PART A

A PUBLIC HEALTH FRAMEWORK FOR REVIEWING THE MONTANA CODE AND ADMINISTRATIVE RULES FOR FOOD AND CONSUMER SAFETY

DRAFT ONLY

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1. INTRODUCTION

We have been asked to review Montana's statutes and administrative rules related to food and consumer safety and to make recommendations for enhancements to those laws in order to promote and protect the public's health.

The Montana statutes and administrative rules that are the subject of our Report are listed in Appendix A ('MT's Food and Consumer Safety Laws'). These laws were sourced from legal search engines, Westlaw, and the websites of the Montana State Legislature and the Montana Department of Public Health and Human Services.

This Report presents a public health approach to Montana's review and reform of its Food and Consumer Safety Laws. It is intended that the relevant agencies in Montana discuss the approach presented here and decide whether this approach should guide Montana in its review of its Food and Consumer Safety Laws.

To this end, in Part 2 of this Report, we set out an analytical framework which could guide the review of MT's Food and Consumer Safety Laws ('Food and Consumer Safety Framework'). The Framework directs attention to the agency which should be responsible for the particular aspect of food and consumer safety, the public health standards which should apply, the methods which should be used for securing compliance with those standards, and the requirements for due process. Part 3 sets down some key principles which could be taken into account in designing a regulatory system for food and consumer safety ('Food and Consumer Safety Principles'). Part 4 of this Report presents an example of how the Food and Consumer Safety Framework and Principles could be applied to review the regulation of Montana's food safety laws. This Part summarizes the findings of a detailed assessment of Montana's Food Safety

Laws which is Part B to this Report. The value of the Food and Safety Framework and Principles becomes evident in this Part of the Report. Part 5 of this Report suggests the future actions which we recommend that Montana take.

2. FOOD AND CONSUMER SAFETY FRAMEWORK

Our suggested Food and Consumer Safety Framework can be used to assess the adequacy of most aspects of MT's Food and Consumer Safety Laws and, if there are found to be gaps in these laws, to construct a new set of laws. The Framework addresses the following essential matters which, in our view, provide an over-arching structure for a food and consumer safety system and should be part of any high quality, responsive, public health-oriented regulatory mechanism:

- Who is responsible for regulating each aspect of food and consumer safety?
- What are the standards which apply to each aspect of food and consumer safety?
- What is the method used for implementing and enforcing the standards which apply to each aspect of food and consumer safety?
- What are the due process requirements which apply to each aspect of food and consumer safety?

Each of the parts of the Framework is discussed below.

a. Food and Consumer Safety Framework: Who is responsible for regulating each aspect of food and consumer safety?

Any system of food and consumer regulation must clearly identify and demarcate the roles and responsibilities of government agencies for specific aspects of the regulatory system. Confusion, uncertainty and duplication of function should be eliminated. Agencies at the federal, state and local level should be considered as part of this exercise. There may also be multiple agencies at each level of government with an 'interest' in the subject of the regulation. The area of responsibility of each of these agencies should be clarified to the greatest possible extent.

The division of responsibilities should start by determining who has regulatory *capacity* in relation to specific aspects of food and consumer safety. This is a legal question and may depend on the content of the Federal or State Constitution, and the statutory or common law rules relating to primacy of one level of government over the other. For example, the US Constitution provides that federal laws are supreme and preempt State laws. Some Federal statutes expressly preempt State law and provide that a State law may not be different to the federal law. This has been the approach taken in many aspects of food and consumer safety. This has the effect of limiting the regulatory capacity of the States.

If there is more than one agency which has regulatory competence to act in a specific area of food and consumer safety, then there needs to be a decision made as to which agency will be empowered to act and/ or have the duty to act. These decisions are not matters of law, but of policy. Determining the agency which is responsible needs to be discussed and decided among the agencies. There are myriad options available to Montana in relation to divisions of regulatory powers and duties for food or consumer safety. Some of these options are discussed here.

