules or proposed legislation and that the Department present proposed administrative rules or legislation to the taskforce prior to their introduction. We understand that no such task force or advisory council exists at present. Should there be provision made for a food safety advisory council in the new statute or rules?

b) Recommendation:

i) We recommend that careful consideration be given to whether Montana wishes to establish a food safety advisory council. We recommend that the statute not provide for the creation of a council, unless a solid institutional and financial commitment is made to the establishment and operation of such a council as soon as the law comes into force. If there is any doubt about the capacity to establish the council, it should not be included in the statute. Montana is not assisted by the current mandatory provision, so should take care with including the same type of provision in the new legislation.

ii) We consider that there would be value to Montana in the establishment of an advisory council if the role and governance system for the council

were properly defined, the council was charged with tasks which are valuable to the Department and the local public health agencies, the council's members were appropriately selected, and the council met at appropriate intervals. Council members could be responsible for soliciting feedback from the groups they represent about the effectiveness of the food safety system, for bringing to the attention of the Department and the local public health agencies, issues or concerns about the food safety system, for offering suggestions for improvement of the food safety system, and for assisting with the development of new food safety rules. The existence of a food safety advisory council may increase the amount of guidance and feedback which the food safety authorities receive. The council mechanism may also be an efficient avenue for the receipt of feedback and constructive criticism, as opposed to contacting individuals or organizations separately for their input.

5) Credentialing and training

a) Issue: MCA 50-50-301(2) provides that 'a person conducting an inspection must be certified and have completed a food safety training program such as the program administered by the national restaurant association educational foundation or its equivalent.' This provision only relates to food safety inspectors. There is no provision which relates to other persons who work in the food safety system to carry out the state's food safety mission.

b) Recommendation:

i) We note that we have made recommendations for changes to this provision as it applies to inspectors in the food safety system: see Issue 13(b) below.

ii) We also recommend that the statute include a provision which addresses the credentialing of all personnel in the Department and the local public health agencies who are involved in carrying out the mission of the agencies. Such a provision should state:

> (1) Consistent with any national system of certification or credentialing for persons working in food safety systems, the Department may adopt food safety certification or credentialing standards for persons working in the Department and the local public health agencies. The standards should be designed to reflect the knowledge, skills and abilities which a person must have in order to competently discharge their duties in furtherance of the food safety mission.
>
> (2) The Department may make available or assure access to effective programs, continuing education, or other tools for training persons working in the Department and the local public health agencies.

iii) This provision make clears that the Department has responsibility for ensuring that persons working in the Department and the local public health agencies have acquired the core competencies to carry out their duties which are necessary for fulfilling the food safety mission of the state of Montana. The provision also makes clear that responsibility of the Department is not only to have personnel complete a certification course, but to ensure that they undergo on-going training which keeps their knowledge and skills current and relevant.

6) Current categories of 'food establishment'

a) Issue: There are currently the categories 'retail food establishment' and 'wholesale food establishments' in Montana's food safety laws. These categories of food establishment are, in turn, defined to include a number of different food establishments. The layers of definition do not make the statutes and rules easy to use. The same terms are sometime used across different food safety laws but with different meanings. This creates confusion. Sometimes, terms are used but with no definition in the statute or the rules. It is very difficult to read Montana's food safety statutes and rules and determine the rules which cover particular categories of food establishment. Is it possible to improve the language of the statute and rules to create greater clarity?

b) Recommendation: The categories of establishments regulated by the statute and rules could be devised as follows based on a version of the definitions in Part 1-2 of the *Food Code*:

Food Establishment:

1) Means an operation that stores, prepares, packages, serves, vends or otherwise provides food for human consumption:
   i) Such as, but not limited to,
      (1) a restaurant or coffee shop or bar;
      (2) a supermarket or food store;
      (3) a satellite or catered feeding location;
      (4) any catering operation if the operation provides food directly to a consumer;
      (5) a market;
      (6) a vending machine;
      (7) a water hauler;
      (8) a conveyance used to transport people;
      (9) a government entity;
      (10) a non-government hospital, school, child day-care provider, and accommodation or care service for children, older persons, persons with disabilities;
      (11) any accommodation available to the public, such as a hotel, motel, rooming house, boardinghouse, bed-and-breakfast establishment;
      (12) a food bank; and

ii) That relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers; and
iii) That includes an element of the operation, such as a transportation vehicle or a central preparation facility that supplies a vending machine or satellite feeding location; and
iv) That includes an operation that is conducted in a mobile, stationary, temporary or permanent facility or location, regardless of whether consumption is on or off the premises and regardless of whether there is a charge for food.

2) Does not include:
   i) Milk producers' facilities, milk pasteurization facilities, milk product manufacturing plants, slaughterhouses, meat packaging plants, meat depots, or producers or harvesters of raw and unprocessed farm products;
   ii) A food processing plant;
   iii) An establishment that offers only prepackaged foods that are not potentially hazardous (time/ temperature control for safety) foods;
   iv) A private organization (except if the organization is a hospital, school, child day-care provider or an accommodation or care service for children, older persons, or persons with disabilities) which serves food only to its members, who have been informed by statements contained in published advertisements, mailed brochures and placards posted at the premises used by the organization that the food is prepared in a kitchen that is not regulated and inspected by the regulatory authority;
   v) A kitchen in a private home if only food that is not potentially hazardous is prepared for sale or service at a function such as a religious or charitable organization's bake sale and if the consumer is informed by a clearly visible placard at the sales or service location that the food is prepared in a kitchen that is not subject to regulation and inspection by the regulatory authority;
   vi) A kitchen in a private home which operates as a small family day-care provider that prepares and offers food to children in the day-care service, if the home is owner occupied, the number of children being cared for does not exceed five, and the parents/ guardians of the children in the day care service are informed by statements contained in materials provided to the parents/ guardians that the food is prepared in a kitchen that is not regulated and inspected by the regulatory authorities;
   vii) A private home that receives catered or home-delivered food;

and
viii) A private home that serves food only to family members and their guests.

Food processing plant:
1) Means a commercial operation that manufactures, packages, labels or stores food for human consumption and provides food for sale or distribution to business entities such as food processing plants or food establishments; and
2) Does not include milk producers' facilities, milk pasteurization facilities, milk product manufacturing plants, slaughterhouses, meat packaging plants, meat depots, or producers or harvesters of raw and unprocessed farm products; and
3) Does not include a food establishment.

Consumer: Means a person who is a member of the public, takes possession of food, is not functioning in the capacity of the operator of a food establishment of food processing plant, and does not offer the food for resale.

i) General comments: 'food establishment'

(1) The definition in para (a) of 'food establishment' is intended to be broad. The definition is intended to cover any operation which serves food to the public directly, or indirectly through a delivery service. This is the key distinction between a 'food establishment' and a 'food processing plant' with the latter only providing food to other food processing plants or to food establishments. A 'food processing plant' does not provide food to consumers.

(2) The definition of 'food establishment' clearly encompasses the concepts which are within the current definition of 'establishment' in the *Retail Food Establishments Act*, such as 'retail food manufacturing establishments', 'food service establishments', 'a meat market', and a 'perishable food dealer'.

(3) The definition also appears able to support the inclusion of a 'water hauler' as defined in the *Retail Food Establishments Act*, however, the term has been explicitly mentioned in sub-para (1)(i)(7) of 'food establishment' to make this clear.

(4) The definition of 'food establishment' is intended to cover the different 'elements' of the operation so it is not just the counter area where the member of public purchases the food or the seating area where the member of the public purchases the food which is covered. It also includes the kitchen where the food is prepared, whether that kitchen is attached to the customer service area or is at a separate site. For example, it is not uncommon for people who own small cafes to do

some food preparation for the café in their home kitchens, such as baking muffins or cookies. Under the definition, the home kitchen is also covered to the extent that it is used to prepare food for the food establishment.

(5) The part of the definition of 'food establishment' in sub-para (1)(iv) makes clear that the definition covers mobile or stationary facilities, permanent or temporary facilities, establishments which provide food for consumption on or off the premises, and establishments which charge or provide food for free.

(6) Sub-para (1)(i) of 'food establishment' are examples only. They are not intended to limit the meaning of 'food establishment' in para (1).

ii) General comments: 'food processing plant'

(1) The definition of 'food processing establishment is 'a commercial operation that manufactures, packages, labels or stores food for human consumption and provides food for sale or distribution to business entities such as food processing plants or food establishments'. This will encompass entities such as a 'wholesale manufacturing establishment', 'wholesale water bottler', 'wholesale food warehouse'. It will include a 'wholesale ice manufacturer' and a 'wholesale food salvage establishment' to the extent that these establishments are not serving consumers. The definition of these terms in the current statute does not make clear that they are not suppliers directly to consumers.

(2) The definition for 'food processing plant' has been developed to fit together with the definition of 'food establishment'. A 'food processing plant' processes food which it provides to other food processing plants or to food establishments. A 'food processing plant' does not provide food to consumers.

(3) The definition of 'food processing plant' has been drafted in accordance with the definitions in the current statute and rules of 'retail food manufacturing establishment' and 'wholesale food manufacturing establishment' so as to exclude 'milk producers' facilities, milk pasteurization facilities, milk product manufacturing plants, slaughterhouses, meat packaging plants, meat depots, or producers or harvesters of raw and unprocessed farm products'. This accords with the division of responsibilities between different state departments in Montana and with the federal and state split of food safety regulation.

iii) Food establishment: Market

(1) **Issue:** Many sellers of products at farmer's markets are currently unregulated in relation to food safety. A farmer's market is defined as 'farm premises, a roadside stand owned and operated by a farmer, or an organized market authorized by the appropriate municipal or county authority. The Department and local health authorities may not adopt rules prohibiting the sale of baked goods and preserves by persons at farmer's markets (§50-50-103 *Retail Food Establishments Act*), nor may they require that these goods be prepared in certified or commercial

kitchens. A license is not required of a gardener, farm owner, or farm operator who sells raw and unprocessed farm products at a farmer's market. A license is not required of a person selling baked good or preserves at a farmer's market (but if the farmer's market is organized by the municipal or county authority, the authority must keep registration records of all individuals and organizations that sell baked goods or preserves at the market: §50-50-202 *Retail Food Establishments Act*). The current definition of 'farmer's market' covers many different operators, including very small, ad hoc stalls that a farmer may set up on the road where they have an excess of produce. However, the definition may also cover commercial operators who have regular stalls at several markets each week. The effect of these laws is that many sellers at a farmer's market may not be licensed (if they only sell farm produce, baked goods or preserves). There is no requirement in the food safety laws that these operators comply with the applicable food safety standards. This means that unsanitary conditions are not prohibited for these retailers under the food safety laws. This is inconsistent with the public health rationale of the food safety laws.

