Food Regulation in Wisconsin: Past, Present and Future

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INTRODUCTION

This is a story about food regulation in Wisconsin. It is partly a legal story, but it is set in the "real world" of history, food production and sales, market power, disease and public policy. It may help you understand Wisconsin food regulation, how we got here, and where we might go from here.

Although food regulation is as old as civilization, it is constantly evolving. Wisconsin food regulation has much in common with regulation elsewhere, but it also has unique features rooted in Wisconsin conditions and history. Regulation has multiple goals: to protect public health and safety, to prevent fraud and unfair competition, and to maintain a secure and abundant food supply. Wisconsin and other states have often led the fight for food safety in the United States.

In the 21st Century we are utterly dependent on food produced elsewhere, by others. Without food systems to sustain us, our life expectancy would be measured in weeks. Major cities typically have access to about one week's supply of food. Food safety, food security and consumer protection have never been more important.

Wisconsin has a proud tradition of food safety, but that tradition is being tested in many ways. With limited resources, Wisconsin faces new food safety and security challenges, including new and more urgent disease threats. According to the Centers for Disease Control, food-borne diseases account for 76 million bouts of illness, 325,000 hospitalizations and 5,000 deaths in the U.S. each year. Meanwhile, animal disease and bio-security hazards threaten our underlying food production systems.

Food systems have been consolidated to an unprecedented degree, and fast-changing technology is challenging traditional regulation. Food is coming to us from far-flung places, via complex and potentially vulnerable systems. Small failures can have widespread consequences. Although our food is arguably cheaper, more convenient and safer than ever, we are engaged in an increasingly precarious "high wire" act.

The agriculture and food industry contributes an estimated $51.5 billion to Wisconsin's economy. The dairy industry alone contributes $20 billion, and is a critical source of interstate "export" revenue. But Wisconsin food industries are facing relentless interstate and global competition. The experience is in some ways like that of traditional main street merchants, as they awaken to the new reality of a Wal-Mart on the outskirts of town.

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What consumers have lost in frontier self-reliance, they have gained in choices. A typical supermarket contains about 45,000 products. Consumers here and elsewhere have a wide array of options, from all over the globe. Their perceptions and choices can make or break individual businesses, industries and regions. To succeed against strong competition, Wisconsin must deliver what consumers want and need.

Consumers are concerned, among other things, about food safety and quality. On these points, Wisconsin has a marketing advantage. "Wisconsin" means wholesomeness, tradition, integrity, craftsmanship and uncompromising quality. But that "brand" image – painstakingly developed over more than 150 years – can be damaged or lost, almost overnight, in a single high-profile food crisis or disease outbreak. It can also be frittered away over time, in many small ways.

In an interconnected food system, problems originating at a single business or location can cause widespread harm to consumers and other businesses. Diseases and other hazards can wreck whole industries, and tarnish the image of an entire state. From both a consumer *and* a business perspective, food regulation remains an important *collective* enterprise for Wisconsin. Farmers, consumers, business and government – we are all in this together.

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1. Beginnings

Early State Laws

In 1839, even before Wisconsin became a state, the Wisconsin Territory enacted a criminal statute to prohibit fraudulent sales of adulterated food. The territorial statute, which became a state law in 1848, said this:

> "If any person shall knowingly sell any kind of diseased, corrupted or unwholesome provisions, whether for meat or drink, without making the same fully known to the buyer, he shall be punished by imprisonment in the county jail not more than six months, or by fine, not exceeding one hundred dollars."[1]

Forty years later, in 1879, Wisconsin also enacted a broad criminal statute prohibiting the fraudulent *misbranding* of food:

> "Every person who shall compound or put up for sale any food, drug or liquor, in casks, boxes, bottles or packages, with any label, mark or device whatever, so as and with intent to mislead or deceive as to the true name, nature, kind and quality thereof, shall be liable to a penalty of not to exceed five hundred dollars for the first offense, and for every offense after the first offense shall be punished by imprisonment in the state prison for not less than one year nor more than ten years."[2]

These early laws were designed to punish intentional fraudulent acts. They reflected early public concern over food adulteration and misbranding, but they were clumsy instruments for dealing with increasingly complex food safety and labeling issues. They did not create preventive food safety standards or a coherent state *program* of food regulation.

By the late 19th Century, the need for such a program was becoming increasingly apparent. Wisconsin's pioneer farming economy was giving way to urban growth and an expanding "food industry," and urban residents were becoming increasingly dependent on distant food sources for basic life support. That created new kinds of risks, and a greater need for state regulation to protect food consumers.

Wisconsin was also becoming "America's Dairyland." The emerging dairy industry faced critical challenges related to food safety, quality control, consumer confidence, product standardization and fair competition. The industry pushed for state regulation to address those challenges. Its work over several decades made Wisconsin a dairy leader, and had a major impact on Wisconsin's entire system of food regulation.[3]

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[1] Wis. Territorial Laws, Nov. 1938-Jan. 1939, p. 350; Revised Wis. Stats. of 1849, ch. 140, sec. 1. Other early laws prohibited the sale of certain *kinds* of adulterated food, such as milk. See Laws of 1866, ch. 6.

[2] Laws of 1879, ch. 248, sec. 3.

[3] Wisconsin Chief Justice Shirley Abrahamson, in her law doctoral thesis, extensively documented and analyzed the regulatory underpinnings for Wisconsin's dairy industry. See *Law and the Wisconsin Dairy Industry: Quality Control of Dairy Products, 1838-1929* (Doctor of Juridical Science Thesis, Univ. Of Wisconsin, 1962).

A State Food Agency

For many years, there was no state agency responsible for enforcing food laws. That changed in 1889 when, at the recommendation of Governor Hoard (a leading dairy pioneer), the Wisconsin Legislature created the office of the State Dairy and Food Commissioner.[4] The Commissioner was appointed by the Governor for 2-year terms, and was authorized to appoint assistants who were experts in dairy products and analytical chemistry.[5] The Commissioner was charged with a duty:

> "to enforce all laws that now exist, or that may hereafter be enacted in this state regarding the production, manufacture or sale of dairy products, or the adulteration of any article of food or drink or of any drug; and . . . to inspect any article . . . of food or drink or drug, made or offered for sale within this state which he may suspect or have reason to believe to be impure, unhealthful, adulterated or counterfeit, and to prosecute, or cause to be prosecuted, any person...engaged in the manufacture or sale of any adulterated or counterfeit article...of food or drink or drug, contrary to the laws of this state."[6]

The Dairy and Food Commissioner was authorized to enter into "any creamery, factory, store, salesroom or other place or building" where food was produced or offered for sale; to open any package or container; and (upon offering payment) to take samples for inspection and analysis. Persons who obstructed inspection were subject to prosecution.[7]

Wisconsin's first Dairy and Food Commissioner, H.C. Thom, was also active in promoting a national system of food regulation. In 1889, Thom was elected as the first president of the National Association of Dairy and Food Commissioners.[8] The most important goal of the association was to develop and promote federal pure food legislation.[9] That effort was part of the long struggle that eventually led to the landmark Federal Food and Drug Act of 1906.

The Dairy and Food Commissioner had a big job. The Commissioner's first annual report included the following comments:

- "...the entire field of human food is comprehended by the scope of the duties of this office."[10]

- "The sole objective of the department is to give the buyer exactly what he pays for, thus protecting his pocketbook and his health, and at the same time place the manufacturers of spurious goods in such a position that they are unable to displace honest products by misrepresentation."[11]

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[4] Laws of 1889, ch. 452, sec. 1.
[5] Laws of 1889, ch. 452, sec. 1.
[6] Laws of 1889, ch. 452, sec. 3.
[7] Laws of 1889, ch. 452, sec. 4.
[8] State Dairy and Food Commissioner of Wisconsin, *First Annual Report* (1890), at p. 12.
[9] *Ibid.*, at p. 12.
[10] *Ibid.*, at p. 4.
[11] *Ibid.*, at p. 10.