The optimal arrangement is for a statute or an administrative rule to designate *a single agency* which has a duty for a certain aspect of food or consumer safety and to grant all the powers which are necessary for that agency to carry out its duty ('Option A'). This arrangement makes clear the responsible agency, which is beneficial for all users of the system. The agency's performance can also be assessed against a specific statement of its responsibilities. The fact that the duty and powers are recorded in statute means that there is some sense of permanence – or at least longevity – to the arrangement. However, the negotiations to reach such a designation should address the practical ability of an agency to carry out the duty in question. The regulatory system loses its impact where an agency is charged with carrying out a task but has no real capacity to do so. This exact problem is seen in relation to the Federal Food and Drug Administration ('FDA') which has broad responsibilities and powers, but deeply inadequate resources to perform its role.

Another option is for statute or rules to grant *more than one agency* the power to regulate the same aspects of food or consumer safety. However, it may not be very efficient for multiple agencies to be exercising the same powers over the same matters. Instead, the empowered agencies could negotiate amongst themselves about which of them will take responsibility for the aspects of food or consumer safety where their powers were overlapping ('Option B'). An administrative rule could then designate which agency (or agencies) has the duty to act in relation to a specific aspect of food or consumer safety. Alternatively, the duty of the agency could be recorded in an agreement between the agencies which are empowered to act. Option B allows for more fluidity in the regulatory arrangements than Option A. The agencies could renegotiate the power-sharing on an annual or biennial cycle, for example. The enshrinement of the duty in a rule or a contract means that it would be easier to change the distribution of responsibilities. If the duties of the agencies are recorded in statute, an amendment to the statute is needed to redistribute those responsibilities. Again, the practical ability of the agency to carry out its duty is very important. This needs to be interrogated as part of the decision-making about which agency should carry the duty. An agreement as to remuneration for the agency carrying out the duty could be negotiated. The main risk associated with Option B is that the agencies are unable to agree on who will bear the responsibility for some aspect of food or consumer safety. This means that time and resources are inefficiently expended on unsuccessful negotiations, that no agency assumes regulatory control of the matter and that the end result is that the public are not adequately protected by way of regulation from food or consumer safety risks.

A variation on Option B would be to include a provision in a rule or an agreement which allows the agency with designated responsibility for an aspect of food or consumer safety law to cease to carry out its responsibility should certain defined circumstances arise ('Option C'). These circumstances may include severe lack of financial or other resource capacity. This occurrence would then require that the agencies with power in relation to the relevant area of food or consumer safety renegotiate the sharing of responsibility. This arrangement gives flexibility to the agencies, but creates a lack of certainty that important public health responsibilities will be carried out and produces inefficiency in having to revisit the same issue. This would also be an unusual provision to find in statute, but may be found in a rule or an agreement.

b. Food and Consumer Safety Framework: What are the standards which apply to each aspect of food and consumer safety?

A regulatory system for food and consumer safety must set specific, current, science-based, public-health oriented safety standards. The aim of these standards should be to make food and other consumer goods and services 'safe' – or as safe as possible given the inherent risks in some goods and services – and to thereby prevent harm and damage to individuals and communities.

MT's Food and Consumer Safety Laws cover, amongst other things, food, water, public accommodation, swimming pools, campgrounds, schools, and day care centers. In order to combat many of the risks associated with this specific set of goods, services and facilities, appropriate standards must be developed and maintained in relation to structures and premises, sanitation and hygiene of premises, pest control, and food and water for human and animal consumption.

Standards for structures and premises would cover matters such as requirements for floors, walls and partitions of bathhouses at public bathing places,[1] signs, buoys and lifesaving equipment for public bathing places,[2] diving boards at public bathing places,[3] the location of swimming pools and spas,[4] the depth of swimming pools,[5] piping systems for swimming pools,[6] lifeguards at swimming pools[7], ventilation and lighting,[8] service buildings at trailer courts and tourist campgrounds,[9] ratio of toilet facilities to people at youth camps,[10] heating in schools,[11] and fire hazards.[12]

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[1] MONT. ADMIN. R. 37.111.1013.
[2] MONT. ADMIN. R. 37.111.1021.
[3] MONT. ADMIN. R. 37.111.1022.
[4] MONT. ADMIN. R. 37.111.1114.
[5] MONT. ADMIN. R. 37.111.1014.
[6] MONT. ADMIN. R. 37.111.1142,
[7] MONT. ADMIN. R. 37.111.1154.
[8] MONT. ADMIN. R. 37.111.1148 (Swimming pools and spas); MONT. ADMIN. R. 37.111.830 (Lighting in schools).
[9] MONT. ADMIN. R. 37.111.230.
[10] MONT. ADMIN. R. 37.111.518.
[11] MONT. ADMIN. R. 37.111.831