(2) Recommendation: We recommend that all market and farmer's market stall holders are brought within the definition of 'food establishment'. Sub-para (1)(i)(5) of 'food establishment' therefore includes 'a market'. This would mean that all market stalls must be licensed and are required to comply with the applicable food safety laws in offering products for retail.

iv) Food establishment: Government entity

(1) Sub-para (1)(i)(9) of 'food establishment' includes a 'government entity' which would bring government schools, government prisons, government health care facilities which serve food within the definition of 'food establishment'.

(2) The Food and Consumer Safety Study Group has indicated schools and hospitals are currently licensed as 'food establishments'. Montana needs to ensure that this provision is in sync with any other state laws concerning schools or hospitals or other government entities.

v) Food establishment: Non-government entities

(1) Sub-para (1)(i)(10) of 'food establishment' includes 'a non-government hospital, school, child day-care provider or accommodation service for children, older persons, persons with disabilities'.

(2) It may be appropriate to expand this to include other non-governmental entities which serve food to potentially vulnerable populations who do not have the capacity – whether physical or mental, financial or otherwise – to choose where their food comes from.

(3) Exception 1: We recommend that *small* child day-care providers who provide care in their own homes be excepted from the definition of 'food establishment': see sub-para (2)(iii) of the definition of 'food

establishment'. The exception further depends on the day-care provider notifying the parents/ guardians of the children who attend the day-care service that the food served by the day-care provider is not prepared in a kitchen which is regulated by the regulatory authorities. This enables parents/ guardians to make a choice about whether to use the service.

vi) Food establishment: Accommodation

(1) Issue: The current food safety statutes and rules do not expressly cover a range of establishments which prepare and serve food, such as hotels, motels, bed and breakfast establishments. However, the food safety standards are sometimes brought to bear on these establishments by way of a provision in the statutes which specifically govern each of these establishments and which says that the food safety laws are to be treated as applying to the establishment. In some other instances, there are detailed food safety laws for a specific type of establishment. In other instances, establishments are not subject to food safety laws at all. For example, ARM 37.111.124, which states that where a food service is operated as an integral part of an establishment (defined as a hotel, motel, tourist room, rooming house or retirement home), compliance with the *Retail Food Establishment* rules is required, unless the food service is only available to the residents.

(2) Recommendation:

(a) We recommend that all food establishments be regulated by a single statute. This means that a range of establishments need to be brought within the jurisdiction of the food safety statute. Sub-para (1)(i)(11) of 'food establishment' therefore includes 'any accommodation available to the public, such as a hotel, motel, rooming house, boardinghouse, and bed-and-breakfast establishment'. There is no compelling reason why places which serve food to residents only (such as retirement villages) should not be subject to food safety laws.

(b) There may be different food safety standards for a B & B compared to a restaurant. These can be included in the sub-chapters within a single food safety statute.

(c) We note that the *Food Code* provides an exception for bed and breakfast establishments which are owner-occupied, have no more than six guest rooms, have no more than 18 guests, serve only breakfast and notify their guests that the food is not prepared in a kitchen which is regulated by the regulatory authorities. We have not included this exception.

vii) Food establishment exception: Private members' organizations

(1) We recommend retaining a version of the current exception for 'private organizations which serve food only to their members' in sub-para (2)(iv) of the definition of 'food establishment'. This exception does not cover 'a non-government hospital, school, day-care provider or accommodation service for children, older persons, or persons with disabilities'. The exception depends on being an establishment which serves food only to *members* of the private organization. This means that if the organization does serve, or wants the option of serving, food to members' guests or the public, the organization would not be covered by the exception. The exception further depends on the private organization notifying members that the food served by the organization is not prepared in a kitchen which is regulated by the Department and the local public health agencies. This enables members to make a decision as to whether to eat food offered by the private organization. For example, they may decide that it is safe to eat from a packet of cookies purchased, opened and offered by the private organization, although another meal may not be considered to be safe.

(2) In the past, the rationale for exempting private organizations which serve food only to their members from the statute and rules may have been that food prepared and offered by these organizations was like that prepared and offered in a private home to family members and their guests. The government does not regulate food preparation and service in private homes and therefore does not want to regulate food preparation and service in a place which is similar to the family home. However, it is not evident that members of such organizations know and accept that food served to them by the organization is not prepared according to food safety laws. This may particularly be the case if the private organization is large and has a kitchen with facilities to prepare food for a large number of people (for example, a large sporting club might have several ovens and fridges). In these circumstances, as opposed to licensing and fully regulating the private organization, the organization may be permitted to offer food to its members but the members should be informed that the food is not prepared in a kitchen which is regulated according to food safety laws.

viii) Food establishment exception: Bake Sales:

(1) Issue: The food from private kitchens which is sold at 'bake sales' is not covered by Montana's food safety laws. This is because the definition of 'food service establishment' in the *Food Service Establishment rules* excludes 'a kitchen in a private home if the food is prepared for sale or service at a function such as religious or charitable organization's bake sale'. However, it is worth noting that 'bake sales' themselves are not exempted from the definition of the 'food service establishment'. They are not required to be licensed if they operate for less than 14 days in each calendar year (MCA §50-5-202(2)) but they are

required to register with the local health officer or sanitarian prior to each operation and to follow all of the other standards for food safety. MCA 50-50-202 also says that the regulatory authorities may not adopt rules prohibiting the sale of baked goods and preserves by not-for-profit organizations and they may not require that baked goods or preserves sold by non-profit organizations be prepared in certified or commercial kitchens. The fact that private kitchens which produce goods sold to the public are not regulated under the food safety laws is inconsistent with the rationale of protecting the public from the risk of food-borne illness. This exemption of private kitchens seems to be motivated by other public policy goals of allowing community groups to continue their traditional fundraising activities which enable them to operate and deliver valuable community services.

(2) Recommendation:

(a) In conjunction with either of the options below which relate to the regulation of private kitchens producing goods for bake sales, the current regulation of the 'bake sales' themselves should remain in place.

(b) In addition, the regulation of the private kitchens which produce the goods for bake sales could be structured according to the proposed definition of 'food establishment' above, which excludes private kitchens producing food for bake sales held by religious or charitable organizations. The exclusion only operates **if** the food produced in the private kitchens is not 'potentially hazardous (time/ temperature control for safety) food' **AND if** 'the consumer is informed by a clearly visible placard at the sales or service location that the food is prepared in a kitchen that is not subject to regulation and inspection by the regulatory authority'. This approach serves the public health purpose better than the current regime. It does not allow unlicensed and unregulated kitchens to produce 'potentially hazardous food'. Unlicensed and unregulated kitchens can only produce food which carries some lower risk of foodborne illness. This approach does not serve the public health purpose by regulating the conditions under which the food is produced, but instead operates by arming the consumer with information about the processing of the food. The food may have been prepared in very unsanitary conditions. The information seems intended to cause the consumer to consider whether they should purchase and consume the food where it has not been prepared in a kitchen which is subject to food safety standards. It is not known what impact, if any, the 'warning' has on consumer behavior.

(c) The alternative is to license and regulate all kitchens producing goods for bake sales.

ix) Food establishment exception: private homes

(1) Issue: The Study Group raised the issue of how to make clear in the law that the food safety laws do not cover private homes when they are serving food in a private capacity to family members and guests. There seems to be an agreed intention not to cover food service in such settings. There was a concern that it might be claimed that when a private household hosts a party for a large number of guests, it is providing food to the public within the definition of a 'retail food establishment'.

(2) Recommendation: The definition of 'food establishment' in sub-para (1) possibly encompasses private kitchens when they are serving family and guests. To avoid all doubt about this issue, we recommend that the exceptions include 'A home that serves food only to family members and their guests'.

x) Wild game processors

(1) Issue: There are inadequate food safety laws applicable to wild game processors. The *Retail Food Establishments Act* §50-50-102(7)(b)(iii) says that the term 'food service establishment' does not include 'custom meat cutters or wild game processors who cut, process, grind, package or freeze game meat for the owners of the carcass for consumption by the owner or the owner's family, pets, or nonpaying guests'. This means that that wild game processors, who provide processed game meat to persons *who are not the owner of the carcass* or *who are owners of the carcass but who intend to serve the game meat to persons other than his or her family, guests or pets*, are covered by the *Retail Food Establishments Act* and rules. The question is whether the law should cover wild game processors when they are processing a carcass for an owner of the carcass, even when the only consumers of the carcass will be the owner, his or her family and guests etc.

(2) Recommendation: There does not appear to be a solid public health rationale for excluding wild game processors from the food safety laws in these limited circumstances. They are covered by the laws in relation to some wild game processing, but not covered for exactly the same food handling activity in relation to other groups of consumers. There does not seem to be a defensible reason for giving most members of the public the protection of food safety laws, but excluding a small group from protection because they are the owner, family or guests of the animal carcass. This excluded group of consumers is obviously no less susceptible to foodborne illness from the processing of the carcass. Therefore, the definition of 'food service establishment' should be amended to remove the current exception for some processing activities of wild game processors.

7) **Farms**
   a) **Issue:** Farms and other places where primary produce is created are generally not regulated for food safety. This has been recognized by many people as a major food safety risk for the United States. Some pathogens causing foodborne illness arise in food at the level of the 'farm' and are not removed, and may in fact be spread, at the subsequent processing stage/s. There is considerable support for the development of standards for food safety at the farm level.
   b) **Recommendation:** We recommend that this issue be held in abeyance for the present. We support the development of laws in this area. The Georgetown University Public Policy Institute currently has a project to develop a model law for produce safety that would be a valuable resource for Montana. We will provide you with a copy of the model law as soon as it is available.

8) **Standards for Food**
   a) **Food, Drugs, Cosmetics Act standards**
      i) **Issue:** These standards apply to 'food' generally and therefore overlap with some of the provisions of the *Retail Food Establishments Act* and the *Wholesale Food Establishments Act*. There is sometimes a lack of consistency with these other statutes and rules. These standards also draw on the Federal FDCA rules. The FDCA statute and rules needs to be reviewed to identify gaps and overlaps and to streamline the provisions.
      ii) **Recommendation:**
      (1) We recommend that Montana make the current provisions of the FDCA which relate to food form a sub-chapter of a single food safety statute. There should be a separate statute for drugs, devices and cosmetics. Of the current food provisions in the FDCA, we recommend amendments as follows for Parts 1, 2 and 5 which are relevant to food safety:
         (a) **MCA 50-31-102** regarding the meaning of 'selling' should be deleted and included in the 'definitions' section;
         (b) **MCA 50-31-103**: The definitions section should be reviewed for consistency with the Federal FDCA;
         (c) **MCA 50-31-104:** The Department is authorized to adopt by reference the regulations adopted by the federal Food and Drug Administration ('FDA'). There should be a single provision in the statute which sets out the power of the Department to make rules under the statute (and not just in relation to the FDCA), including by reference to regulations adopted by the FDA.
         (d) **MCA 50-31-105:** The Department may publish information regarding judgments, decrees and court orders which have been rendered under the chapter. This should be part of a sub-chapter on compliance and enforcement of all food safety laws.