- "[The consumer's] health and longevity should be protected at any cost."[12]

- "Unless one has given the matter careful consideration, no conception of the magnitude of the work can be estimated."[13]

One of the Commissioner's top priorities was to establish a laboratory, and a systematic inspection and sampling program. The Commissioner was also eager to hire an attorney and establish a systematic enforcement program. The Commissioner compiled and distributed 15,000 copies of the state's food laws to food manufacturers and dealers. However, the Commissioner was concerned that:

> "The laws of the department are weak in many respects. No decisions by the courts have been passed upon them. No attempt has been made, prior to the creation of the office, to administer them....The most important work for the first two years, is to test the laws that already exist, and formulating *[sic]* new ones."[14]

Adulterated Food

In 1897, Wisconsin strengthened its food adulteration laws and, for the first time, defined "adulterated" food.[15] The Wisconsin definition was similar to the definition later used in the Federal Food and Drug Act of 1906.[16] Under the Wisconsin definition, a food was adulterated:

> "*First*, if any substance or substances have been mixed with it, so as to lower or depreciate or injuriously affect its strength, quality or purity;
> *second*, if any inferior or cheaper substance or substances have been substituted wholly or in part for it;
> *third*, if any valuable or necessary ingredient has been wholly or in part abstracted from it;
> *fourth*, if it is an imitation of, or is sold under the name of another article;
> *fifth*, if it consists wholly, or in part, of a diseased, infected, decomposed, putrid, tainted or rotten animal or vegetable substance or article, whether manufactured or not;
> *sixth*, if it is colored, coated, polished or powdered, whereby damage or inferiority is concealed or if by any means it is made to appear better or of greater value than it really is;
> *seventh*, if it contains any added substance or ingredient which is poisonous, injurious or deleterious to health, or any deleterious substance not a necessary ingredient to its manufacture;

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[12] *Ibid.*, at p. 7.
[13] *Ibid.*, at p. 3.
[14] *Ibid.*, at p. 8.
[15] Laws of 1897, ch. 166.
[16] Both definitions apparently borrowed from other sources, and can ultimately be traced to British legislation from 1875. See Hutt and Hutt, "A History of Government Regulation of Adulteration and Misbranding of Food," *Food, Drug and Cosmetic Law Journal 39*, 2-73 (1984), at 34 and 53.

provided, that the provisions of this act shall not apply to mixtures or compounds recognized as ordinary articles of food, if the same be distinctly labeled as mixtures or compounds, and from which no necessary ingredient in its preparation is eliminated."

Harmful Food Additives

In the late 19th Century, as food manufacturers adopted industrial methods and expanded their distribution networks, they began to use more food additives and preservatives. By the end of the century, there was growing concern over the safety of those additives and preservatives.

In 1900, Congress appropriated funds to the United States Department of Agriculture (USDA) "to investigate the character of proposed food preservatives and coloring matters; to determine their relation to digestion and health; and to establish the principles which should guide their use."[17] The USDA Bureau of Chemistry conducted extensive chemical tests, and a "poison squad" of 12 USDA employees volunteered as human subjects to test the safety of various food additives. The results were published between 1904 and 1908, and provoked intense public interest.[18]

Apparently spurred by these national developments, Wisconsin enacted a number of food additive regulations. In 1905, Wisconsin prohibited food additives such as formaldehyde, sulphurous acid, sulphites, boric acid, borates, salicylic acid and salicilates.[19] In 1909, Wisconsin also prohibited benzoic acid and benzoates in food.[20]

Licensing and Sanitation

Early in the 20th century, the Wisconsin Legislature singled out key food businesses for licensing. By 1920, the Dairy and Food Commissioner licensed bakeries and confectionaries,[21] milk condensaries,[22] canning factories,[23] butter and cheese factories,[24] soda water beverage manufacturers[25] and cold storage warehouses.[26] By 1939, Wisconsin licensed all dairy plants.[27]

At about the same time, Wisconsin began to adopt preventive sanitation standards for food operations. New laws prohibited the sale of food produced under unsanitary conditions, regardless of whether the food itself was known to be contaminated. That expanded the underlying concept of "adulteration," and marked a whole new preventive approach to food regulation.

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[17] Hutt and Hutt, at 47, 51.
[18] Hutt and Hutt, at 51.
[19] Laws of 1905, ch. 33.
[20] Laws of 1909, ch. 399.
[21] Laws of 1903, ch. 230; Laws of 1917, ch. 684.
[22] Laws of 1919, ch. 651.
[23] Laws of 1919, ch. 651.
[24] Laws of 1915, ch. 597.
[25] Laws of 1917, ch. 562.
[26] Laws of 1917, ch. 428.
[27] Laws of 1939, ch. 471.

In 1903, for example, Wisconsin prohibited the sale of "unsanitary" milk, which the statute defined as follows:

> "Milk which shall be drawn from cows that are kept in barns or stables which are not reasonably well lighted and ventilated, or that are kept in barns or stables that are filthy from an accumulation of animal feces and excreta or from any other cause; or milk which shall be drawn from cows which are themselves in a filthy condition; or milk kept or transported in dirty, rusty or open-seamed cans or other utensils; or milk that is stale, putrescent, or putrid; or milk to which has been added any unclean or unwholesome foreign substance; or milk which has been kept exposed to foul or noxious air or gases in barns occupied by animals, or kept exposed in dirty, foul or unclean places or conditions, is hereby declared to be unsanitary milk."[28]

Finally, in 1909, the Legislature prohibited the manufacture or sale of *any* food that was not "securely protected from filth, flies, dust or other contamination, or other unclean, unhealthful or unsanitary conditions."[29] The Dairy and Food Commissioner was authorized to inspect for compliance, and violations were punishable as misdemeanors. Under this law, the Commissioner could take action against unsanitary food operations *without* having to prove that the food itself was contaminated, and *without* having to prove criminal or fraudulent intent.[30]

Federal Food and Drug Act

In 1906, after more than 26 years of debate,[31] Congress enacted the Federal Food and Drug Act.[32] The 1906 act broadly prohibited food adulteration and misbranding. It also created an agency (eventually called the Food and Drug Administration, or FDA) to administer the new law.[33]

The new federal law did not preempt state laws, but did provide a foundation for a coherent national system of food regulation. Among other things, the new federal law prohibited poisonous or deleterious food additives. In 1914, the U.S. Supreme Court interpreted the law to prohibit any additive that *might* make the food injurious to health, regardless of whether actual injury was shown.[34]

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[28] Laws of 1903, ch. 67. By 1917, Wisconsin also restricted milk sales from diseased herds (Laws of 1917, ch. 592, sec. 5).

[29] Laws of 1909, ch. 334.

[30] This is just one example of a broader shift to "liability without fault" food laws. See Remington et al., "Liability Without Fault Criminal Statutes – Their Relation to Major Developments in Contemporary Economic and Social Policy: The Situation in Wisconsin," *1956 Wisconsin Law Review* 625, at 641-644.

[31] Hutt and Hutt, at 52.

[32] 34 U.S. Stats. 768 (1906).

[33] The 1906 act recreated the USDA Bureau of Chemistry as a regulatory agency. The agency's name was changed to the Food, Drug, and Insecticide Administration in 1927, when its non-regulatory research functions were transferred elsewhere. In 1930 the name was shortened to Food and Drug Administration (FDA). FDA remained in the Department of Agriculture until 1940, when it was moved to the Federal Security Agency. In 1953 it was transferred to the Department of Health, Education, and Welfare (HEW). In 1968 it became part of the Public Health Service within HEW, which was later recreated as the Department of Health and Human Services.

[34] *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).

Federal Meat Inspection Act

The debates leading up to the Federal Food and Drug Act of 1906 focused relatively little attention on the meat industry. But in 1906, Upton Sinclair published *The Jungle*, which included vivid descriptions of the industrialized meat packing houses of Chicago:

> "There was never the least attention paid to what was cut up for sausage; there would come all the way back from Europe old sausage that had been rejected, and that was moldy and white--it would be dosed with borax and glycerine, and dumped into the hoppers, and made over again for home consumption. There would be meat that had tumbled out on the floor, in the dirt and sawdust, where the workers had tramped and spit uncounted millions of consumption germs. There would be meat stored in great piles in rooms; and the water from leaky roofs would drip over it, and thousands of rats would race about on it. It was too dark in these storage places to see well, but a man could run his hand over these piles and sweep off handfuls of the dried dung of rats. These rats were nuisances, and the packers would put poison bread out for them, they would die, and then rats, bread and meat would go into the hoppers together."[35]

President Theodore Roosevelt ordered an investigation of conditions in the Chicago stockyards. The resulting report labeled the conditions as "abominable" and "unsanitary," and recommended corrective federal action.[36] Congress subsequently enacted the Federal Meat Inspection Act of 1906 and 1907.[37] Congress assigned USDA to administer the act.[38]

The federal act required *ante mortem* (pre-slaughter) and *post mortem* (post-slaughter) inspection of meat intended for interstate or foreign commerce. It authorized USDA inspectors to condemn unwholesome meat, including meat containing unwholesome ingredients. It required inspection of meat establishments, and prohibited false or deceptive meat labels. The act remained in effect, with periodic amendments, until it was expanded and modernized in 1967.[39]

Wisconsin meat establishments were not covered by the federal act unless they produced meat for interstate commerce. There was no *state* program of *ante mortem* and *post mortem* inspection until 1965. But early state statutes prohibited the sale of diseased meat,[40] established standards for sausage and sausage mixtures,[41] and prohibited adulteration by means of artificial coloring, chemical preservatives or antiseptics.[42]

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[35] Sinclair, *The Jungle* (2005 Barnes and Noble Classics paperback edition) at 141. The 1906 edition (p. 136) is quoted in Hutt and Hutt, at p. 53.
[36] Hutt and Hutt, p. 54.
[37] 34 Stat. 669, 674 (1906), 34 Stat. 1256, 1260 (1907).
[38] The meat inspection program was assigned to a new Bureau of Animal Industry within USDA. The program was separate from food regulatory programs administered by the USDA Bureau of Chemistry (later called the FDA). Meat inspection remained at USDA when the FDA was moved out of USDA in 1940. See *footnote 33* above.
[39] P.L. 90-201; 81 U.S. Stat. 584 (1967).
[40] Laws of 1891, ch. 431.
[41] Laws of 1909, ch. 381.
[42] Laws of 1901, ch. 243.