Standards for sanitation and hygiene of premises would include requirements regarding trash disposal at public bathing places,[13] the quality of the water supply,[14] sewage facilities,[15] exclusion of persons with a communicable disease from certain places,[16] disinfectant and chemical feeders for swimming pools and spas,[17] laundering of bedding, towels and washcloths in bed and breakfast establishments ('B & B'),[18] housekeeping in B & Bs,[19] blood-borne pathogen protection in B & Bs,[20] pets on premises,[21] and cribs and diapers for children in child care facilities.[22]

Standards for pest control cover measures to prevent or minimize the presence of pests (such as rodents, flies, insects and other vermin) on premises. Examples can be found in MT's Food and Safety Laws in relation to B & Bs,[23] trailer courts and campgrounds,[24] youth camps,[25] work camps,[26] and schools.[27]

Standards for safe food and water for human consumption include controls to prevent the adulteration of food, and the proper labeling and branding of food. The best regulatory systems would apply standards from 'farm to fork', but many apply standards to processors, retailers and providers of food, but do not apply them to farmers and primary producers of food. In Montana, food and water safety regulation applies to retail food establishments, wholesale food establishments, B & Bs,[28] youth camps,[29] work camps,[30] schools,[31] child day care centers,[32] community homes for persons with physical disabilities,[33] and community homes for persons with developmental disabilities.[34]

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[12] MONT. CODE ANN. 52-2-734 (Day care facilities); MONT. ADMIN. R. 37.100.420 (Community homes for persons with disabilities).
[13] MONT. ADMIN. R. 37.111.1011.
[14] MONT. ADMIN. R. 37.111.1010 (Public bathing areas); MONT. ADMIN. R. 37.111.206 (Trailer courts and tourist campgrounds).
[15] MONT. ADMIN. R. 37.111.1012 (Public bathing places); MONT. ADMIN. R. 37.111.328 (Bed and breakfast establishments); MONT. ADMIN. R. 37.111.116 (Hotels, motels, tourist home etc); MONT. ADMIN. R. 37.111.207 (Trailer courts and tourist campgrounds).
[16] MONT. ADMIN. R. 37.111.1023 (Public bathing places).
[17] MONT. ADMIN. R. 37.111.1139.
[18] MONT. ADMIN. R. 37.111.335.
[19] MONT. ADMIN. R. 37.111.336.
[20] MONT. ADMIN. R. 37.111.342.
[21] MONT. ADMIN. R. 37.111.344 (B & B); MONT. ADMIN. R. 37.111.226 (Trailer courts and tourist campgrounds).
[22] MONT. ADMIN. R. 37.95.210.
[23] MONT. ADMIN. R. 37.111.330.
[24] MONT. ADMIN. R. 37.111.217 – 218.
[25] MONT. ADMIN. R. 37.111.532.
[26] MONT. ADMIN. R. 37.111.621.
[27] MONT. ADMIN. R. 37.111.846.
[28] MONT. ADMIN. R. TITLE 37, CHAPTER 111, SUB-CHAPTER 3.
[29] MONT. ADMIN. R. 37.111.522.
[30] MONT. ADMIN. R. 37.111.618.
[31] MONT. ADMIN. R. 37.111.842.
[32] MONT. ADMIN. R. 37.95.214.
[33] MONT. ADMIN. R. 37.100.421.
[34] MONT. ADMIN. R. 37.100.320.

Montana should test whether it has adequate standards for structures and premises, sanitation and hygiene, pests, and food and water. Where there are standards in existence, there needs to be a check that the standards reflect current knowledge about the risks which come with the goods, services or facilities and about the best strategies for combating the risks. There need to be mechanisms for keeping these standards current. The standards should aim to safeguard the health and safety of individuals, as well as communities. Public health and safety goals should be given considerable weight in the setting of standards and should generally take precedence over many other interests. The setting of standards may raise difficult questions over the protection of other individual rights, such as the liberty of the person, privacy and personal property rights. Care should also be taken that the standards are not unnecessarily burdensome. Where the achievement of public health goals are reflected in standards, the aim should be to provide a very high level of safety.

c. Food and Consumer Safety Framework: What is the method used for implementing and enforcing the standards which apply to each aspect of food and consumer safety?