(e) **MCA 50-31-106:** Inspections and taking of food samples. A revised provision regarding inspections and samples is discussed below. There need only be a single 'inspections' provision for the statute which should be part of a compliance and enforcement sub-chapter. There needs to be power to conduct inspections on establishments other than retail and wholesale food establishments, being any establishments 'in which food is manufactured, processed, packed or held for introduction into commerce' for the purpose of establishing whether any of the FDCA provisions have been violated.

(f) **MCA 50-31-107:** We recommend that Montana retain the definition of 'false or misleading representations', but ensure that the statute only includes a single definition of 'false or misleading representations' *unless* a different definition should apply to specific situations.

(g) **MCA 50-31-108:** This section grants a power to make regulations concerning additives. This should be retained but all powers to make regulations should be grouped together (such as with MCA 50-31-104) and not scattered throughout the statute.

(h) **MCA 50-31-109:** This section bears on the meaning of 'unsafe' and 'adulterated'. It should be grouped with these sections dealing with these terms.

(i) **MCA 50-31-110**: This section concerns the meaning of 'color additives'. Again, this section should be grouped with others which define key terms.

(j) **MCA 50-31-111:** This section concerns the meaning of labeling and should be grouped with other terms which define the meaning of 'labeling'.

(k) **MCA 50-31-201:** This section authorizes the Department to adopt food standards. This provision should be with other provisions relating to the powers of the Department.

(l) **MCA 50-31-202:** This section defines 'adulteration' of food and should be in the definitions section. The definition of 'adulteration' should be constant across the food safety statute unless there is reason for a different definition to be used in certain circumstances.

(m) **MCA 50-31-203:** This section defines when food is 'misbranded' and should be in the definitions section. The definition of 'misbranded' should be constant across the food safety statute unless there is reason for a different definition to be used in certain circumstances.

(n) **MCA 50-31-204:** This section concerns the labeling requirements for products in semblance of honey or containing honey. This provision should be deleted and included in the rules only.

(o) **MCA 50-31-208:** This section concerns the sale of hamburger and beef patty mix. This provision should be deleted and included in the rules only.

(p) **MCA 50-31-237:** This section concerns health claims for bottled water. This provision should be deleted and included in the rules only.

(q) **MCA 50-31-501:** This section defines the prohibited acts under the FDCA. This section should be in a sub-part concerning compliance and enforcement with the FDCA standards.

(r) **MCA 50-31-502:** This section states that it is unlawful for anyone to sell or offer for sale any honey product. This should be moved to the rules.

(s) **MCA 50-31-503:** This section states that there is no requirement that the Department report minor violations of this chapter for the institution of proceedings whenever the Department believes that the public interest will be adequately served in the circumstances by a suitable written warning. If this provision were retained, it should be part of the chapter of the statute on 'Compliance and Enforcement'.

(t) **MCA 50-31-504:** This section provides that before a violation of the FDCA is reported to the state or county attorney for prosecution, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the Department or its designated agent, either orally or in writing, with regard to the contemplated proceeding. We recommend that this section be deleted. It is unnecessary that the person against whom the proceedings are contemplated be given the opportunity for a hearing prior to the decision about prosecution being made.

(u) **MCA 50-31-505:** Each state attorney or county attorney to whom the Department reports a violation of this chapter shall cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. This provision should be retained in the Compliance and Enforcement sub-chapter of the statute.

(v) **MCA 50-31-506:** This is the penalties provision in relation to misdemeanors relating to honey or hamburger/ beef patty mix. It would be preferable for the penalties provision to not be linked to very specific misdemeanors and to be linked to more general categories of misdemeanor. There are no penalties provisions other this one. This is a gap and a penalty provision needs to be created for all conduct which constitutes a crime under the statute.

(w) **MCA 50-31-508:** This is an injunction provision relating to violations of the honey or hamburger/ beef patty mix provisions. There is no injunction provision other this one. This is a major

gap because the statute does not authorize the Department and the local public health agencies to apply for an injunction in relation to violations of the FDCA or the rules. A general injunction provision is required.

(x) MCA 50-31-509: This provision relates to the detention, tagging, embargoing and destruction of adulterated or misbranded food. This type of provision should properly form part of the 'Compliance and Enforcement' sub-chapter of the statute.

(y) MCA 50-31-508: This provision allows for the condemnation or destruction of perishable foods where they are unsound, filthy, decomposed, etc. This type of provision should be included in the 'Compliance and Enforcement' section.

(2) Recommendation: A new version of the FDCA rules must reference the most current versions of the Federal FDCA rules. It is essential that the rules be kept updated.

b) Standards for food establishments

i) Issue: There must be current food safety standards for all food establishments, including retail food establishments and wholesale food establishments.

ii) Recommendations:

(1) We recommend that the statute include a sub-chapter with standards for 'retail food establishments' as defined above. There can be a separate chapter for standards for 'wholesale food establishments' as defined above. The statute should include only very basic provisions regarding the standards for 'retail food establishments' and 'wholesale food establishments', with the detailed standards being included in the rules.

(2) For the content of the rules for 'retail food establishments', Montana should adopt the most current version of Parts 1 – 7 of the FDA *Food Code* into its rules, monitor for further updates and, as soon as an update is available, amend its rules to reflect the most recent version of the Code. The Code could be adopted 'by reference' (with or without amendment) or it could be adopted 'section by section' into Montana administrative rules. If Montana is able to adopt the Code by reference, this would be the most straight-forward approach. Montana should work on complying with the *Retail Food Regulatory Program Standards* ('*Retail Food Program*'). It seems that the Department and many or all of the local public health agencies are enrolled in the *Retail Food Program* but have not progressed completely through the assessment levels.

(3) For the content of the rules for 'wholesale food establishments', there are no published standards by the FDA like the *Food Code*, but there is the *Manufactured Foods Regulatory Program Standards* ('*Manufactured Food Program*'). We recommend that Montana comply with the *Manufactured Food Program Standards*. We therefore also

recommend that the current standards be reviewed for deficiencies and that they be updated to repair any defects.

c) **Standards for specific items**
   i) **Issue:** Should standards for specific items (such as honey and hamburger and beef patty mix) be in the statute or in the rules?
   ii) **Recommendation:** Standards for specific items should not be in the statute. They should be in the rules only, as is currently the case with vending machines: see ARM 37.110.401 – 429. We recommend that the following provisions be moved from the statutes to the rules:
   (1) MCA 50-31-204 relating to honey;
   (2) MCA 50-31-208 relating to hamburger and beef patty mix;
   (3) MCA 50-50-217 relating to the licensure of water haulers; and
   (4) MCA 50-50-401 – 403 regarding frozen food lockers for carcasses of game animal, game bird, or any quarter, half or whole carcass of beef or veal.

9) **Compliance and Enforcement: General**
   a) **Issue:**
      i) At present, there are provisions relating to how to handle violations of food safety standards in several different statutes and sets of rules. There are different procedures in relation to different standards which do not seem to always be justified. For example, there are different processes for enforcement of FDCA standards and the retail food establishments standards.
      ii) Provisions relating to compliance and enforcement are also often scattered throughout the statute or rule and not gathered together in one chapter or part of the statute or rule. This is potentially confusing and creates difficulties in locating and therefore acting in compliance with all of the relevant provisions.
      iii) In some respects, the compliance and enforcement provisions are incomplete and food safety authorities do not have all of the compliance and enforcement tools which they require to uphold food safety standards and protect the public. For example, there is no power in the FDCA to seek or grant injunction in relation to violation of the standards in the FDCA, except for those for honey and hamburger/ ground beef patty mix.
   b) **Recommendation:**
      i) There should be a common, or close to common, set of compliance and enforcement mechanisms for all of Montana's food safety standards, including standards under the FDCA and standards for retail food establishments and wholesale food establishments. Where it is necessary to have a special enforcement mechanism for a particular standard, then this can be included, as an exception or addition to the common set of compliance and enforcement provisions.

ii) Chapter 8 of the FDA *Food Code* provides a model for compliance and enforcement which we recommend. Although the *Food Code* relates to retail food establishments, it provides a very valuable structure for all food safety compliance and enforcement. We have relied on the *Food Code* and the *Food Safety Modernization Act 2007* as models in developing some of the recommendations below for specific aspects of the food safety compliance and enforcement regime.

iii) Compliance and enforcement procedures should not be different in different local or county jurisdictions. However, compliance and enforcement procedures should be structured so they can primarily be administered at the local level, with the state only becoming involved if the local public health agencies are unwilling to do so. All of the compliance and enforcement provisions have been drafted with the local public health agency as the subject of the power or the duty, unless otherwise expressly stated. However, we also recommend that there be a separate provision which states that, in the event that the local public health agency is unwilling to exercise its powers to enforce the food safety statute and rules, the Department may exercise all of the enforcement powers of local public healthy agency.

(1) In the event that a local public health agency fails to exercise the powers contained in this sub-chapter, the Department may exercise all of the powers contained in this sub-chapter to ensure compliance with the food safety laws.

(2) When the Department exercises powers under this sub-chapter:
(a) all references to the 'local public health agency' or the 'local public health agencies' shall be read as references to the 'Department':
(b) the Department shall be subject to the same restraints and requirements, as if it were the local public health agency exercising the powers; and
(c) a person or food establishment subject to the exercise of the powers by the Department shall have the same rights as if it were the local public health agency exercising the powers; and
(d) the Department shall use the state administrative or judicial procedures which are relevant to the powers being exercised under this sub-chapter.

10) Constitutional protection

a) Issue: The constitutional protections which apply to the food safety laws should be made clear.

b) Recommendation: We recommend the inclusion of provisions such as the following in the statute/ rules:

(1) A local public health agency shall justly apply the remedies according to law and the food safety statute and rules, to preserve the rights to equal

protection and due process of a person to whom the remedies are applied.

(2) A recipient of an order or decision by a local public health agency may file a petition for judicial review in a court of competent jurisdiction after available administrative appeal remedies have been exhausted.

11) Plan submission and approval processes

a) Making common plan review provisions

i) Issue: There are differences between the current statutory provisions regarding the submission and authorization of plans for retail and wholesale food establishments.

ii) Recommendation: Although the rules regarding submission of plans seem to generally be sound, we recommend that the current rules for the different types of establishments be consolidated into one rule, except to the extent that there need to be specific requirements for different types of food establishments.

b) Fees for plan reviews

i) Issue: The current provisions do not authorize a local public health agency to charge a fee for the review of plans.

ii) Recommendation: The rules regarding plan submissions and approval should enable the local public health agency to charge a fee for the review of food establishments' plans. The amount of the fee should also be set in rules, and not in the statute.