Food Labeling

The Federal Food and Drug Act of 1906 prohibited deceptive labeling of food, but did not establish any affirmative labeling requirements. Wisconsin initially took the same approach, but there was a growing movement to require affirmative disclosures. As early as 1897, for example, Wisconsin required canned foods to be "distinctly labeled with the grade or quality" of the food, "together with the name and address of the person, firm or corporation packing, canning or preserving the same...."[43]

Finally, in 1913, Wisconsin established general packaging and labeling requirements for most packaged food.[44] Under the new law, a packaged food was "misbranded" unless clearly labeled with the manufacturer's name and address, and with the net food contents declared by weight, measure or count. In the same year, Congress enacted similar requirements under the Gould Amendment to the Federal Food and Drug Act.[45]

Weights and Measures

Accurate food labeling requires accurate weights and measures. Indeed, a reliable system of weights and measures is essential for all modern commerce. The average U.S. family spends over half of its household budget on food and other goods that are sold by weight or measure.[46] Short weights and measures may go undetected by individual consumers, but may have an enormous aggregate impact on consumers and competition.

In 1839, the Wisconsin Territory created a system for standardizing weights and measures in the territory.[47] That system continued when Wisconsin became a state in 1848.[48] The statutes designated a custodian for Wisconsin's official weights and measures standards (for example, the state's official "pound" weight). The state custodian used those standards to certify test standards used by local weights and measures "sealers." The "sealers," in turn, certified scales and measuring devices used by local merchants (including food merchants).[49]

Because of the close connection between food regulation and weights and measures enforcement, the 1911 Legislature designated the Dairy and Food Commissioner as the state's superintendent of weights and measures.[50] The Commissioner was responsible for *all* weights and measures, not just food weights and measures.[51] The Commissioner did all of the following:

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[43] Laws of 1897, ch. 166, sec. 4.
[44] Laws of 1913, ch. 311.
[45] 37 U.S. Stats. 732 (1913).
[46] Estimate by the National Conference on Weights and Measures (2006).
[47] 1839 Territorial Statutes of Wisconsin, p. 175.
[48] 1849 Revised Statutes of Wisconsin, ch. 42.
[49] "Sealers" apply official seals to scales and measuring devices, to certify their accuracy.
[50] Laws of 1911, ch. 566.
[51] 1925 Wis. Stats., ch. 125.

- Kept Wisconsin's official weights and measures standards.

- Certified test standards used by local "sealers."

- Monitored local inspection and enforcement.

- Inspected commercial scales and measuring devices in areas that had no local inspection.

- Checked the accuracy of package labels.[52] Food packages, in particular, were required to bear an affirmative declaration of weight, measure or count.[53]

- Enforced state statutes prohibiting false weights and measures.[54]

- Enforced state statutes requiring the sale of commodities by weight, measure or count.[55] The Legislature prescribed more specific methods of sale for some commodities – for example, coal by weight,[56] fruits and vegetables in standard dry measure containers,[57] milk and cream in standard bottles,[58] and bread in standard loaves.[59]

Standardized Foods

In various ways, early statutes defined "adulteration" in terms of an undesirable departure from an implicitly assumed (but undefined) "standard" food. That worked to address crude adulterations of traditional foods, but it did not work to address subtler forms of adulteration and unfair competition. An industrialized food system required greater "standardization" of food products.

Beginning in 1907,[60] the Wisconsin Legislature created more explicit definitions of "standard" foods, against which adulterated products could be compared. The Legislature enacted voluminous food standards defining hundreds of individual food products, including dairy products, meat products, fruit and vegetable products, sugar, syrup, candy, honey, spices, flavoring extracts, oils, coffee, tea, wine and salt, among others.

The state standards were largely based on federal and industry guidelines. Federal standard-setting got a boost from a 1914 U.S. Supreme Court decision, which said the purpose of the 1906 Food and Drug Act was "to make it possible that the consumer should know that an article purchased was what it purported to be; that it might be bought for what it really was and not upon misrepresentations as to character and quality."[61]

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[52] Laws of 1923, ch. 51; 1925 Wis. Stats., sec. 125.02(8).
[53] Laws of 1913, ch. 311.
[54] Laws of 1856, ch. 88; 1925 Wis. Stats., sec. 343.33.
[55] Cf., 1925 Wis. Stats., sec. 125.08(25).
[56] 1925 Wis. Stats., sec. 125.11.
[57] 1925 Wis. Stats., sec. 125.13(11).
[58] 1925 Wis. Stats., sec. 125.10.
[59] 1925 Wis. Stats., sec. 125.21.
[60] Laws of 1907, ch. 205; Laws of 1909, ch. 398; 1911 Wis. Stats., sec. 4601-4a.
[61] *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914).

To carry out that purpose, federal authorities developed and published numerous food standards.[62] The initial standards did not have the force of law, but did influence court decisions (and state legislation).[63] Eventually, in 1938, Congress authorized FDA to adopt standards having the force of law.[64]

Food Advertising and Sales Practices

By the early 20th century, mass advertising was becoming an increasingly powerful market force, and there was growing concern over deceptive advertising and sales practices. Food laws addressed deceptive food *labels*, but did not yet address *non-label* advertising and sales claims. A 1917 federal report noted the lack of federal jurisdiction over non-label food claims, calling it a "serious limitation" of the 1906 Food and Drug Act.[65]

In 1914, the U.S. Congress created the Federal Trade Commission (FTC) and gave it broad authority to regulate anticompetitive business practices.[66] In 1938, Congress expanded the FTC's authority to attack unfair business practices harming consumers, *regardless* of whether those practices also harmed competition.[67] That gave the FTC adequate authority to regulate deceptive food advertising and sales claims. In 1938, Congress also authorized the FDA to regulate sales claims that *accompany* food products but are not part of the product label itself.[68]

By then, Wisconsin had also taken action to prohibit deceptive advertising. In 1913, Wisconsin enacted a Fraudulent Advertising Law that prohibited any "untrue, deceptive or misleading" sales claims for any kind of good or service (the state Treasury Agent was eventually assigned to enforce the law).[69] In 1927, the Legislature also enacted a narrower prohibition against fraudulent *food* advertising (the Dairy and Food Commissioner was assigned to enforce that law).[70] Both laws are still in effect.[71]

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[62] Hutt and Hutt, p. 59-61.
[63] Hutt and Hutt, p. 60.
[64] 52 U.S. Stat. 1040 (1938); 21 U.S.C. 321 et seq.
[65] See Hutt and Hutt, pp. 61-62.
[66] Chapter 311, sec. 5, 38 U.S. Stats. 719 (1914).
[67] Act of March 21, 1938, ch. 49, 52 Stat. 111. The FTC's expanded authority was finally confirmed in *FTC v. Sperry and Hutchinson Co.*, 405 U.S. 233 (1972).
[68] 52 U.S. Stat. 1040 (1938); 21 U.S.C. 321 et seq. Accompanying materials are called "labeling" (as distinct from "label") materials. The FDA and FTC have concurrent jurisdiction over "labeling" claims.
[69] Laws of 1913, ch. 510. The Treasury Agent was first assigned to enforce the law in 1925 (before that there was no state-level enforcement). See Laws of 1925, ch. 264. The Office of the Treasury Agent was originally created in 1867 (ch. 176, Laws of 1867) to enforce the "Hawkers and Peddlers" Law dating from 1858 (ch. 50, Revised Wis. Stats. of 1858).
[70] Laws of 1927, ch. 80.
[71] The general Fraudulent Advertising Law (later renamed the Fraudulent Representations Law) is now found at s. 100.18, Wis. Stats. The fraudulent *food* advertising law is now found at s. 100.183, Wis. Stats. In 2006, the Wisconsin Court of Appeals held that the general law (s. 100.18, Wis. Stats.) did not apply to food advertising, because the Legislature had enacted a more specific law related to food advertising (s. 100.183, Wis. Stats.). *Gallego v. Wal-Mart*, 288 Wis. 2d. 229 (Court of Appeals).

In 1921, Wisconsin enacted an even more sweeping consumer protection law[72] modeled after the Federal Trade Commission Act.[73] Wisconsin's "Little FTC Act" broadly prohibits unfair and deceptive business practices affecting consumers or competition. Even today, it is probably the strongest state consumer protection law in the nation.[74]

The original impetus for the "Little FTC Act" actually came from Wisconsin's agricultural sector, which was concerned about unfair business practices affecting agriculture. Legislative opponents tried to confine the act to agriculture,[75] but the law that finally emerged from the Legislature was much broader in scope. Today, just as in 1921, the "Little FTC Act" applies to nearly every business sector in the state (including, but not limited to, food and agriculture).[76]

The 1921 Legislature created a brand new Department of Markets to enforce the "Little FTC Act."[77] The department was authorized to adopt rules and issue orders prohibiting "unfair" business practices. It was also authorized to conduct investigations, to issue subpoenas and investigative demands, and to regulate agricultural commodity grading, storage and procurement.