The development and promulgation of standards is a first step in protecting against risks of harm to the public. Strategies need to be designed and implemented for the enforcement of public health standards, because compliance with the standards is essential for securing the public's health. Given the importance of the standards, it should not be assumed that public health standards are being met by those subject to regulation. There need to be measures in place for checking at appropriate intervals whether standards are, in fact, being met. Where standards are not being met, there need to be clear consequences of non-compliance, and/ or steps taken to secure compliance, and/ or measures taken to protect the public from risks which arise from the non-compliance.

Licenses: In order to facilitate monitoring for compliance with standards, it is valuable to have a licensing system for individuals or organizations which are subject to specific public health standards. The key features of an effective licensing system are an application process which elicits all relevant information from the license applicant, the careful and objective application of relevant criteria for the grant of a license, a clear statement of the responsibilities of license-holders, and a prohibition on the operation of an establishment or the provision of goods or services in the absence of a license.

In many systems, there are requirements for the renewal of the license at suitable intervals. It may also be considered important that the applicant pay a fee for the license. Often, these fees are nominal amounts, with it being unclear how the original fee was calculated (many years earlier) and with the fee simply being increased annually in accordance with inflation. An alternative is for a fee scale to be established which reflects the total cost to the regulatory authority of regulating a single (compliant) license-holder in a financial year. In this system, there may be different fees for different 'types' of individuals and organizations. The fee scale could be based on a number of variables, such as risks associated

with establishments, patron capacity (eg, for restaurants, B & Bs, community homes), physical size (eg, for campgrounds), or annual financial turnover. Whichever measure is used for developing a scaled-fee system, the guiding principle should be that the measure is clear and can be tested against objective evidence. This will reduce the administrative burden and costs associated with operating a scaled fee system.

We would suggest that it is essential that there be powers in the regulator to summarily suspend or cancel licenses. The summary suspension power is particularly valuable where there is an urgent public health risk and the management of that risk requires that the establishment be prevented from offering goods or services until the risk is eliminated.

Testing and surveillance: It is important that there be a methodical system for seeking, receiving, testing, analyzing and tracking information on injuries and harms which are arising from the food and consumer safety areas subject to regulation. This information enables harms to be connected to their sources and measures to be taken to prevent the reoccurrence of such incidents. This is particularly important with contagious illnesses, which can spread quickly through the population. The effectiveness of the testing and surveillance systems depends on adequate resourcing, with expert personnel and sound and up-to-date equipment. It is also important that the regulatory system be established with proper procedures for seeking, obtaining, rendering and retaining information which is essential to the surveillance effort.

Inspection: It is very important that there be inspections of licensed persons and organizations to determine whether there is compliance with food and consumer safety standards and reinforce the requisite standards. A priority requirement for an effective inspection regime is credentialing and training of inspectors. There needs also to be an appropriate schedule for conducting inspections. This schedule may have a minimum requirement for inspections (eg, annually), with scope for modification based on the risks posed by license holder to the public health and/or the history of compliance by the license holder with the standards. It is essential that inspectors have a right to unimpeded access premises for inspection purposes. Where access is denied, there should be provisions for applying for, and making, an order for access. The inspection process should be rigorous and exacting and calibrated to the standards which have been set down for food or consumer safety.

Abatement: It is important that there is a power in the relevant regulatory agency to abate any nuisance which is a threat to public health standards in relation to food or consumer safety. There should be a power to make orders prohibiting the continuation of the conduct which is causing the nuisance or requiring the removal or destruction of the nuisance.