12) Licenses to operate

a) Rules for licensing wholesale food establishments

i) Issue: There are detailed administrative rules for the licensing of retail food establishments but there are no comparable rules in relation to wholesale food establishments. The *Wholesale Food Establishments Act* has some limited provisions in relation to licensing of wholesale food establishments. The current licensing regime for wholesale food establishments is inadequate and there could be some improvements to the regime in relation to retail food establishments.

ii) Recommendation: There should sufficient detail in relation to the licensing process for both wholesale and retail food establishments. The rules should be drafted to cover both retail and wholesale food establishments, with there being specific rules for retail and wholesale food establishments where necessary.

b) Right to a license

i) Issue: The *Retail Food Establishments Act* §50-50-204 provides that licenses shall be granted as a matter of right unless grounds for denial or cancellation exist. A similar concept is found in ARM 31.110.238(1) for retail food establishments. In relation to wholesale food establishments, MCA 50-57-207 provides that there is a right to the renewal of a license. The focus on an individual right to a license seems misplaced in the licensing regime which has been developed as a mechanism for protecting the public's health.

ii) Recommendation: All references to there being a right to a license or a right to the renewal of a license should be removed from the statute and rules.

c) Who determines license applications?

i) Issue:

(1) Do the state *and/ or* local public health agencies have the power to decide applications for licenses for food establishments? Should the state *and/ or* local public health agencies have the power to decide applications for licenses for food establishments?

(2) The *Food Service Establishment* rules provide for applications for licenses to be made on forms provided by the Department. It is not stated that the application must be made to the Department; however, it is stated that 'The Department will issue a license to an applicant ….'. It is also the Department which may revoke a license for retail food establishments. The *Food Service Establishment* rules also contemplate a role for the local health authorities to inspect the proposed food establishment, before the license application is decided, to determine compliance with the rules. However, the *Retail Food Establishments Act* provides that the local boards of health 'shall submit to the Department a list of the establishments in each jurisdiction that are licensed under this chapter.' *Retail Food Establishments Act* §50-50-214 also states that 'a license issued by the Department under this chapter is not valid until signed by the local health officer in the county where the establishment is located or until the license is otherwise validated by the local health officer and is in accordance with the rules established by the board of review'. There is a similar provision in the *Wholesale Food Establishments Act*. These last three provisions suggest that licensing is, at least in part, a matter for the local public health agencies, as opposed to the Department.

(3) The statute does not seem to accord with current practice. We understand that the Department issues the license and the local public health agencies validate the license issued by the Department. There is not usually an inspection of the food establishment prior to the validation of the license. We are unclear how this process serves the public health mission for food safety.

ii) **Recommendation:** There do not seem to be federal or state constitutional or other legal provisions which determine which level of government should have responsibility for deciding license applications. This means that it is entirely up to Montana policy-makers to determine how to allocate the power and duty to determine license applications. Whatever decision is made as to the allocation of powers and duties, the agency which has responsibility, and the process, for licensing of food establishments should be clearly identified in the statute. Practice should accord with allocation of responsibilities and procedure set down in the statute. Within these parameters, we note the following options:

(1) Option A: The power could rest wholly with the Department to determine an application for a license, with no role for the local public health agencies. The local public health agencies could be notified of the food establishments which have been licensed in their jurisdiction. Centralizing the license process within the Department seems inconsistent with the current model in Montana where many local health agencies play a significant role in upholding public health laws.

(2) Option B: The power to determine licenses could rest solely with the local public health agencies. There could be provision made for the licenses issued by the local public health agencies to be notified to the Department if it were thought necessary for the Department to have a current list at all times of licensed food establishments. Whether this is the preferred approach will depend, in part, on whether the local public health agencies have the administrative and financial capacity to consider the license applications which they would receive.

d) Making and determining a license application

i) **Issue:** There are some features of the license application process in the *Food Code* which may be useful additions to the Montana food establishment licensing process. Some of these additions may assist with some of the issues which the Study Group has raised with us relating to establishments operating with expired licenses or where license fees have not been paid.

ii) **Recommendations:**

(1) We recommend that there be a provision like in sec. 8-302.11 of the *Food Code* which places the responsibility on the applicant to apply for a license at least *30 days* before the date planned for opening of a food establishment or the expiration date of the current license.

(2) We also recommend that consideration be given to whether the Montana food establishment license application form would benefit from amendment to include some of the items included in the *Food Code* application form, as set in sec. 8-302.14 of the *Food Code*.

(3) We also recommend that the rules make explicit the criteria for the grant of a license. In sec. 8-302.13 of the *Food Code*, these criteria are that the applicant shall:

(a) be the owner of the food establishment or the officer of the legal ownership;
(b) comply with the requirements of the food safety laws as confirmed by an inspection of the food establishment prior to the determination of the license application;
(c) agree to allow access to the food establishment and to provide required information;
(d) pay the applicable permit fees *at the time the application is* submitted; and
(e) (if applicable) meet the requirements of the plan approval process.

A license should not, under any circumstances, be issued if these criteria are not met. This is because the criteria represent what the public policy-makers have determined are the essential requirements for an establishment to be operational. They represent what the public is entitled to expect of an establishment which has a license to operate.

e) 'Pending compliance'

i) Issue: In Montana, the category 'pending compliance' is used in relation to licenses and food establishments in various ways. As we understand it, in some counties, the term is used for internal administration to signify that the local public health agency is waiting for documents or information from a license applicant. However, the license will not be issued until all the criteria are met ('Scenario 1'). In other counties, the term is not used in connection with the licensing process. An establishment may have a license but it has been found by the local public health agencies to be in violation of some of the food safety standards. During the period of time which the food establishment has been given to correct the violation, it is categorized as 'pending compliance' ('Scenario 2'). Our understanding is that this category does not change the establishment's license status (of course, if the establishment fails to correct the violations, the authorities may take action to suspend/revoke the establishment's license). In a third example which the Study Group provided, the term was used where an applicant for a new license for a trailer court did not meet the criteria for the issuance of a license (because the trailer court was not in compliance with the standards), but the sale of the trailer court to the prospective new owner/ applicant would not have been able to proceed without a license and the sale of the trailer court to the new owner was essential to the repairs to the trailer court being conducted ('Scenario 3'). If there were no license for the trailer court, the trailer court could not have continued in operation and residents of the trailer court would have had to leave the trailer court and would have most likely been left homeless.

The term ‘pending compliance’ is not found in the statute or rules. Is it acceptable to use this category? The use of the term ‘pending compliance’ in Scenario 1 and Scenario 2 above is acceptable. In Scenario 1, ‘pending compliance’ is an internal administrative category and the relevant food safety official in Montana has said that a license is not issued until all of the criteria have been met. In Scenario 2, the category ‘pending compliance’ does not relate to the decision to issue or not to issue a license. The use of the category ‘pending compliance’ in Scenario 3 is not currently permitted under the statute or the rules. There is no license category available in Montana which is similar to ‘pending compliance’. The law relating to the licensing regime in Montana is structured so that an applicant should only be issued with a license if they meet all the criteria for the issuance of a license.

ii) **Recommendation:** We recommend that, in relation to food safety, there be no legal category of ‘pending compliance’ or similar concepts added to the statute in relation to new licenses. We consider that licenses should only be issued where the applicant meets all of the criteria for the issuance of a license which includes compliance with the food safety laws. Licenses should not be issued to applicants whose establishment is not compliant with the food safety standards. During the life of a license, there may be periods when the license holder’s establishment is not fully compliant with the food safety standard, but, as is discussed in Issue 13(m) below, there must be a plan and strict time frame for correction of such violations. A license holder should not start out in a state of violation.

f) License fees

i) **Issue:** The license fees for food establishments for Montana are currently set down in the statute. This makes it difficult to change the fees as required.

ii) **Recommendation:** We strongly recommend that the fees for licenses be set down in the rules. This will enable the fees to be updated as often as is required in terms of Montana’s fee-setting policy.

g) Review of a decision to deny an application for a license

i) **Issue:** MCA 50-50-211 provides that a license ‘may not be denied … by the Department without delivery to the applicant of a written statement of the grounds for denial… and the opportunity to answer at a hearing before the Department to show cause, if any, why the license should not be denied…In such case, the licensee must make a written request to the Department for a hearing within 10 days after notice of the grounds …have been received.’ Under this provision, the onus is on the Department to offer and provide a hearing to the applicant before making a decision about whether to grant the applicant a license. This requirement creates an unnecessary administrative and

financial burden for the Department. What should be the process for making a decision to deny a license application?

ii) Recommendation:

(1) We note that the process which is adopted for the denial of an application for a license must be in sync with the process which Montana adopts for determining license applications: see Issue 12(c) above. For example, if you decide that license applications will be determined by the Department, then the process for reviewing the decision to deny a license must involve the Department. If the local public health agencies have responsibility for determining license applications, the process of review will need to be modeled to suit the local public health agencies. The recommendations which follow assume that the local public health agency is the decision-maker in relation to license applications.

(2) The current burden on the Department to give the applicant a 'second chance' to provide information about the application for a license should be removed. The applicant should have adequate opportunity on the application form to make the case for being granted a license. (It is therefore essential that the application form solicit from the applicant all of the information which the local public health agency requires to make a determination regarding the license application.) If the local public health agency has asked the applicant to provided it with all the information which is relevant to its decision-making and the applicant has either not provided the information or has provided information which does not, according to the decision-maker, meet the criteria, it is proper for the local public health agency to deny the application.

(3) We recommend that a safety net for the applicant be introduced by offering a review mechanism. In this system, the onus then shifts to the applicant to decide whether to apply for a review of the licensing decision. Sec. 8-303.30 of the *Food Code* suggests that 'If an application for a [license] is denied, the regulatory authority shall provide the applicant with a notice that includes: the specific reasons and citations [from the statute and the rules] for the [license] denial, the actions, if any, that the applicant must take to qualify for a [license], and advertisement of the applicant's right of review and the process and time frames for review'.

(4) We recommend that the review of a decision to deny a license to an applicant be conducted at an administrative hearing ('Review Hearing'). This process for review of a licensing decision by the local public health agency needs also to be synchronized with Montana's general administrative law regime. Advice on this question should be sought from legal counsel to the Department. If it is compatible with Montana's general administrative law regime, we recommend that the Review Hearing be conducted by an individual within the local public health agency who has not been involved in the initial decision to deny the license application. An alternative would for the Review Hearing to be conducted by a *multi-person panel* appointed by the local public health

agency. It does not seem to us necessary that a first-level review of a licensing decision be conducted by more than one person.

(5) Sec. 8-805.10(D) of the *Food Code* suggests that the Review Hearing should be requested within 10 days of the determination to deny a permit application (or some shorter time if specified). Sec. 8-805.50(A)(2) of the *Food Code* suggests that the hearing must be held no sooner than 7 days after the request for a hearing is made and no later than 30 days after the request for a hearing is made.