The "Little FTC Act" supplemented state laws related to fraudulent advertising, food adulteration and misbranding, and weights and measures. In fact, the Legislature directed the Department of Markets to assist the Treasury Agent and the Dairy and Food Commissioner in the enforcement of those laws.[78] Eventually (as we shall see), all of those agencies were consolidated into a single department.

The Food Chain -- Land to Consumer

Modern food production involves complex interactions between the industrial, commercial and biological worlds. As Wisconsin's "food industry" developed in the late 19th Century, the state became more systematically involved in issues related to resource management, agricultural inputs, animal and plant health, and agricultural production and marketing. For example:

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[72] Laws of 1921, ch. 571, sec. 2, creating s. 1495-14, Wis. Stats. A key provision of the 1921 act is currently found in s. 100.20, Wis. Stats.

[73] The Wisconsin act was, from the beginning, designed to protect consumers as well as fair competition. It was not until 1938 that the federal act was amended to include similar consumer protection authority.

[74] See 80 Harvard Law Review 1005 (1967). Wisconsin's law includes broad rulemaking authority (most states must proceed case-by-case). Wisconsin's law also includes strong penalties and a strong private remedy (see ss. 100.20 and 100.26, Wis. Stats.). The private remedy is an important supplement to state enforcement, especially in an age of diminishing state resources.

[75] Wisconsin State Journal, June 15, 1921, page 1.

[76] In 2006, the Wisconsin Court of Appeals held that the "Little FTC Act" applies to deceptive food advertising and labeling. *Gallego v. Wal-Mart*, 288 Wis. 2d. 229 (Court of Appeals).

[77] Laws of 1921, ch. 571; 1925 Wis. Stats., secs. 99.14-15. An earlier version of the law was briefly enforced by the Department of Agriculture. See Laws of 1919, ch. 670, sec. 1.

[78] Laws of 1921, ch. 571; 1927 Wis. Stats., sec. 99.18.

- In 1885, the Legislature created the office of State Veterinarian.[79]

- In 1895, the Legislature enacted the state's first fertilizer regulations, aimed at preventing fraud in the sale of commercial fertilizer.[80] The regulations were initially administered by the University of Wisconsin, College of Agriculture experiment station.

- In 1897, the Legislature created a Board of Agriculture to run the state fair and "promote the interests of agriculture, dairying, horticulture, manufactures and the domestic arts."[81] In 1901, the Legislature authorized the Board to collect and report agricultural statistics.[82]

- In 1897, the Legislature created a State Inspector of Apiaries to control honeybee pests that threatened honey and crop production.[83]

- In 1899, the Legislature created a State Orchard and Nursery Inspector, to control serious plant pests and diseases.[84]

- In 1901, the Legislature created a State Livestock Sanitary Board, with authority to quarantine and condemn livestock infected with serious communicable diseases.[85]

- In 1901, the Legislature enacted the state's first commercial feed regulations,[86] initially administered by the University of Wisconsin, College of Agriculture.

- In 1909, the Legislature enacted the state's first commercial seed regulations,[87] initially administered by the University of Wisconsin, College of Agriculture.

- In 1911, the Legislature enacted the state's first pesticide regulations,[88] initially administered by the University of Wisconsin, College of Agriculture.

In 1915, the Legislature combined most of these functions in a new state Department of Agriculture.[89] For a time, the University of Wisconsin continued to regulate commercial feed, seed, fertilizer and pesticides. But later, those functions were also moved to the new department.[90] The first biennial report of the Department of Agriculture described the department's role as follows:

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[79] Laws of 1885, ch. 467.
[80] Laws of 1895, ch. 87.
[81] Laws of 1897, ch. 301.
[82] Laws of 1901, ch. 79.
[83] Laws of 1897, ch. 150.
[84] Laws of 1899, ch. 180.
[85] Laws of 1901, ch. 440.
[86] Laws of 1901, ch. 377.
[87] Laws of 1909, ch. 173.
[88] Laws of 1911, ch. 325.
[89] Laws of 1915, ch. 413.
[90] Laws of 1917, ch. 593; Laws of 1923, ch. 152, s. 157.

> "Because of the important and fundamental place which agriculture occupies among the industries of the state, the Legislature deemed it wise to set aside a special part of the agricultural work of the state in a department separate from the college of agriculture and state experiment station. It has been an important duty of the Commissioner to select, define and establish the field of work which the Department of Agriculture is to handle....
>
> [A]gricultural control and regulatory work...including the control of diseases among animals and crops and the enforcement of inspection laws....has been adopted as the field of work for the Department of Agriculture. It is a work distinct and separate from...that of the experiment station and the college. The importance of this line of work is so great, and the need for a distinct type of worker....is so important that the establishment of a separate department to handle this work was a most necessary step...."[91]

The new Department of Agriculture focused on the base of the human food chain, starting with land, plants and animals. The department was familiar with agricultural production and marketing, and was equipped to address disease and other biological threats. It was thus a key part of the emerging state system of food regulation.

[91] Biennial Report of the Wisconsin Department of Agriculture (Department of Agriculture Bulletin No. 10), December 31, 1916, at p. 2.

2. Consolidation

State Agency Merger, 1929

By 1929, the basic elements of Wisconsin's food regulatory program were in place, but they were scattered among different agencies. The 1929 Legislature consolidated these programs into a single state agency, which could serve as a focal point for a modern and comprehensive food regulatory program.

The new agency was initially called the Department of Agriculture and Markets. The agency had broad authority over the entire food chain from land to consumer, but its jurisdiction was by no means limited to food. The Legislature created the new department by consolidating the following agencies (the new department assumed all of the powers of the component agencies):[92]

- *Dairy and Food Commissioner (created in 1889):*[93]
    - FDA equivalent (before FDA was created in 1906).
    - Food safety and labeling.
    - Weights and measures (food and nonfood).
    - Consumer product safety.
    - Inspection, sampling and lab analysis.
    - Laws dating from 1839.
- *Treasury Agent (created in 1867):*[94]
    - Deceptive advertising and sales (Fraudulent Advertising Law, first enacted in 1913).
    - Itinerant sales (Hawkers and Peddlers Law, first enacted in 1858).
- *Department of Markets (created in 1921):*[95]
    - FTC equivalent.
    - Nation's strongest consumer protection law (enacted in 1921).
    - Unfair and deceptive business practices.
    - Markets and competition.
    - Product grading.
    - Agricultural storage warehouses.
    - Market information.
    - Subpoenas and investigations.

[92] Laws of 1929, ch. 479.
[93] See, generally, 1927 Wis. Stats., chs. 98, 111, 125, 134 , 342 and 352.
[94] See, generally, 1927 Wis. Stats., ch. 129 and s. 343.413.
[95] See, generally, 1927 Wis. Stats., ch. 99.

- *Department of Agriculture (created in 1915):*[96]

    - Animal health and disease control.
    - Plant pest and disease control.
    - Pesticides, fertilizer, feed and seed (from UW).
    - Agricultural surveys, statistics, information and assistance.
    - Quarantine and condemnation authority.
    - Inspection, sampling, lab analysis and diagnosis.

The New Department

The new Department of Agriculture and Markets was headed by 3 full-time Commissioners appointed by the Governor. In their first biennial report, in 1931, the Commissioners described the broad jurisdiction of the new agency:

> "The powers and duties of the Department of Agriculture and Markets relate to every phase of the agricultural industry of Wisconsin from the time the seed is selected for planting to the time the finished product is absorbed by the consumer. In addition its jurisdiction extends into business and industry, insofar as it has power to prosecute practices which interfere with free and fair competition."[97]

The Commissioners emphasized the regulatory responsibilities of the new agency:

> "...all matters concerning research and education will be left with the College of Agriculture, and it is the duty of the Department of Agriculture and Markets to attend to the enforcement of all laws of control and regulatory measures."[98]

Finally, the Commissioners noted that:

> "...the department as now organized will be much better able to cope with these problems than the individual departments that existed in the past."[99]

The 1929 merger strengthened the state's food regulatory program in several ways:

- It consolidated the administration of closely related laws, including laws on food adulteration and misbranding, deceptive advertising, unfair and deceptive business practices, weights and measures, food grading, food warehousing and procurement, and the licensing of food processors and distributors. That permitted more comprehensive, consistent and efficient regulation.

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[96] See, generally, 1927 Wis. Stats., chs. 93 to 97.
[97] Wisconsin Department of Agriculture and Markets, Biennial Report (January 8, 1931), p. 3.
[98] *Ibid*., p. 3.
[99] *Ibid*., p. 4.