Criminal or civil liability: The statute should also provide for civil and/ or criminal penalties for violations of the standards set down and other conduct. The basis for liability should be made clear: what is the act or conduct which gives rise to liability (actus reus)? What state of mind must the wrong-doer have at the

time of the conduct to give rise to liability (mens rea)? For example, in relation to the actus reus, is it the act of adulterating a food product or selling an adulterated food product or both which is the wrong? In relation to the mens rea, it seems that MT's Food and Consumer Safety Laws often do not provide for strict liability, but require that an individual 'purposefully or knowingly' commit the wrongful act. If the wrongs were based on strict liability, the wrong-doer's state of mind is irrelevant and even an 'innocent', accidental deviation from the standard constitutes a wrong. It is advisable that penalties for public health wrongs be consistent across all statutes. Often, penalties for public health wrongs seem to be very low and it is worth revisiting the penalties which attach to these types of misconduct to ensure they achieve the ends of punishment and deterrence.

Other enforcement powers: There are a range of powers which it is valuable for a regulatory authority to have in order to enforce public health standards in relation to food or consumer safety. For example, in relation to food, it can be very effective to have powers to order the holding or tagging of food which is suspected to be contaminated. Similarly, proper enforcement of food safety standards may require that there be a power to recall contaminated food which has been provided to other processors or retailers in the food supply chain or to consumers.

d. Food and Consumer Safety Framework: What are the due process requirements which apply to each aspect of food and consumer safety?

There is a well-understood Constitutional requirement that due process be accorded when any governmental action threatens to interfere with the right of an individual (eg, right to liberty, right to property). We advocate that food and consumer safety statutes particularize the procedural safeguards to be applied when food or consumer regulation has the potential to impact on an individual's rights. For example, food and consumer safety statutes should specify the agency which has the power to make decisions which impact on individuals. It should indicate when the regulatory authority has the relevant power to make a decision or take certain action and when the regulatory authority is required to apply to an administrative body or a court for an order that would authorize the regulatory authority to take certain action. The orders which are available to be made by the administrative body or the court should also be specified. The procedural steps which must be followed, such as the form of applications for orders, the notice to be given to an individual of a hearing, any requirements for hearings, should also be listed to the greatest level of detail possible. These details could be included in rules to the statute.

3. FOOD AND CONSUMER SAFETY PRINCIPLES

In addition to the Food and Consumer Safety Framework, we also recommend the use of several important Food and Consumer Safety Principles. These Principles should be properly taken into account when applying the Framework to the development of specific food and consumer safety laws for Montana. You will

notice that we have woven some of these Principles into the discussion of the Framework in Part 2 above. We consider that the Principles set out below apply universally to all food and consumer safety systems in developed countries. However, you may want to add to these Principles to reflect concerns arising from the particular State and local culture and environment in Montana. The Principles which we suggest are as follows:

- *High quality, science-based standards should be used for food and consumer safety*. It is essential that current science be used as the basis for assessing risks from food and consumer goods and services. There need to be mechanisms in place in the regulatory authority for keeping abreast of scientific developments relating to food and consumer safety and for expediting the updating of laws to reflect these developments. There are obviously different levels of protection against risks which can be instituted through law. We advocate that a high level of protection be the target for Montana and that consumers not be exposed to risks which could be eliminated through reasonable requirements being imposed on manufacturers or retailers in food or consumer safety.
- *There should be continuous improvement in the food and consumer safety system.* It is essential that mechanisms be built into the food and consumer safety system for eliciting and receiving feedback which would assist to increase food and consumer safety. This feedback then needs to be used for reforms of the system.
- *The food and consumer safety system should be open, accessible and responsive to users of the system.* For consumers, the system should be protective of their health and safety and there should be mechanisms for them to give feedback and express concerns about food and consumer products which do not meet the requisite standards. At the same time, the regulatory system should be designed to facilitate the entry and retention of manufacturers and retailers of food and consumer products in the market. Regulations to protect the public health should be least burdensome and obstructive to commercial activities.
- *The regulatory system should be designed with regard to the financial and other resources which are required by the regulatory authorities to implement and enforce the regulations.* This means that a regulatory system should be designed to be as efficient and cost-effective as possible. Unnecessary procedures or standards should be eliminated. Where there are equally effective alternate procedures or standards, the choice should factor in the costs of administering the procedures or standards. Having regard to resourcing also means that the regulatory authority may want to structure the regulatory system so that it is fully or, more likely partly, self-funding. This may occur through the use of a license fee system which reflects the actual cost of regulating different types of businesses. This may also be seen in the charging of fees for re-

inspection of businesses which do not meet the standards at the time of the first inspection and are required to take remedial action.