(6) The process for appealing a decision made at a Review Hearing also needs to fit with Montana's general administrative law regime. There are various options:

- **(a) Option A:** Where the Review Hearing has been conducted by a single person in the local public health agency, the appeal could be to multi-person panel appointed by the local public health agency.
- **(b) Option B:** Alternatively, an appeal could be to the District Court for a judicial hearing. This means that there is one round of administrative review only and then, if either party seeks further review, this hearing is conducted by a court.

h) Responsibilities of the local public health agencies when issuing a license

- **i) Issue:** The statute and rules are silent on the responsibilities of the local public health agencies when issuing a license.
- **ii) Recommendation:** Sec.8-304.10 of the *Food Code* includes a short provision which we would recommend to Montana which provides:

> (1) At the time a permit is first issued, the local public health agency shall provide to the license holder a copy of [the food safety laws] so that the license holder is notified of the compliance requirements and the conditions of retention of the license, that are applicable to the license.
>
> (2) Failure to provide the information specified in (A) does not prevent the local public health agency from taking authorized action or seeking remedies if the license holder fails to comply with the food safety laws or an order, warning, or directive of the local public health agency.

i) Responsibilities of the license holder

- **i) Issue:** There is no provision in the statute and rules which sets out the responsibilities of the license holder.
- **ii) Recommendation:** We recommend that a detailed provision like that found in the sec. 8-304.11 of the *Food Code* be included in the Montana rules.

> Upon acceptance of the license issued by the local public health agency, the license holder in order to retain the license shall:

(1) Post the license in a location in the food establishment that is conspicuous to consumers;
(2) Comply with the provisions of the food safety laws, including any variances and the approved plans for the establishment;
(3) Comply with the HACCP plan (if any) for the food establishment;
(4) Immediately contact the local public health agency to report an illness of a food employee as required in the rules;
(5) Immediately discontinue operations and notify the local public health agency if an imminent health hazard may exist as required in the rules;
(6) Allow representatives of the local public health agency to access the food establishment as required in the rules;
(7) Comply with the directives of the local public health agency including times frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the local public health agency in regard to the permit holder's food establishment or in response to the community emergencies;
(8) Be subject to the administrative, civil, injunctive and criminal remedies authorized in law for failure to comply with the statute/ rules or a directive of the local public health agency, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

j) Renewing a license application

i) Issue: The process for renewal of a license is not clear in the current statute or rules.

ii) Recommendation:

(1) We recommend that the statute use a provision like that in 8-303.20 of the *Food Code*:

> The local public health agency authority may renew a permit for an existing food establishment or may issue a permit to a new owner of an existing food establishment after a properly completed application is submitted, reviewed and approved, fees are paid, and an inspection shows that the establishment is in compliance with the food safety standards in the statute and rules.

(2) The effect of such a provision is that a person cannot be licensed if they do not make application for renewal and if they do not do all that is required, including paying their license fees.

(3) The recommended provision requires that an inspection be conducted between the time the application to renew is received and the decision whether to renew is made. It may be that this is not a practical requirement.

(4) We also recommend that there be a right to appeal a decision not to renew a license, which follows the same procedure as for appeals from refusals to issue a license: see Issue 12(g) above.

k) Late renewal of a license

i) Issue: The current statute imposes a small charge on a person who does not renew their license before the expiration date of the license. From the date the license expires, the food establishment is unlicensed. It is not clear in the current statute or rules for how long, after the expiry of a license, a food establishment can be unlicensed. It is also not clear when a food establishment whose license has expired is required to apply for a renewal of its license or to apply for a new license.

ii) Recommendation:

(1) We recommend that Montana continue to set a fee for the late renewal of licenses.

(2) We also recommend that Montana have a rule which provides that an establishment can only seek a renewal of its license up to two weeks (or some very short period given that the license only runs for one year) after the expiry of its license. If it has not renewed its license within this time period, the local public health agencies should move to close the food establishment because it is operating without a license: see below Issue 12(l). If the person wants to obtain a license at this stage, they will need to apply for a new license and follow the process and pay the fees applicable to new license applications.

l) Absence of a current license

i) Issue: In relation to retail food establishments, ARM 37.11.238 states that 'No person shall operate a food service establishment without a valid license'. In relation to wholesale food establishments, MCA §50-57-201 states that 'A person operating an establishment shall procure an annual license from the Department.' There is no provision in relation to wholesale food establishments which says that 'a person may not operate a food establishment without a valid license'. It is not clear from the statute or rules the steps which can be taken by the local public health agencies where a food establishment is operating without a valid license. At present, seeking an injunction seems to be the most useful option.

ii) Recommendation:

(1) The new statute must make clear that, in relation to all food establishments, 'No person shall operate a food establishment without a valid license'. A valid license means a license which has been properly issued for the current licensing year: see Issue 12(d) above.

(2) It is unacceptable for a person to operate an establishment without a valid license. The local public health agencies should have a clear power to close a food establishment which is operating without a license.

This should be done by the local public health agency issuing a notice for a hearing before an administrative decision-maker ('Administrative Hearing'). This process for conducting an Administrative Hearing in relation to the closure of a food establishment needs also to be synchronized with Montana's general administrative law regime. Advice on this question should be sought from legal counsel to the Department. If it is compatible with Montana's general administrative law regime, we recommend that the Administrative Hearing be conducted by an expert, independent individual within the local public health agency. An alternative would for the Administrative Hearing to be conducted by a multi-person panel appointed by the local public health agency. It does not seem to us necessary that an Administrative Hearing involve a multi-person panel to make a decision about the closure of a food establishment. The question which is to be answered at the Administrative Hearing is a straightforward one: does the food establishment have a valid license? There may be aspects of the case which will be contested but it is not a difficult legal or factual exercise for a hearing officer to conduct at an Administrative Hearing.

(3) The *Food Code* sets down the content of the notice of hearing to be issued by the food safety agencies and suggests that the owner/s of the food establishment, the respondent, have 7 calendar days to respond to the notice of hearing. At the Administrative Hearing, the administrative decision-maker may or may not order the closure of a food establishment which is operating without a license.

(4) The local public health agencies may wish to apply at the Administrative Hearing for the imposition of a civil penalty hearing for the violation of a term of the food safety laws that a person not operate a food establishment without a license: see below Issue 20. Note that a criminal penalty can only be imposed following prosecution and conviction at a judicial hearing: see below Issue 20.

(5) If one of the parties wished to appeal a finding of an Administrative Hearing, this process also needs to fit with Montana's general administrative law regime. There are various options:

- **(a) Option A:** Where the Administrative Hearing has been conducted by a single person in the local public health agency, the appeal could be to multi-person panel appointed by the local public health agency.
- **(b) Option B:** Alternatively, an appeal could be to a court for a judicial hearing. This means that there is one round of administrative decision-making only and all appeals are to the courts.

m) Suspending a License

i) Issue: There is currently no express power for the suspension of a license. We assume that an injunction may be used to prevent a food establishment operating which is effectively a 'suspension' of their

license. Should there be an express power to suspend a license? What should be the process for doing so?

ii) **Recommendation:** We recommend that the local public health agencies have the power to suspend a food establishment license. The suspension of a license is a temporary measure and does not extinguish the license. Once the suspension ends, the license is re-activated. We recommend that a procedure modeled on that in sec. 8-804.10 – 8-804.50 in the *Food Code* be used by Montana as follows:

(1) What are the grounds for suspending a license?

(a) The local public health agency may summarily suspend a permit to operate a food establishment if it establishes through inspection or examination of employees, food, records, or other means as specified in the statute/ rules that an imminent health hazard exists.

(b) An 'imminent health hazard' is 'a significant threat or danger to health that is considered to exist where there is evidence to show that a product, practice, circumstance or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on (1) the number of potential injuries, and (2) the nature, severity and duration of the anticipated injury.

(2) What is the process for suspending a license?

(a) A designated person in the local public health agency may summarily suspend a person's permit by providing written notice of the summary suspension to the license holder or the person in charge, without prior warning, notice of a hearing or a hearing.

(b) The notice of suspension of a license must state: the food establishment permit is immediately suspended and all food operations shall cease and may not resume until the summary suspension ends, the reasons for the summary suspension, the name and address of the representative of the local public health agency to whom a request for reinspection can be made and who may certify that the reasons for suspension are eliminated, and that the license holder may request a review of the decision.

(c) A copy of the notice must be posted at the public entrance to the food establishment.

(3) What is the process for requesting a review of a decision to suspend a license?

(a) The license holder may request a Review Hearing to review the decision to summarily suspend the permit. The procedure should be the same as the procedure which applies to the review of other decisions of the local public health agencies such as the determination to deny a license application in Issue

12(g) above: see above for the discussion regarding the process of review.

(4) How does the suspension of the license come to an end?

(a) A successful appeal by the license holder may bring the license suspension to an end.

(b) A summary suspension should remain in effect until the conditions in the notice of suspension no longer exist and their elimination has been confirmed by the local public health agency through reinspection.

(c) The license holder may make corrections and request reinspection of the premises by the local public health agency. Reinspection should be conducted by the local public health agency within two days after the request for reinspection (being two days during which the local public health agency's offices are opened to the public).

(d) The suspended license should be reinstated immediately if the local public health agency determines that the public health hazard or nuisance no longer exists. A notice of reinstatement should be provided to the license holder.

n) Cancelling a license

i) Issue: Should there be a power to cancel a license? What should be the process for doing so? MCA 50-50-209 provides that 'the Department may cancel a license if it finds, after proper investigation, that the licensee has violated this chapter or a rule effective under this chapter and the licensee has failed or refused to remedy or correct the violation. MCA 50-50-211 states that 'a license may not be … canceled by the Department without delivery to the applicant or licensee of a written statement of the grounds for cancellation … or the charge involved and an opportunity to answer at a hearing before the Department to show cause, if any, why the license should not be … canceled. In such a case, the licensee must make written request to the Department for a hearing within 10 days after the notice of the grounds has been received.

ii) Recommendation:

(1) We recommend that the decision to cancel a license be taken by an administrative decision-maker at an Administrative Hearing. The same procedure for seeking an order to cancel a license should be followed as when seeking an order to close a food establishment which is operating without a license: see Issue 12(l) above. At the hearing, the administrative decision-maker may or may not order the cancellation of the license. The procedure for appealing the decision at the Administrative Hearing for canceling a license should be the same as the procedure for appealing an administrative decision to close a food establishment.

(2) We recommend that the doing of a 'prohibited act' as defined in the statute be a ground for the cancellation of a license: see Issue 20 below.

(3) We recommend that Montana may wish to retain its provision in MCA 50-57-211 which allows the submission and execution of a plan of correction within the time prescribed to be a bar to the cancellation of a license.