- It consolidated the administration of food regulatory programs over the entire length of the food chain, from land to consumer. That made it possible to identify and address problems at their source.

- It recognized that food production, processing, distribution, sale and consumption are closely interconnected, and that the food chain is only as secure as its weakest link. A safe and secure food system is important to consumers and the food industry alike.

- It consolidated regulatory tools, including rulemaking, investigation and enforcement tools. The consolidated agency had a "toolbox" sufficient to the task at hand.

- It allowed for the pooling of facilities and expertise, including expertise related to food chemistry and biology, disease control and prevention, food production and processing, food distribution, and food advertising and sales practices.

Organizational Changes After 1929

Not long after it was created, the new department underwent some important changes. Depression-era legislation changed the department's name and governance, but did not change its broad statutory mission.

In 1937, the Legislature replaced the department's 3 full-time commissioners with a part-time 7-member board.[100] The Governor was required to appoint board members for staggered 6-year terms (to protect the board from overtly partisan political control). Unlike the prior commissioners, board members were required to be "actively engaged in agriculture" (later changed to "experienced in farming" [101]). The board appointed a full-time director (later called the department "secretary"[102]) who served at the pleasure of the board.

In 1939, the Legislature changed the name of the agency to the Department of Agriculture (the word "Markets" was dropped).[103] However, the department retained all of its broad regulatory responsibilities.[104] In the following decades, there were no fundamental changes in the mission or structure of the department (although new programs were added).[105]

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[100] Laws of 1937 (special session), ch. 9, sec. 5. This change was part of a government reorganization enacted during a 1937 special legislative session.
[101] Laws of 1939, ch. 85.
[102] Laws of 1967, ch. 75, as implemented by Laws of 1967, ch. 327.
[103] Laws of 1939, ch. 85.
[104] 1940 Wisconsin Blue Book, p. 274.
[105] The Kellett Committee, which in 1965 made recommendations for reorganizing the executive branch of state government, recommended no changes to the department and praised its overall management and efficiency (Kellett Committee Report, September 30, 1965). The Kellett Reorganization Act of 1967 renamed the "Director" as "Secretary" but did not significantly change the powers of the office (Laws of 1967, ch. 75, as implemented by Laws of 1967, ch. 327).

The department continued to exercise the broadest consumer protection and regulatory authority of any agency in state government. But over time, because of its name and the composition of its governing board, it acquired a somewhat narrow "farm" image. That presented a growing problem for the department, as the state population (and electorate) became overwhelmingly urban.[106]

The Legislature eventually addressed the problem when, in 1977, it renamed the agency the *Department of Agriculture, Trade and Consumer Protection* to reflect the full range of its responsibilities.[107] In 1977, and again in 1996 and 1997, the Legislature also changed the composition of the department's governing board.[108] The current 9-member board must include 7 members who are "experienced in agriculture" and 2 consumer representatives.[109]

In 1996, the Legislature confirmed the department's historical role as the state's primary consumer protection agency, and consolidated state consumer protection programs in the department.[110] In 1996, the Legislature also gave the Governor (rather than the board) the power to appoint the department secretary.[111] Although the secretary now serves at the pleasure of the Governor, the board still approves department rules and policy.[112]

Today, the Department of Agriculture, Trade and Consumer Protection (DATCP) is Wisconsin's primary consumer protection agency, with broad authority related to food safety, unfair business practices, disease control, bio-security, and agricultural resource management. The department has broad jurisdiction over the entire food chain, from land to consumer, and broad authority related to business practices and competition. The department exercises a broad array of rulemaking, licensing, investigation and enforcement powers.

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[106] In 1870, nearly 70 percent of Wisconsin residents lived on farms (or in small farm-related hamlets). By 1920, this percentage dropped to 35%; by 1970 to 10%; and, by the start of the 21st Century, to only 2%. At the start of the 21st Century, farm families represented only about 8% of Wisconsin's *rural* population. See *Wisconsin Bluebook (2003-04)*, p. 109.

[107] Laws of 1977, ch. 29, sec. 31m. The Board of Agriculture unanimously endorsed the change (Board minutes, February 17, 1977).

[108] Laws of 1977, ch. 29, section 31m; 1995 Wis. Act 27; 1997 Wis. Act 95.

[109] See s. 15.13, Wis. Stats.

[110] 1995 Wis. Act 27.

[111] 1995 Wis. Act 27.

[112] See ss. 15.05 and 15.13, Wis. Stats.

3. Modernization

By 1930, the foundations of Wisconsin's food regulatory program were in place, and enforcement was consolidated in a single agency.[113] At the federal level, a basic regulatory framework was also in place. But many programs were still in their infancy. After 1930, food regulation continued to evolve in response to a rapidly changing world.

Food Adulteration and Misbranding

In 1938, the U.S. Congress enacted landmark legislation known as the Food, Drug and Cosmetic Act of 1938.[114] The act strengthened and modernized the nation's food laws, including federal prohibitions against food "adulteration" and "misbranding." Over the years, Wisconsin made similar changes to its laws.[115] Wisconsin's prohibitions against food "adulteration" and "misbranding" are now broadly consistent with federal law.[116]

Other federal and state laws supplement the basic prohibitions against "adulteration" and "misbranding." Those laws include specific requirements related to food processing and handling, food standards of identity, food ingredients, food safety and testing, food packaging, and food advertising and labeling.

At the federal level, at least 4 different agencies (FDA, USDA, the Federal Trade Commission and the Environmental Protection Agency) administer regulations that relate, directly or indirectly, to food adulteration or misbranding. In Wisconsin, nearly all of the equivalent state-level functions have been consolidated in a single agency since 1929.

Food Additives

The federal Food, Drug and Cosmetic Act of 1938 prohibited harmful food additives, but required no advance determination of safety. The FDA still had the burden of proving that suspect additives were unsafe. Subsequent federal amendments, including the Food Additive Amendment (1958)[117] and Color Additive Amendment (1960),[118] shifted that burden.

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[113] In 1935, the Legislature consolidated (into chs. 93-100, Wis. Stats.) the many different statutes enforced by the new department. See Laws of 1935, ch. 550. The consolidation drew statutes from a number of sources including the general criminal code. The resulting statutory organization has continued, with some changes, to the present day. Food statutes are mainly contained in ch. 97, Wis. Stats., but other chapters affecting food regulation include ch. 94 (Plant Industry, including feed and pesticide laws), ch. 95 (Animal Health), ch. 98 (Weights and Measures), and ch. 100 (Marketing and Trade Practices, including fraudulent advertising laws and the "Little FTC Act"). Many of the department's general powers are found in ch. 93, Wis. Stats.

[114] 52 U.S. Stat. 1040 (1938); 21 U.S.C. 321 et seq.

[115] See Laws of 1953, chs. 421 and 198; Laws of 1955, ch. 302; Laws of 1963, ch. 119; Laws of 1969, ch. 286; Laws of 1971, ch. 156, secs. 7-8.

[116] See ss. 97.02, 97.03 and 97.10, Wis. Stats.

[117] P.L. 85-929 (1958); 72 U.S. Stat. 1784.

[118] P.L. 86-618 (1960); 74 U.S. Stat. 397.

A pre-market safety determination is now required for essentially all food additives. In the case of color additives, FDA must make the determination (the manufacturer must submit supporting information). For other additives, the manufacturer may make the initial determination but must notify FDA. If FDA raises a challenge, the manufacturer must show that its determination is based on adequate evidence.

FDA publishes a list of substances that are generally regarded as safe (GRAS substances). If a substance is on the GRAS list, a manufacturer does not have to make an independent safety finding. A manufacturer may use an additive that is not on the GRAS list, but only if the manufacturer or FDA specifically determines that the additive is safe.

Federal law permits some residues of pesticides needed for food production, as long as the residues are within safe tolerances.[119] Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[120] pesticide manufacturers must now register all pesticides and pesticide uses with the U.S. Environmental Protection Agency (EPA). As part of the registration process, EPA establishes pesticide tolerances in food. The tolerances are enforced by FDA and the states. If EPA has not established a tolerance for a pesticide, the pesticide is not allowed in food at any concentration.

Food Packaging and Labeling

The federal Food, Drug and Cosmetic Act of 1938 authorized FDA to adopt standards for food containers. The act prohibited containers that might contaminate food contents. It required all containers to be labeled with the name and address of the manufacturer, and the net quantity of contents. It also prohibited slack filling and the use of deceptive containers. Wisconsin law includes comparable provisions.[121]

The federal Fair Packaging and Labeling Act of 1966 expanded labeling requirements for packaged commodities, including food.[122] The act required uniform display panels and standard declarations of package contents, net weight and seller's identity. Wisconsin rules incorporate the same requirements.[123]

The federal Nutrition Labeling and Education Act of 1990 (NLEA)[124] revolutionized the labeling of processed, packaged food. The NLEA spelled out standards for nutrition labeling (fat content, etc.), label format, ingredient disclosures, health claims, substitute foods (such as *reduced fat, light, low-fat and fat-free* foods) and other matters.[125] Wisconsin rules incorporate NLEA rules by reference.[126]

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[119] The original 1938 exemption was clarified by the Pesticide Amendment of 1954, P.L. 83-518 (1954); 68 U.S. Stat. 511.