- *Food and consumer safety laws should be drafted to ensure clarity, consistency and correctness.* It is preferable that statutes and rules be drafted such that the statute sets down the over-arching principles and concepts and that the administrative rules provide the details which are needed to make the principles and concepts in the statute operational. For example, a statute may state that a fee will be charged for an application for a license to operate a public bathing place. The amount of that fee is not properly the subject of a statute. It is an administrative matter which should be included in the rules. This is particularly the case because the level of fees should be reviewed on a regular basis – in many instances, annually – and it is impractical to seek legislative amendment to update fee scales in statutes each year. Similarly, detailed standards about particular premises or products should be in the rules and not in the statute. At present, most standards for foods in Montana are in rules, but standards for honey and hamburgers have made their way into statute.

  Another guiding rule is that terms of art must be used consistently across all inter-related statutes and rules. The term 'food service establishment' should have the same meaning in all Montana food safety statutes. At present, it does not. Furthermore, careful attention must be taken in relation to definitions of key terms to ensure that they cover the intended subjects of regulation. There should not be gaps in the regulatory scheme simply because an important term has been poorly defined.

  A more technical aspect of this Principle is that headings of sections in statutes should match the content of the section and not mistakenly summarize the section. When statutes are under review, such errors should be removed.

4. FOOD SAFETY

We have used the Food and Consumer Safety Framework and Principles set out above to prepare a very detailed analysis of Montana's Food Safety Laws. This analysis is Part B. We have completed this analysis in order for you to see the value of the Food and Consumer Safety Framework and Principles. The resulting analysis of Montana's Food Safety Laws has a clear public health focus, is comprehensive and exacting, and draws out the aspects of the laws which require reform.

We note that we also chose to focus on food safety for our detailed review of Montana's Food and Consumer Safety Laws because we regard food safety as the most pressing consumer issue. There are considerable concerns about the security of the US food supply. Although the United States has one of the

most well-developed food safety programs in the world,[35] a number of adverse food events (involving, amongst other things, spinach, lettuce, and raspberries) in recent years have caused significant damage to members of the public, the food production industries, and government agencies.[36]

In the United States, 'food-borne diseases cause approximately 76 million illnesses annually among the country's 294 million residents.'[37] Over five-thousand deaths per year can be attributed to *Salmonella*, *Listeria*, and *Toxoplasma*, among other food-borne pathogens.[38] Another 325,000 people are hospitalized from illness relating to unsafe food. Children, the elderly and those who are immunocompromised or immunosupressed are more likely to suffer adverse consequences as a result of food-borne illness.[39]

The cost of such incidents is vast. In 2006, the U.S. Department of Agriculture estimated that hospitalizations, lost productivity, and deaths caused by common pathogens in food cost over $6.9 billion per year.[40] However, as a result of contracting food-borne illnesses, many victims develop complications that involve long-term medical and emotional costs. An entire industry may also be affected as a result of the incident. A rash of food-safety problems can sharply reduce consumers' confidence in particular foods and food industries and see them divert their spending dollars to other foods.[41] After the 2006 E.coli outbreak related to spinach grown in California, spinach farmers lost over $350 million as a result of 'declining [consumer] confidence.'[42] At a time when eating fresh produce is regarded as essential for good health, a consumer's reluctance to purchase such products because of fear of illness hurts both the industry and the consumer.

Adverse incidents related to food safety may also reduce consumer confidence in public agencies charged with regulating food. In particular, the 2006 E.coli outbreak caused many to question the FDA's role in promoting food safety.[43]

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[35] *See, e.g.*, Center for Science in the Public Interest. *Local and Global: Food Safety Around the World* (Washington: Center for Science in the Public Interest, 2005), 53 (stating that 'the North American Region is considered to have one of the most advanced food safety programs').