13) Inspections

a) Frequency of inspections

i) Issue: ARM 37.110.239(1) provides that inspections of food service establishments (a type of retail food establishment) must occur twice every twelve months. ARM 37.110.370 provides that the rules regarding inspections for food service establishments apply also to wholesale food establishments. ARM 37.110.239(1) also provides that the schedule for inspections may be modified by way of signed agreement between the local board of health and the Department. The same provision also says that 'Additional inspections of food service establishments must be performed as often as necessary for the enforcement of [the rules].' Is this inspection timetable adequate to meet the public health purpose of Montana's food safety laws?

ii) Recommendation:

(1) We recommend that the inspection occur every 6 months, rather than twice every 12 months. Sec. 8-401.10 of the *Food Code* provides for inspection every six months and it seems that, subject to a decision that more or less frequent inspection is mandated because of risk factors or the history of the food establishment, six months is considered the optimal time between inspections. 'Twice every 12 months' is not as precise as once every 6 months and may give rise to a situation where an establishment has its 1st inspection in month 10 and its 2nd inspection in month 12. This does not accord with what the FDA suggests is good inspection practice.

(2) We also recommend that the statute or the rules provide the ability for inspections to occur less frequently than once every 6 months and set out the bases on which an inspection schedule may be modified. Sec. 8-401.10(B) of the *Food Code* provides:

> The local public health agency may increase the interval between inspections beyond 6 months if:
> (a) The food establishment is fully operating under a HACCP plan [as provided in the statute and rules];
> (b) The food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every 6 months the establishment is contacted by telephone or other means by the local public health agency to ensure that the establishment and the nature of the food operations are not changed; or

(c) The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not potentially hazardous (time/temperature control for safety) food such as carbonated beverages and snack food such as chips, nuts, popcorn and pretzels.'

(3) We also recommend that the rules provide the ability for inspections to occur more frequently than once every 6 months and set out the bases on which an inspection schedule may be modified. Sec 8-401.20 of the *Food Code* provides:

The local public health agency shall prioritize, and conduct more frequent inspections based upon its assessment of the food establishment's history of compliance with the statute and rules and the establishment's potential as a vector of foodborne illness by evaluating:
(a) Past performance, for nonconformance with the statute or rules or HACCP Plan requirements that are critical;
(b) Past performance, for numerous or repeated violations of the statute or the rules or HACCP Plan requirements that are noncritical;
(c) Past performance for complaints investigated and found to be valid;
(d) The hazards associated with the particular foods that are prepared, stored or served;
(e) The type of operation including the methods and extent of food storage, preparation, and service;
(f) The number of people served; and
(g) Whether the population served is a highly susceptible population.

b) Competency of inspectors

i) Issue: MCA 50-50-301 states that 'A person conducting an inspection must be certified and have completed a food safety training program, such as the program administered by the national restaurant association educational foundation or its equivalent.' Is this course adequate to equip inspectors with the knowledge and skills they require to conduct inspections?

ii) Recommendation: An option would be to include in the rules a more general provision such 'An authorized representative of a food establishment who inspects a food establishment or conducts plan reviews for compliance with this the food safety laws shall have the knowledge, skills and ability to adequately perform the required duties': see *Food Code* 8-402.10. The substitution of the more general provision means that the completion of a 'food safety training course' would no longer be conclusive evidence of a person's 'knowledge, skills and ability' to conduct inspections. The more general requirement includes the concept of continuing education and training. For example, the *FDA Draft Voluntary National Retail Food Regulatory*

Program Standards suggest that each employee accumulates 20 hours of continuing education every 36 months after his or her initial training, with one hour of training being equivalent to one hour's participation at regional seminars/ technical conferences, professional symposium/ college courses, workshops, and food-related training provided by government agencies. This standard for professional development need not be included in the rules but could be part of a policy of the Department or the local public health agency. The recommended provision also links in with the provision recommended above in Issue 5 for the Department to setting standards for credentialing and training of food safety personnel employed by the Department or a local public health agency.

c) Access to premises

i) Issue: The key issue in relation to the inspection program is gaining access to the food establishments. MCA 50-50-302 provides that 'State and local health officers [and others] must be provided free access to establishments at all reasonable hours for the purpose of conducting investigations and inspections required under this chapter.' There is the same statutory provision in relation to wholesale food establishments. ARM 37.110.239 provides that, 'State and local health officers, after proper identification, must be permitted to enter any food service establishment at any reasonable time for the purpose of making inspections to determine compliance with this subchapter and must be permitted to examine the records of the establishment to obtain information pertaining to food and supplies purchased, received or used, or to persons employed.' These are all solid provisions, but there is no provision in the statue or rules about responding to a denial of access.

ii) Recommendations: We recommend that express provision be made to address the situation where a person denies an inspector access to a food establishment. The following process is recommended and is, in part, modeled on sec. 8-402.11 – 40 of the *Food Code*:

(1) If person denies access to the establishment, the local public health agency shall inform the person that access is required, that access is a condition of the acceptance and retention of a food establishment license to operate (see above Issue 3(i) regarding responsibilities of license holders), and that if access is denied, an order for access will be sought according to law. The inspector shall make a final request for access.

(2) If after the local public health agency presents credentials and provides notice as specified above, explains the authority upon which access is requested, and makes a final request for access, the person in charge continues to refuse access, the local public health agency shall provide details of the denial of access on the inspection form,.

(3) If denied access to a food establishment:

(a) **Option A:** The local public health agency may issue an order for access for inspection. Like with the decision to suspend a license discussed in Issue 3(m) above, a designated person within the agency could make the order for inspection, without notice of a hearing being given or a hearing being held. We would recommend that the designated person be a person other than the inspector who was refused access to the food establishment. To accompany this option, there should be the option for the license holder to apply for the review of the decision at a Review Hearing as discussed in Issue 12(g) above. This option has the benefit of being easier and quicker to use than a process involving a contested hearing. There may be circumstances in which an inspection should be urgently conducted. This type of provision would facilitate access in these circumstances. This is the preferred option.

(b) **Option B:** The local public health agency may apply to an Administrative Hearing for an order for access for the inspection. Like with an application to close an establishment which is operating without a license or to cancel a license, an application to access a food establishment for the purpose of inspection could be made by way of a notice for a hearing before an administrative decision-maker, being either an individual or a panel.

d) Addressing violations found during inspection

i) Issues: The *Food Service Establishment* rules set time frames for correction of violations identified during an inspection. 'Critical items' must be corrected within 10 days or sooner: ARM 37.110.239(4)(a). All other violations must be corrected as soon as possible but before the time of the next routine inspection: ARM 37.110.239(4)(b). 'Critical violations' is a broad term in the rules. It is defined as 'a provision of this sub-chapter that, if violated, is more likely than other violations to contribute to food contamination, illnesses, or environmental degradation.' Furthermore, 'the inspection report must state that failure to comply with any time limits for correction of critical item violations may result in cessation of food service operations.' These rules apply to wholesale food establishments by way of the provision in ARM 37.110.370. Are these time frames for correction adequate for protecting the public health?

ii) Recommendations:

(1) We recommend that you consider the time frames for correcting violations found during the inspection as provided in the *Food Code* set out below. These time frames are stricter than the current Montana timeframes. The local public health agency – represented by the inspector at the premises – should be granted the power to order the correction of violations in accordance with the time frames below:

(a) Imminent health hazard: immediate correction. An 'imminent health hazard' means 'a significant threat or danger to health that is considered to exist where there is evidence sufficient to show that a product, practice, circumstances or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on: (a) the number of potential injuries, and (b) the nature, severity and duration of the anticipated injury.' This category does not exist in Montana's law.

(b) Critical item violation: immediate correction or no more than 10 calendar days after the inspection. A 'critical item' is a provision of the statute or rules that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness or environmental health hazard' or a specific item of the statute or rules which is designated as a critical item. This would be similar to the list in ARM 37.110.239(4)(a)(i).

(c) Non-critical item violation: time frame to be set but no more than 90 days after the inspection, unless a written schedule of compliance is submitted by the license holder and no health hazard exists or will result from allowing an extended schedule for compliance.

(2) Imminent health hazard:

(a) We recommend that where there is an 'imminent health hazard' as defined above (which, according to the proposed rules, requires immediate correction), the license for the food establishment should be suspended for as long as the imminent health hazard exists: see Issue 12(m) above.

(b) If an order by the local public health agency to correct an imminent health hazard is not complied with, the process for enforcement discussed in Issue 21 below should be followed.

(c) It may also be appropriate to seek the imposition of a civil penalty at the Administrative Hearing and/or criminal penalty through a prosecution: see Issue 20 below.

(3) Critical item violation:

(a) Where there is a critical item violation which is to be corrected immediately or within 10 days, we recommend that the local public health agency verify that the critical item violation has been corrected.

(b) If the critical item violation has not been corrected at the end of the correction period, then we recommend that the local public health agency apply to an Administrative Hearing to enforce the orders: see Issue 21 below.

(c) It may also be appropriate to seek the imposition of a civil penalty at the Administrative Hearing and/or criminal penalty through a prosecution: see Issue 20 below.

(d) If the failure to correct the violation within the requisite time frame results in there being an 'imminent health hazard', then the license for the establishment should be suspended in accordance with Issue 12(m) above.

(4) Non-critical item violation:

(a) Where there is a non-critical item violation, we recommend that the local public health agency verify that the critical item violation has been corrected within the ordered timeframe.

(b) If the non-critical item violation has not been corrected at the end of the correction period, then we recommend that the food safety agency apply to an Administrative Hearing to enforce the orders: see Issue 21 below.

(c) It may also be appropriate to seek the imposition of a civil penalty at the Administrative Hearing and/or criminal penalty through a prosecution: see Issue 20 below.

(d) If the failure to correct the violation within the requisite time frame results in there being an 'imminent health hazard', then the license for the establishment should be suspended in accordance with Issue 12(m) above.

e) Charging for re-inspection where there is a correction of a violation

i) Issue: Should there be a power to charge establishments for re-inspections which are required to verify correction of violations?

ii) Recommendation: The power to charge for reinspections should be set down in the rules and a fee for reinspections (possibly increasing for each reinspection after the first 'unsuccessful' inspection) should also be included in the rules.

14) Responsibility of license holder to cease operations if imminent health hazard exists

i) Issue: There does not seem to be a provision in the statute or rules requiring a license holder to voluntarily cease operations as soon as they identify that their operations pose an imminent health hazard.

ii) Recommendation: We recommend that the statute impose a clear duty on license holder to cease operations if an imminent health hazard exists because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of apparent foodborne illness outbreak, gross unsanitary occurrence or conditions, or other circumstance that may endanger public health. It should be the duty of the license holder to notify the local public health agency if an imminent health hazard exists in their operations. There should be a requirement that the establishment have approval from the local public health agency to recommence operations. For an example of such a provision, see sec. 8-404.11 of the *Food Code*.