[120] 7 USC 136 et seq.

[121] See s. 97.03, 97.10(1), 98.07 and 98.26(1)(c), Wis. Stats.

[122] P.L. 89-755 (1966); 80 U.S. Stat. 1296. The FTC administers the Fair Packaging and Labeling Act.

[123] See ch. ATCP 90, Wis. Adm. Code.

[124] P.L. 101-535 (1990), 104 U.S. Stat. 2353. See FDA rules at 21 CFR 101 et seq.

[125] Under the NLEA, *ingredient labeling* is now required for *all* processed packaged foods (standard foods were previously exempt). Labeling must disclose the amount of fat, calories, and other food contents *per serving*.

[126] See ATCP 90.10, Wis. Adm. Code.

NLEA labeling requirements help consumers make informed food choices, including choices that may affect their long-term health. The Food Allergen Labeling and Consumer Protection Act of 2004 also protects consumers by requiring disclosure of common allergens.[127]

Standard and Substitute Foods

Evolution of Federal Law

The federal Food, Drug and Cosmetic Act of 1938 authorized FDA to adopt food standards of identity having the force of law. FDA exercised that authority and, by the 1960's, roughly half of the food in the United States was covered by a standard of identity.[128] In 1969, Wisconsin adopted federal standards by reference (subject to possible state modification by rule) and repealed most of its older state standards.[129]

Standards of identity are designed to prevent deceptive substitution of inferior ingredients. A standard of identity is essentially a generic "recipe" for a standard food product (such as "ice cream"). Standards typically give manufacturers some latitude to choose alternative ingredients, but only within specified limits. A food may not be sold under the name of a standard food, or otherwise represented as a standard food, unless it conforms to the standard of identity.

Food technology has made it easier to modify traditional foods and create whole new substitute foods. That has forced a more flexible approach to food standards of identity. The U.S. Supreme Court opened the door to a new approach when, in 1951, it held that federal law did not prohibit the sale of substitute foods that were made to resemble standard foods, as long as they were labeled as "imitations."[130] The FDA then opened the door still further.[131]

The FDA now permits many substitute foods, as long as differences from standard foods are clearly labeled. FDA does not ordinarily require sellers to label substitute foods as "imitations" unless they are nutritionally inferior to the standard foods. However, substitute foods must normally use fanciful names rather than standard names (for example, "Choco-riffic" rather than "chocolate milk"), unless they differ from standard foods only in specifically authorized ways (for example, *reduced fat*, *light*, *low-fat* or *fat-free* chocolate milk).

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[127] P.L. 108-282(2004), effective January 1, 2006. See FDA guidance at *http://www.cfsan.fda.gov/~dms/alrguid4.html*.

[128] Hutt and Hutt, p. 66.

[129] Laws of 1969, ch. 286; s. 97.09, Wis. Stats.

[130] *U.S. v. Jam*, 340 U.S. 593, 71 S. Ct. 593, 95 L.Ed. 566 (1951).

[131] Hutt and Hutt, pp. 66-73. Junod, "The Rise and Fall of Federal Food Standards in the United States: The Case of the Peanut Butter and Jelly Sandwich," presentation to the Society for the Social History of Medicine, Spring Conference, 1999.

FDA has reduced its enforcement of identity standards, and has revised standards to allow greater substitution of ingredients and manufacturing processes. However, FDA still prohibits certain substitutions (for example, a manufacturer may not substitute vegetable oil for milkfat in a product sold as a standard dairy product). Like FDA, Wisconsin has also reduced its enforcement of identity standards in order to concentrate scarce resources on food *safety* issues.

Wisconsin Regulation of Dairy Product Substitutes

Wisconsin has always worried about dairy product substitutes. Early laws prohibited "filled" dairy products, in which milkfat was replaced by cheaper fats or oils.[132] Wisconsin also restricted products like oleomargarine that resembled dairy products but were not milk-based.[133] Wisconsin prohibited *colored* margarine (colored to resemble butter) until 1967,[134] and imposed a special margarine tax until 1973.[135]

In 1951, Wisconsin replaced some of its older regulations with a broad new "imitation dairy products" law.[136] On its face, the 1951 law appeared to *prohibit* products (milk-base and non-milk-base) that resembled dairy products but deviated from dairy product standards of identity. It prohibited those products *regardless* of whether they were labeled as "imitations" or sold under fanciful names, and *regardless* of whether the relevant differences were disclosed to consumers. The 1951 law prohibited *colored* margarine, but exempted margarine sold in "a separate and distinct form and in such manner as will advise the consumer of its real character, and free from coloration or ingredient that causes it to look like butter."

Several court actions successfully challenged the prohibition as applied to products with fanciful names like "Dairy Queen," "Coffee-Rich" and "Choco-riffic."[137] The Legislature also amended the prohibition to exempt sales of colored margarine[138] and "coffee whiteners."[139] The Legislature ultimately repealed the prohibition in favor of a *labeling* statute in 1982.[140]

Under the 1982 labeling statute, non-standard products "made to resemble" standard dairy products must be labeled as "artificial" products (the statute no longer prohibits the products altogether).[141] The "artificial" labeling requirement does not apply to margarine that is labeled as margarine,[142] or to "coffee whitener" provided at a restaurant.

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[132] See Laws of 1885, ch. 361, and later laws at ss. 97.39 and 97.43, Wis. Stats. (1935).

[133] See, for example, ss. 97.42, 97.43, 97.44 and 97.46, Wis. Stats. (1935). For a brief period, from 1925 to 1929, Wisconsin prohibited *all* sales of margarine (see Laws of 1925, ch. 279; repealed by Laws of 1929, ch. 482, s. 10).

[134] The ban against colored margarine was repealed by Laws of 1967, ch. 42.

[135] The tax, which took various forms, was ultimately repealed by Laws of 1973, ch. 90, section 465.

[136] Laws of 1951, ch. 517.

[137] See *Dairy Queen of Wisconsin v. McDowell*, 260 Wis. 471 (1951); *Coffee-Rich, Inc. v. McDowell*, 25 Wis. 2d 99 (1964); *Coffee-Rich, Inc. v. Crandall's Restaurant, Inc. v. Department of Agriculture and Donald Wilkinson*, 70 Wis. 2d 265 (1975); *Dean Foods Co. v. DATCP (D.C. 1979) 478 F. Supp. 224, reargument 504 F. Supp. 520.*

[138] Laws of 1967, ch. 42.

[139] Laws of 1971, ch. 212.

[140] Laws of 1981, ch. 345 (effective May 6, 1982).

[141] Section 97.48, Wis. Stats. According to the current statute, a product is "made to resemble" a dairy product if it physically resembles a dairy product or is packaged, displayed or labeled to resemble a dairy product.

[142] Under s. 97.18, Wis. Stats., margarine sold at retail must be sold in packaged form and must be clearly identified as margarine (both on the package and on product wrappers).

The 1982 labeling statute is still in effect, but it is inconsistent with current federal labeling standards. Enforcement is problematical, especially for nutritionally equivalent products sold in interstate commerce under fanciful names (not under the name of a "standard" food). The reality is that few products today bear the "artificial" label declaration.

"Reduced Fat" and Similar Substitutes

The federal Nutrition Labeling and Education Act of 1990 changed the federal approach to substitute foods, especially *reduced fat, light, low-fat* and *fat-free* substitutes. FDA rules now allow certain modifications of standard foods (such as "*reduced fat* ice cream" or "*light* ice cream"), provided that they conform to FDA criteria:[143]

- The food name must use standard terms (such as *reduced fat* or *light*) defined by FDA.
- The food must comply with the traditional standard of identity, except for the allowed modification.
- The food may not be nutritionally inferior to the standard food. Nutrients must be added, if necessary, to maintain nutritional equivalency.
- The food must have performance characteristics (physical properties, flavor, functional properties and shelf life) similar to the standard food, unless the label discloses significant differences (such as "not recommended for baking").
- The food must contain a significant amount of every ingredient required in the standard food.
- The food may not substitute ingredients prohibited by the traditional standard of identity (for example, vegetable oil may not replace milkfat in "light" sour cream).
- The food may only contain ingredients permitted in the standard food, except that ingredients may be used to improve texture, flavor, shelf life, appearance, etc., so that the food is not inferior in performance characteristics to the standard food.

Dairy Safety

Dairy products are important for public health and nutrition. But they can carry disease if not produced, pasteurized and distributed under safe conditions. In 1938, before nationwide milk regulations were fully implemented, milk-borne disease outbreaks represented 25 percent of all food- and water-borne disease outbreaks nationwide.[144] Diseases included tuberculosis and brucellosis (undulant fever), among others.

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[143] 21 CFR 130.10

[144] Forward to the Grade A Pasteurized Milk Ordinance (2005 edition), published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration.