[36] Stacy Finz, "Fresh Spinach Recall After E. Coli Outbreak," *San Francisco Chronicle*, Sept. 16, 2006, http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2006/09/16/MNGN6L72NR1.DTL (last visited Sept. 29, 2008); Rong-Gong Lin II & Mary Engel, "Lettuce Was Culprit in Latest Cases," *Los Angeles Times*, Jan. 13, 2007, at A1; Marian Burros, *Produce is Growing Source of Food Illness*, N.Y. TIMES, SEPT. 16, 2006, *available at http://www.nytimes.com/2006/09/16/us/16bag.html* (last visited Oct. 3, 2008).

[37] Center for Science in the Public Interest. *Local and Global: Food Safety Around the World* (Washington: Center for Science in the Public Interest, 2005), 53.

[38] *Id.*

[39] *See, e.g.*, Janet C. King et al., *Food-borne Illnesses and Nutritional Status: A Statement from an American Society for Nutritional Sciences Working Group*, J. NUTRITION 2613, 2614 (2000).

[40] *See* Center for Science in the Public Interest, *Building a Modern Food Safety System: For FDA Regulated Foods* 2, *available at* http://www.cspinet.org/new/pdf/fswhitepaper.pdf.

[41] *Id*.

[42] *Id*.

[43] *See, e.g.*, Tracie Cone, *California-Style Food Safety Rules Urged by FDA Official*, DAILY NEWS, Sept. 26, 2008, *available at* http://www.dailynews.com/ci_10572440 (last visited Oct. 7, 2008).

Food is also the single consumer issue which affects all people. The other consumer issues being tackled by Montana, such as camp grounds, B & Bs, swimming pools, are very important, but affect much smaller segments of the population.

Our detailed review of MT's Food Safety Laws produced the following findings:

- *Who is responsible for regulating each aspect of food and consumer safety?* There is no clear guidance on the mission, and the specific powers and duties of the various Federal, State and local agencies in Montana's food safety system. The local agencies are mentioned on many occasions in the statutes, but the exact division of responsibilities and powers between the State and local operations is not evident.
- *What are the standards which apply to each aspect of food and consumer safety?* There are gaps in Montana's regulatory coverage of the range of establishments that grow, process and provide food to consumers. Farms are unregulated. Montana's standards for food safety are not in accordance with current food science and do not provide a high level of protection for consumers. Montana is not exercising its legislative competence to the full extent possible to enact standards for safe food.
- *What is the method used for implementing and enforcing the standards which apply to each aspect of food and consumer safety?* There is considerable room for reform in this area. Montana's laws do not address the question of food safety surveillance. There is no trace back system for food. There are changes that could be made to Montana's food safety inspection laws that would strengthen credentialing of inspectors, the inspection process, and the public health powers of inspectors. The civil and criminal liability provisions do not reflect the seriousness of violations of food safety standards. There are holes in the system in terms of powers of enforcement which are necessary to operate an effective food safety system. For example, there is no power to summarily suspend the license of a retail or wholesale food establishment. There is no power to recall adulterated food.
- *What are the due process requirements which apply to each aspect of food and consumer safety?* It is not clear what powers of enforcement the regulatory authority holds and what procedures must be followed for the exercise of those powers.
- *Structure of MT's Food Safety Laws*: there are many structural and technical improvements that could be made to the laws to make them more user-friendly. Too many matters of detail appear in the statutes. There are errors in drafting. There is inconsistent use of terminology which results in gaps in the coverage of the laws.

We recommend that you read the detailed analysis in Part B to understand the facts and reasoning which lead to our conclusions about Montana's Food Safety Laws as summarized above.

5. FUTURE STEPS

We suggest that Montana take the following steps to progress the review of its Food and Consumer Safety Laws:

a. Review this Report, including the detailed analysis of Montana's Food Safety Laws;

b. Discuss and determine whether the Framework and Principles reflect the approach which Montana wishes to adopt for the review of its Food and Consumer Safety Laws. The discussion may identify additional matters to be taken into account in the review; and

c. Discuss and determine the order of review for MT's Food and Consumer Safety Laws. The laws cover a vast number of subjects and whilst regard must be had to achieving overall coherence in any reform of food and consumer safety laws, successful management of any review and reform process suggests that a staged approach should be adopted.

Please let us know if you have any questions. We look forward to discussing the Report with you at our meeting on 30 October 2008.

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