15) Consumer complaints

a) **Issue:** There is no provision in Montana's laws which allows the Department or local public health agencies to receive and act on complaints from the public about the safety of food.

b) **Recommendation:** We recommend that there be a provision added to Montana's food safety laws as set out below. The provision enables a person to make a complaint and places an obligation on the agencies to 'investigate'. The obligation to investigate would require that the Department or the local public health agencies fully consider the complaint and take appropriate steps if the complaint is found to have substance.

> (1) A person that has reason to believe that a food, which is or was at a wholesale food establishment or is or was at a retail food establishment, may be in violation of a food safety law, should immediately notify the Department and the local public health agencies of the identity and location of the food.
>
> (2) The Department and the local public health agencies must investigate all complaints received under section (1).

16) Examining, holding and destroying food

a) **Issue:** In relation to food service establishments, ARM 37.110.240 provides that an owner or person in charge shall allow the food safety agency to examine and sample food within the establishment at all reasonable times as is necessary for the enforcement of rules relating to food service establishments: (1). If the food safety agency finds or has probably cause to believe that food it has examined or sampled is adulterated or misbranded, it shall detain or embargo food by affixing a tag to it which prohibits its removal or use until permission is given by the regulatory authority or a court: (2). If food safety agency finds that the food is not adulterated or misbranded, it shall authorize its release; however, if it finds that it is adulterated or misbranded, it shall petition a justice court, city court or district court for an order condemning the food and authorizing its destruction: (3). However, there is a different provision for 'perishable food'. 'If a food safety agency finds that a perishable food is unsound or contains any filthy, decomposed, or putrid substance or that may be poisonous or deleterious to health or otherwise unsafe, the food safety agency shall immediately condemn or destroy the article or in any other manner render the article unsalable as human food. A 'perishable food' means 'any food of such type or in such condition as may spoil'. The Study Group says that it is not always clear when food can be destroyed and that the process of seeking a judicial order for the destruction of food is highly burdensome. We also note that there are no provisions for examining, holding or destroying food in relation to food manufacturing establishments. This means that food in these establishments cannot lawfully be examined, held or destroyed.

b) **Recommendation:**

i) There should be powers to examine, hold and destroy food, whether the food is in a food service establishment or a wholesale food establishments or elsewhere. These powers should not only apply to food located in licensed food establishments.

ii) Furthermore, we recommend that there is the same provision in relation to 'perishable' and 'non-perishable' foods.

iii) We recommend that the following provisions for making hold orders be enacted based on sec.8-803.10 of the *Food Code*:

(1) The representative of the representative of the local public health agency may place a 'hold order' on food if he or she has reasonable cause to believe that the food originated from an unapproved source, may be unsafe, adulterated or not honestly presented, is not labeled according to law, or is not otherwise in compliance with the statute or the rules.
(2) If the local public health agency has reasonable cause to believe that that the hold order will be violated or finds that the order is violated, the local public health agency may remove the food that is subject to the order to a place of safekeeping.
(3) The local public health agency is not required to give a prior warning, notice of hearing, or hearing on the hold order.
(4) The contents of the hold order shall:
(a) state that the food subject to the order may not be used, sold, moved from the food establishment, or destroyed without written release of the order from the local public health agency;
(b) state the specific reasons for putting the food under the hold order;
(c) completely identify the food subject to the hold order;
(d) state that the license holder has the right to appeal the hold order;
(e) state that the local public health agency may order the destruction of the food if a timely request for an appeal is not received; and
(f) provide contact details for the appeal.
(5) Food under the hold order may not be used, sold, served or moved from the establishment by any person.
(6) Only the local public health agency may remove hold order tags, labels or other identification from the food subject to the hold order.
(7) A copy of the order shall be clearly posted at a public entrance to the food establishment. Food which is subject to the hold order should be officially tagged.
(8) The local public health agency may examine, sample and test food in order to determine its compliance with the statute and the rules.

iv) Appeal: The license holder may request a Review Hearing to review the hold order. The same process should be followed for this Review Hearing as for the Administrative Hearings following the denial of a license, suspension of a license etc: see Issues 12(g) and (m) above. However, there should be provision made for a Review Hearing to review a decision to tag food to be held more quickly than hearings into

other matters. We recommend providing that the hearing take place no later than 5 days after an application for review is filed. It may be appropriate with perishable goods for the Review Hearing to be held within 1 – 2 days.

v) If a hold order is sustained upon appeal or if a timely request for a review is not filed, the food safety agency may order the license holder to bring the food into compliance with this statute or the rules if possible to do so or to destroy or denature the food under the local public health agency's supervision.

vi) The local public health agency shall issue a notice of release from a hold order and shall remove hold tags, labels or other identification from the food if the hold order is vacated.

17) Recall of food

a) Issue: Is it necessary to have a power in the Department and the local public health agencies to recall adulterated food? Most establishments voluntarily recall products because there is sufficient commercial incentive for them to do so. There are also powers in the state and local agencies to detain and dispose of food which where certain circumstances exist. However, there may be a situation where unsafe food is no longer at a food establishment which is regulated by the law – it may now be at a private home – and the manufacturer/ distributor/ retailer of the food refuses to voluntarily recall the food. There is no power in the Department and the local public health agencies to recall food in these circumstances. Should they have the power to recall food?

b) Recommendation: Although the recall power may be used infrequently, it is a very important tool to have available to the Department and the local public health agencies. We recommend that the power be drafted as follows based on sec. 403 of the *Food Safety Modernization Act*:

i) Application of the recall power: There is currently no power for mandatory recall of foods in Federal law. The lack of the power at the Federal level means that care needs to be taken into account in drafting a recall power for inclusion in Montana's law to ensure observance of the express Federal preemption in the regulation of meat, milk and eggs. (We note that whilst there is express federal preemption of state law in relation to poultry, there is an exemption which allows poultry processors to be regulated by both the state and federal governments: Public Law 90-492.) The definitions of 'wholesale food manufacturing establishment' and 'retail food manufacturing establishments' in the MCA 50-50-102 and 50-57-102, with their exclusions of 'milk producers' facilities, milk pasteurization facilities, or milk manufacturing plants, slaughterhouses, meat packing plants, meat depots, producers or harvesters of raw and unprocessed farm products' have been drafted so as to avoid violation of express Federal preemption provisions. The recall power should apply to 'wholesale food establishments' (which encompass 'wholesale food manufacturing

establishments' with the exclusions outlined above) and 'retail food establishments' (which encompass 'retail food manufacturing establishments' with the exclusions outlined above).

ii) We recommend that the provision provide for voluntary and, failing that, mandatory recall:

(1) If:
(a) the Department or a local public health agency has reasonable cause to believe that the food originated from an unapproved source, may be unsafe, adulterated or not honestly presented, is not labeled according to law, or is not otherwise in compliance with the statute or the rules; and
(b) there is reasonable probability that the food, if consumed, would present a threat to public health,
the Department or a local public health agency shall give the appropriate persons (including manufacturers, distributors, or retailers of the food), an opportunity to:
(c) Cease distribution of the food;
(d) Notify all persons processing, distributing or otherwise handling the food to immediately cease such activities with respect to the food;
(e) Notify persons to which the food has been distributed, transported or sold to immediately cease distribution of the food;
(f) Recall the food; and/or
(g) In conjunction with Department or a local public health agency, provide notice of the finding of the Department or a local public health agency to consumers to whom food was or may have been distributed and to federal, state and local public health officials.

(2) If a person given an opportunity to make a voluntarily recall refuses to, or does not adequately, carry out the actions described in that paragraph within the time period and in the manner prescribed by the Department or a local public health agency, the Department or a local public health agency shall:
(a) Have authority to control and possess the food, including ordering the shipment of the food from the food establishment to the Department or a local public health agency at the expense of the food establishment or, in an emergency, at the expense of the Department or a local public health agency;
(b) By order, require, as the Department or a local public health agency determines to be necessary, the person to immediately:
(i) Cease distribution of the food;
(ii) Notify all persons – processing, distributing or otherwise handling the food to immediately cease such activities with respect to the food;
(iii) Notify all persons if the food has been distributed, transported or sold to cease distribution of the food.

(3) The Department or a local public health agency shall, as the

Department or a local public health agency determines to be necessary, provide notice of the recall to consumers and federal, state and local public health agencies, and provide notice to the public of the names and addresses of the retail locations at which recalled food products were available for sale.

(4) A person that processes, distributes or otherwise handles food or to which food have been distributed, transported or sold, and that is notified of the recall, shall immediately cease distribution of the food.

(5) Each person that processed, distributed or otherwise handled food shall make available to the food safety agency information necessary to carry out this subsection regarding persons that processes, distributed or otherwise handled the food, and the persons to which the food has been transported, sold, distributed or otherwise handled.

iii) **Appeal of an order:** The Department or a local public health agency shall provide any person subject to a recall order with the opportunity for a hearing to be held as soon as practicable, but not later than two days after the issuance of the order. The hearing should be by way of Review Hearing: see Issue 12(g) above.

18) Prevention of foodborne disease transmission by employees

a) **Issue:** There are no provisions which expressly provide for the exclusion of food employees from food manufacturing establishments. The only way to exclude these employees from food manufacturing establishments is by way of an injunction to prevent them breaching the requirement in MCA 50-57-105 that 'A person who has a communicable disease…may not work in any establishment or in the handling or processing of food'. This is not a straightforward and expeditious process. By contrast, there are provisions in ARM 37.110.242 setting down the process for the exclusion of employees from 'food service establishments' where 'there is reasonable cause to suspect possible disease transmission by a food employee'. Are these provisions adequate?

b) **Recommendation:**

i) There should be the same powers to restrict, exclude and obtain medical information in relation to food employees of food service and food manufacturing establishments.

ii) We also consider that the basis for exercising powers in relation to food employees could be broader than in situations where there is 'possible disease transmission by a food employee': ARM 37.110.242 It is not clear whether it has to be suspected that *has been* disease transmission or it has to be suspected that there *could be* disease transmission. This should be clarified.

iii) We also consider that it should be made clear when the local public health agencies can release a food employee from restrictions or exclusions. This brings clarity to the exercise of powers by the local public health agencies by identifying the restraints to be imposed on their powers. It is important for the food employees subject to the agencies' powers of restrictions, exclusion and medical examination to understand the limits of these powers.

iv) We recommend that the following provisions be enacted based on the provisions on Part 8-5 of the *Food Code*:

(1) The local public health agency shall act where it has reasonable cause to believe that a food employee has possibly transmitted disease, may be infected with a disease in a communicable form that is transmissible through food, may be a carrier of infectious agents that cause a disease that is transmissible through food, or is affected with a boil, an infected wound, or acute respiratory infection.

(2) The actions which the local public health agency may take are:
(a) Securing a confidential medical history of the food employee suspected of transmitting disease or making other investigations as deemed appropriate;
(b) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis of a suspected food employee or conditional food employee.

(3) Based on the findings of an investigation related to a food employee who is suspected of being infected or diseased, the local public health agency may issue an order to the suspected food employee or license holder instituting one or more of the control measures:
(a) Restricting the food employee;
(b) Excluding the food employee;
(c) Closing the food establishment by summarily suspending a license to operate in accordance with the procedures set down in this statute or rules.