Since then, milk-borne disease outbreaks have dropped dramatically due to milk pasteurization, better sanitation, and better control of animal diseases. Milk-borne disease outbreaks currently represent less than one percent of food- and water-borne disease outbreaks nationwide.[145]

This improvement cannot be taken for granted, however. In 1985, a Chicago *salmonella* outbreak linked to post-pasteurization contamination of milk at a single Illinois dairy plant caused 16,000 illnesses and several deaths.[146] Disease outbreaks associated with *E. coli*, *Listeria*, *Campylobacter* and *Yersinia* have also been linked to milk.[147] Significant disease outbreaks from unpasteurized ("raw") milk continue to occur in Wisconsin and elsewhere.[148]

The stakes are high for "America's Dairyland." The dairy industry is a mainstay of Wisconsin's economy, and the entire industry can be affected by problems originating at a single location. For example, the Chicago *salmonella* outbreak had a broad impact on Wisconsin dairy product sales in the Chicago metropolitan area, even though the outbreak originated from just one dairy plant in Illinois.

Grade A Milk

In 1924, the United States Public Health Service published a model regulation for use by state and local milk regulatory agencies.[149] The updated model regulation is now known as the *Grade A Pasteurized Milk Ordinance* ("PMO").[150] The *National Conference on Interstate Milk Shipments* (consisting of representatives from participating states) works with FDA to develop and update PMO standards.

The PMO applies to fluid milk and fluid milk products (like sour cream and yogurt). Those products must be made from Grade A farm milk, and must be processed according to Grade A standards. The PMO does *not* apply to cheese or other non-fluid products (those products may be made from Grade A *or Grade B* milk). However, most Wisconsin cheese is made from Grade A milk. In fact, about 96% of all Wisconsin milk (*including* milk used for cheese) is produced on Grade A farms. Grade A farms must meet PMO standards, even if their milk is ultimately used for non-fluid products such as cheese.

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[145] *Ibid.*

[146] "A Closer Look at Dairy Safety," *FDA Consumer*, Vol. 20, No. 3, April, 1987, p. 14.

[147] FDA position statement on sale and consumption of raw milk, M-I-03-4 (March 18, 2003), posted at *http://www.cfsan.fda.gov/~ear/mi-03-4.html*.

[148] Milk and fluid milk products shipped in interstate commerce must be pasteurized, per the *Grade A Pasteurized Milk Ordinance* ("PMO") discussed below. Wisconsin law also prohibits the *intrastate* sale of raw milk or fluid milk products, subject to limited exceptions (see s. 97.24(2), Wis. Stats., and s. ATCP 60.235, Wis. Adm. Code). Cheese must be made from pasteurized milk, except that cheese may be made from raw milk if it is aged for more than 60 days (see 21 CFR 133, incorporated by reference in s. 97.09(1), Wis. Stats.).

[149] Forward and Preface to the Grade A Pasteurized Milk Ordinance (2005 edition), published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration.

[150] Grade A Pasteurized Milk Ordinance (2005 edition), published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration.

All of the states cooperate with FDA to enforce the PMO.[151] FDA audits each state's compliance, and may "de-list" an entire state or an individual milk shipper (such as a dairy plant) that fails to comply. Other states may prohibit interstate shipments from "de-listed" states or shippers. Most of Wisconsin's dairy production is sold in interstate markets, so PMO compliance is important for the Wisconsin dairy industry.

Wisconsin statutes, dating from 1949, require compliance with PMO standards.[152] Beginning in 1949, Wisconsin adopted detailed rules for Grade A milk production and processing based on the PMO.[153] Beginning in 1956, Wisconsin also adopted rules for Grade B milk production and processing.[154]

Dairy Regulation Today

Since 1988, DATCP has licensed all Wisconsin dairy farms (Grade A *and Grade B* farms).[155] A Grade A producer must hold a Grade A permit in addition to a license, and must meet higher standards than a Grade B producer.[156] Wisconsin has just over 12,000 Grade A dairy farms and just over 2,000 Grade B dairy farms.[157]

DATCP inspects most Grade A farms at least twice annually (per the PMO).[158] DATCP inspects Grade B farms less frequently. If DATCP suspends a Grade A farm permit (for violating Grade A standards), the producer may still operate as Grade B unless DATCP also suspends the producer's dairy farm license (for violating Grade B standards).[159] Grade B producers often receive lower milk prices than Grade A producers.

DATCP rules spell out milk quality standards, including standards for bacteria counts, somatic cells and antibiotic drug residues. Dairy plants must test producer milk, report test results to DATCP and, in some cases, reject producer milk shipments. In 2007, for example, Wisconsin dairy plants dumped over 11 million pounds of milk contaminated with antibiotic drug residues (not quite 1/10 of 1 percent of all milk produced in Wisconsin that year).

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[151] The state-federal cooperative agreement is known as the *Cooperative State-Public Health Service Program for the Certification of Interstate Milk Shippers*.

[152] Laws of 1949, ch. 517; s. 97.24, Wis. Stats.

[153] Wisconsin Department of Agriculture, General Order 124, In the Matter of Standards and Regulations for Milk and Cream to be Processed or Manufactured as Milk for Man, 1949.

[154] Chapter Ag 30, Wis. Adm. Code (1956).

[155] 1987 Wis. Acts 399; s. 97.22, Wis. Stats.

[156] See ch. ATCP 60, Wis. Adm. Code.

[157] DATCP Division of Food Safety, *2006 Annual Report*, p. 1.

[158] The PMO makes very limited allowance for different inspection intervals, based on dairy farm performance. Although most farms must be inspected twice-a-year, inspection intervals may range from once-a-year to 4-times-a-year based on performance. See s. ATCP 60.245, Wis. Adm. Code.

[159] A grade A permit may be suspended by written notice (typically after prior warnings), subject to a prompt follow-up hearing. A license suspension normally requires a pre-suspension hearing and a formal order by the DATCP Secretary or designee (a license may be summarily suspended in an emergency, subject to a prompt follow-up hearing). See ch. ATCP 60, Wis. Adm. Code.

DATCP currently licenses and inspects a wide range of dairy operations, including dairy farms, dairy plants and milk haulers.[160] DATCP also certifies dairy laboratories,[161] regulates dairy product testers,[162] and audits required industry testing for bacteria, drug residues and other key safety measures.[163]

The dairy industry, like other industries, has undergone rapid consolidation. Large interstate operations have largely replaced the traditional creamery at the crossroads. Production and processing are often highly automated. The traditional inspection process is being replaced, to a significant extent, by a HACCP (hazard analysis and critical control point) approach. Pasteurization is a critical safety control point.

Meat Inspection

Federal Law

Originally, the federal Meat Inspection Act applied only to meat establishments producing meat for interstate commerce. However, the federal Wholesome Meat Act of 1967 expanded the law to cover in-state operations.[164] Federal law now requires federal or state inspection of *all* meat establishments.

A state inspection program, if any, must be at least "equal to" the federal program. In states without qualifying programs, all meat establishments must be federally-inspected. Until now, only federally-inspected establishments could produce meat for interstate commerce.[165] But under recent law changes, small state-inspected meat establishments (25 or fewer employees) will soon be able to ship their meat products to buyers in other states.[166]

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[160] See s. 97.22, Wis. Stats., and ch. ATCP 60, Wis. Adm. Code (dairy farms); s. 97.20, Wis. Stats., and ch. ATCP 80, Wis. Adm. Code (dairy plants); s. 97.21, Wis. Stats., and ch. ATCP 82, Wis. Adm. Code (milk haulers and distributors).

[161] See s. 93.12, Wis. Stats., and ch. ATCP 77, Wis. Adm. Code.

[162] These include dairy lab analysts (ch. ATCP 77, Wis. Adm. Code), drug residue testers (ATCP 80.28) and milk component testers (ATCP 80.28).

[163] See chs. ATCP 60 (dairy farms), 77 (dairy laboratories), 80 (dairy plants) and 82 (milk haulers), Wis. Adm. Code.

[164] P.L. 90-201; 81 U.S. Stat. 584 (1967).

[165] The prohibition against interstate sales of state-inspected meat has not been applied to state-inspected meat from captive game animals or captive game birds.

[166] See Title XI of the Federal Food, Conservation and Energy Act of 2008 (otherwise known as the 2008 Farm Bill), Public Law 110-246, enacted June 18, 2008. The new interstate shipment authorization will not take effect until USDA adopts implementing rules (the act directs USDA to adopt rules within 18 months). Meat establishments with more than 25 employees are still precluded from shipping meat in interstate commerce unless they are federally inspected. State-inspected plants with 25-35 employees may sell in interstate commerce for an initial "grace period" of 3 years, but must transfer to federal inspection if they want to continue interstate sales beyond that "grace period."

Wisconsin Meat Inspection

The meat industry is the 4th largest manufacturing industry in Wisconsin, with a total economic impact of over $12.3 billion.[167] Wisconsin enacted its own meat inspection law in 1965.[168] Although the Wisconsin law predates the federal Wholesome Meat Act of 1967, it meets the standards prescribed in the federal act. The state law provides for an inspection program at least "equal to" the federal program,[169] including *ante mortem* and *post mortem* slaughter inspection of meat produced and sold within the state.