(4) There is no requirement for a warning, notice of hearing or a hearing required if the order by the local public health agency states the reasons for the restriction or order, states the evidence which is required to be provided in order to demonstrate that the reasons for the restriction or exclusion are eliminated, states that the suspected food employee or license holder may request an appeal hearing by submitting a timely request, and provides the name and address of the representative to whom a request for an appeal hearing may be made.

(5) A copy of the order must be clearly posted at a public entrance to the food establishment.

(6) The license holder may request an a hearing review the exclusion or restriction order.

(7) The local public health agency shall release a food employee from restriction or exclusion according to law and the conditions specified in the statute or rules regarding the requirements on food establishments to exclude or restrict their employees.

19) Injunctions

a) **Issue:** There is currently power in MCA 50-50-106 and MCA 50-57-106 for the regulatory authority to bring an action for an injunction against the continuation of an alleged violation of the statute or the rules for retail food establishments and wholesale food establishments respectively. The provision to make injunctions in relation to the FDCA only applies in relation to certain products (eg, honey and hamburgers). This is a omission from the FDCA.

b) **Recommendation:** We recommend the inclusion of a provision to empower the Department or the local public health agencies to seek an injunction to prevent the occurrence of, or continuation of, violations of any of the provisions of the food safety statute and the rules. A provision like that suggested in sec. 8-812.10 of the *Food Code* could be used in Montana:

The Department and the local public health agencies may, according to law, petition a court of competent jurisdiction for temporary or permanent injunctive relief to achieve compliance with the provisions of the statute or the rules or its orders.

20) Prohibited acts and penalties

a) **Issue:** When should a civil or criminal penalty be imposed for a violation of a food safety standard? What should the penalties be?

   i) At present, MCA 50-50-108 and MCA 50-57-108 provide that a person who 'purposefully or knowingly violates provisions of this chapter or rules adopted by the Department is guilty of a misdemeanor' and 'upon conviction, the person shall be … fined not less than $50 or more than $100 for the first offense, fined not less than $75 or more than $200 for the second offense, fined not less than $200 and imprisoned in the county jail for not more than 90 days for the third and subsequent offenses.' MCA 50-50-109 and MCA 50-57-109 also provide that 'an establishment which violates this chapter or the rules adopted by the Department under this chapter is subject to a civil penalty not to exceed $500.' The mental element is stricter for a finding that a misdemeanor has been committed as it needs to be demonstrated that the person purposefully or knowingly violated the food safety provision.

For a civil penalty to be imposed, the mere violation of the food safety standard, regardless of the person's state of mind, is sufficient. This, however, does not correlate with the penalty provisions with the civil penalty being more onerous than the criminal penalties, except in relation to the option for imprisonment.

ii) By contrast, the FDCA 50-31-501 sets down a number of acts (and the causing of those acts) which are prohibited, such as 'the manufacture, sale or delivery, holding or offering for sale of any food … that is adulterated or misbranded', 'the adulteration or misbranding of any food…', and 'the receipt in commerce of any food … that is adulterated or misbranded … and the delivery or proffered delivery of any food…or pay or otherwise'.

b) Recommendation: We would recommend the civil and criminal penalty regime be amended as follows:

i) General provision:

(1) There should be the following provisions entitled 'Prohibited acts' which state that 'Within the state of Montana, it is prohibited for a person to:

(a) act in violation of any of the standards in the sub-part X (food service establishments) and Y (wholesale food establishments) of the statute or the rules;

(b) do or cause any of the following acts…' and then list the acts which are prohibited under the FDCA 50-31-501; and

(c) act in violation of the orders made by the local public health agencies, at an administrative hearing or at a judicial hearing under this statute or the rules.

(2) We recommend retaining the defenses to the prohibited acts in FDCA 50-31-501(1) and (3).

ii) Civil penalties:

(1) When may a civil penalty be imposed?: Based on an amalgamation of sec. 405(a)(1)(A) of the *Food Safety Modernization Act* and sec. 8-813.10 of

(2) the *Food Code*: 'Any person that commits a prohibited act is subject to a civil penalty not exceeding $X. Each day on which the prohibited act occurs is a separate violation under this section.' We note that the MCA currently applies civil penalties to 'establishments' only. We advise that the term 'person' be used to refer to a legal person, which could be an individual, a corporation, a government department, a legal partnership etc.

(3) What is the process? The local public health agencies may apply to an Administrative Hearing for a civil penalty to be imposed on a person who violates the food safety statute or rules or a food safety order.

(4) What is the amount of a civil penalty? We recommend that the civil penalties be significantly increased. We note:

(a) Sec 405(a)(1)(A) of the *Food Safety Modernization Act* states that the civil penalty should be no more than $1 million for each

act of violation. We suggest that it is unrealistic for Montana to provide for such penalties, even as maximum amounts.

(b) We would recommend that the setting of the civil penalties for doing a prohibited act carefully take into account the civil penalties provided in Montana for other conduct. However, if the other civil penalties are found to be too low, this should not constrain the setting of higher civil penalties for prohibited acts.

(c) We consider that a daily civil penalty for each prohibited act of *up to* $5,000 would not be inappropriate.

(d) In sec. 405(a)(2)(B) of the *Food Safety Modernization Act*, it provides that the amount of the civil penalty shall be determined after considering the gravity of the violation, the degree of culpability of the person, the size and type of the business of the person, and any history of prior offenses by the person under food safety law. Including a provision like that in the *Food Safety Modernization Act* would enable the penalty to take into account the fact that the person's food establishment was a small operation run by the owners of the business, as compared to, for example, a national restaurant chain.

(5) Review of the order: We recommend making provision for judicial review of the civil penalty order made at the Administrative Hearing.

iii) Criminal penalties:

(1) When may a criminal penalty be imposed? We recommend that Montana include the following provision in its statute: 'A person who purposefully or knowingly does a prohibited act is guilty of a misdemeanor.' We recommend that Montana retain the requirement that the act be committed 'purposefully or knowingly'. Montana may also want to introduce an additional 'severe violation' as follows: 'A person that purposefully or knowingly does a prohibited act, after having being convicted of a prohibited act, or who commits such a prohibited act with intent to defraud or mislead, shall be fined up to $20,000, imprisoned for a period of not more than one year, or both'. The latter provision is intended to address the situation of 'repeat offenders' and offenders who commit the violation with a particularly egregious state of mind: the intention to mislead or defraud.

(2) Who may impose a criminal penalty? It should only be the courts which have the power to impose a criminal penalty.

(3) What is the process? MCA 50-50-107 suggests that the current process for the criminal prosecution of persons who commit a prohibited act is that the local public health agency refers the matter to the county attorney for prosecution and that 'the county attorney *shall* prosecute any person, firm or corporation violating' the food safety laws. The same provision appears in relation to wholesale food establishments in MCA 50-57-107. There seems to be discretion in the regulatory authorities as to whether to refer the matter for prosecution. However, the county attorney has no discretion about whether or not to proceed with the

prosecution. We recommend that the statute explicitly state that 'Nothing in the statute requires the food safety agencies to report for prosecution a prohibited act under the statute or the rules in a case in which the food safety agencies finds that the public interest will be adequately served by the assessment of a civil penalty under section X.' We recommend that Montana retain the provision which requires the county attorney to proceed with a prosecution which has been referred to it by the food safety agency.

(4) What is a criminal penalty? We recommend that the criminal penalties be significantly increased. The setting of the exact level of the penalty is a matter for Montana, however, we note:

- **(a)** We would recommend that the setting of the criminal penalties for a prohibited act carefully take into account the civil penalties provided in Montana for other conduct.
- **(b)** We consider that a daily criminal fine for each prohibited act of up to $10,000 would not be inappropriate.

21) Enforcement of orders made by the Department or the local public health agencies or at an administrative hearing

- **a) Issue:** There is a need to be clear about the process for enforcing orders which are made by the Department or the local public health agencies or by an administrative decision-maker at a Review Hearing or at an Administrative Hearing.
- **b) Recommendation:**
  - **i)** We recommend that where a person refuses to follow an order made by the food safety agency, then it is appropriate for the food safety agency to apply to an Administrative Hearing for an order that the food safety agency's order be followed. We recommend that there be provision made for a multi-person panel to hear an application for enforcement of an order made by the Department or the local public health agencies.
  - **ii)** We recommend that where a person refuses to obey an order made by an administrative decision-maker at an Administrative Hearing or a Review Hearing, then it is appropriate for the Department or the local public health agencies to apply to the court for an order that the administrative decision-makers order be followed.

22) One enforcement action not bar to other enforcement action

- **a) Issue:** MCA 50-50-109 states that 'Civil action to impose penalties, as provided under this section, does not bar injunctions to enforce compliance with this Chapter or to enforce compliance with a rule adopted by the Department pursuant to this chapter.
- **b) Recommendation:** We recommend that an enlarged version of this provision be included in a revised statute as follows: 'Any one of the remedies provided in the statute or the rules may be exercised in addition to any other remedies that may be available.

23) Notices

a) **Issue:** There are no provisions regarding the proper method of service of notices relevant to enforcement of food safety laws.

b) **Recommendations:**

i) **Option A:** It is open to Montana to follow the methods for service of notices for enforcement of food safety laws which are to be found in Montana's civil and criminal procedure statutes and rules.

ii) **Option B:** It is also open to Montana to include specific provisions regarding notices in its food safety statute or rules. Examples include the provisions in the *Food Code* Part 8-7. Whilst most of these provisions deal with food safety enforcement action generally, there is a provision in sec. 8-701.20 which sets down special notice requirements for restriction or exclusion orders, hold orders, and summary suspension orders. These orders shall be 'personally served by the regulatory authority, a law enforcement officer or a person. We would recommend that, even if Montana were to follow, in most instances, the notice procedures in its general civil and criminal procedure statutes, it should adopt these particular notice provisions in relation to these food safety compliance and enforcement mechanisms.

24) Other enforcement provisions

a) **Issues:** There are a number of other compliance and enforcement provisions in Montana's statute and rules. Should they be retained?

b) **Recommendations:**

i) **Pre-inspection review:** The rules providing for pre-operation inspection should be retained: ARM 37.110.303

ii) **Licenses:** Some of other provisions regarding licenses should be retained:

(1) The allowance regarding separate licenses: MCA 50-57-201.

(2) The requirement for return of licenses for destruction upon cancellation: MCA 50-50-213.

iii) **Discovery of food capable of causing foodborne illness:** Delete MCA 50-50-304 regarding the health officer issuing a report in writing recommending that food be withheld from sale. This provision is redundant given the enforcement provisions recommended above.

iv) **Costs recovery:** The costs recovery power in MCA 50-50-110 and MCA 50-57-110 should be retained.

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