DATCP licenses and inspects all Wisconsin meat establishments, except for those (mainly large) establishments that are federally-inspected. DATCP inspects meat facilities and equipment, meat slaughter and processing, and meat labeling. DATCP may condemn unwholesome or diseased meat, and may issue holding orders to stop the distribution of suspect meat.

Wisconsin's program addresses the special needs of Wisconsin's meat industry. Wisconsin has a diverse livestock population (including a large number of dairy cattle) and a large number of meat establishments (including many that produce their own traditional or specialty meat products). While the federal program is designed for large interstate meat plants, the state program focuses mainly on smaller local establishments. Wisconsin currently licenses approximately 360 meat establishments.

Federal dollars fund 50 percent of the state meat inspection program. The state must "match" federal funds with state tax dollars, *not* license fee revenues (other Wisconsin food safety programs are funded to a greater degree by license fees). Federal audits ensure that the Wisconsin program is at least "equal to" the federal program, and that the state makes its required (tax dollar) funding match.

Since 1971, state rules have spelled out detailed meat inspection standards, including standards for slaughter, processing, facilities, equipment, transportation, storage, condemnation of unwholesome and adulterated meat, denaturing and disposal of inedible by-products, and formulation and labeling of meat products.[170]

Custom Slaughter Operations

Slaughter inspection is not required for *custom slaughter* services, such as the custom slaughter of farm livestock for on-farm consumption. A *custom slaughter* operator does not *sell* the meat, but merely provides a service to the animal owner. The animal owner must use the meat solely for household consumption, not sale.

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[167] DATCP Livestock News, Issue 1 No. 1 (August-September, 2007).
[168] Laws of 1965, ch. 582; s. 97.42, Wis. Stats.
[169] Wisconsin's program is, by some key measures, *more* effective than the federal program.
[170] Rules were initially codified in chs. Ag 7 and 48, Wis. Adm. Code (1971). Current rules are contained in chs. ATCP 55 and 57, Wis. Adm. Code. Within the past few years, Wisconsin has comprehensively overhauled and modernized its rules (ATCP 55 in 2002 and ATCP 57 in 2008).

Although custom slaughter operations are exempt from slaughter inspection, they must be licensed and must comply with sanitation requirements. Custom-slaughtered meat must be marked *not for sale*. Special requirements apply to mobile (on-farm) custom slaughter operations.

Wisconsin is a major deer hunting state (nearly ¾ of a million hunters each year).[171] Many Wisconsin meat establishments supplement their regular business by custom processing wild deer carcasses for hunters. DATCP does not regulate that processing directly. However, processors must comply with rules to prevent cross-contamination of other meat. When chronic wasting disease was found in Wisconsin deer, DATCP gave special scrutiny to custom processing operations (even though chronic wasting disease is not known to be a food safety threat to humans).

A Changing Program

Federal and state meat inspection programs have traditionally regulated the production and sale of meat from domesticated food animals such as cattle, swine and poultry. More recently, they have also regulated meat from other animals such as farm-raised deer, ratites (ostriches and emus), captive game animals and captive game birds.[172]

In the late 1990's, Congress and USDA completely overhauled the federal meat inspection program. They replaced the old system, based almost entirely on visual inspection, with a new "hazard analysis and critical control point" (HACCP) system that includes pathogen testing and scientific validation of critical process methods. In 1999, the Wisconsin Legislature incorporated the new federal standards into state law.[173] DATCP and the University of Wisconsin-Extension have helped small meat establishments develop HACCP plans.

Food Licensing

DATCP licenses over 30,000 food businesses (over 70,000 if you count registered livestock premises[174]). In 1988, the Wisconsin Legislature made sweeping changes to Wisconsin's food licensing system.[175] The Legislature streamlined license categories and funded more of Wisconsin's food safety program with license fees (the license fee funding share has continued to grow since 1988). The 1988 legislation created the following license categories (often by consolidating prior categories):

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[171] The Department of Natural Resources reports that it issued 738,413 deer hunting licenses (of all kinds) in 2006.
[172] See ch. ATCP 55, Wis. Adm. Code. DATCP also regulates farm-raised deer herds to prevent the spread of disease (see ch. ATCP 10, Wis. Adm. Code).
[173] 1999 Wis. Act 9; s. 97.42(4m), Wis. Stats.
[174] See s. 95.51, Wis. Stats. Some registered livestock premises, such as dairy farms, also hold food safety licenses.
[175] 1987 Wis. Act 399.

- ***Dairy Farms.*** Dairy farm operators must hold a DATCP license (and Grade A permit if applicable).[176] Operators must comply with DATCP rules.[177]

- ***Dairy Plants.*** Dairy plant operators must hold a DATCP license (and Grade A permit if applicable).[178] Operators must comply with DATCP rules.[179]

- ***Milk Haulers.*** Milk haulers must hold a DATCP license (and Grade A permit if applicable) for each tanker vehicle.[180] Milk haulers must be licensed to weigh and sample farm milk,[181] and must comply with DATCP rules.[182]

- ***Food Processing Plants.*** Food processing plant operators (canning factories, frozen food processors, bakeries, confectionaries, breweries, soft drink bottlers, etc.) must hold a DATCP license.[183] Operators must comply with DATCP rules.[184] Special requirements apply to canning operations (improper canning can pose a botulism risk).

- ***Retail Food Establishments.*** Retail food establishment operators (grocery stores, delicatessens, bakeries, confectionaries, ice cream shops, etc.) must hold a DATCP license.[185] Operators must comply with DATCP rules.[186]

- ***Food Warehouses.*** Food warehouse operators (including cold storage operators and milk distributors) must hold a DATCP license.[187] Operators must comply with DATCP rules.[188]

Food Laboratories

In 1995, the Legislature transferred much of Wisconsin's laboratory certification program from the Department of Health Services (then known as the Department of Health and Social Services) to DATCP.[189] Since then, DATCP has been responsible for certifying laboratories that test *milk, food* and *drinking water* for compliance with public health standards.[190]

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[176] See s. 97.22, Wis. Stats.
[177] See ch. ATCP 60, Wis. Adm. Code.
[178] See s. 97.20, Wis. Stats.
[179] See ch. ATCP 80, Wis. Adm. Code.
[180] See s. 97.21, Wis. Stats.
[181] See s. 98.146, Wis. Stats.
[182] See ch. ATCP 82, Wis. Adm. Code.
[183] See s. 97.29, Wis. Stats.
[184] See ch. ATCP 70, Wis. Adm. Code.
[185] See s. 97.30, Wis. Stats. The Department of Health Services (DHS) licenses hotels, restaurants and vending machine operations (*see* s. 254.64, Wis. Stats.). Local governments may license on behalf of DATCP and DHS (see discussion below).
[186] See ch. ATCP 75, Wis. Adm. Code.
[187] See s. 97.27 and 97.21, Wis. Stats.
[188] See ch. ATCP 71, Wis. Adm. Code.
[189] 1995 Wis. Act 27; s. 93.12, Wis. Stats.
[190] The Department of Health Services ("DHS") retains jurisdiction over certain public health laboratories, such as medical laboratories. The Department of Natural Resources certifies laboratories that test for chemical contaminants (as opposed to bacterial contaminants) in groundwater.

Laboratory testing is a key part of many food safety programs. For example, dairy plants must test farm milk and processed dairy products, and must report test results to DATCP.[191] Laboratory certification helps to ensure accurate testing.

Certified laboratories must comply with DATCP rules.[192] Laboratories must be properly equipped, and must use recognized test methods. In order to certify a *milk* or *food* laboratory, DATCP must also certify the competency of individual lab analysts. DATCP does not certify individual *water* lab analysts, but does evaluate overall laboratory proficiency.

DATCP also conducts its own laboratory tests of food, feed and other commodities. DATCP conducts routine surveillance tests, as well as in-depth testing related to food contamination and law enforcement. Wisconsin was one of the first states to spot E. coli contamination of spinach in 2006, based partly on DATCP lab tests (the finding led to a nationwide recall).

Retail Food

Wisconsin has developed a cooperative state-local system for regulating retail food establishments, based on the national Model Food Code. DATCP licenses grocery stores and other retail establishments such as bakeries and delicatessens,[193] while the Department of Health Services (DHS) licenses restaurants.[194] DATCP works closely with DHS. Both agencies work closely with county and local health departments, which may license and inspect retail establishments on behalf of the state.

State Agency Roles

DATCP is Wisconsin's primary food agency. However, DHS has important responsibilities related to public health and disease prevention. In the early days of statehood, public health was primarily a function of local governments. But in 1876, the Legislature established a state Board of Health, and directed the Board to "make sanitary investigations and inquiries respecting the causes of mortality, and the effects of localities, employments, conditions, ingesta, habits and circumstances on the health of the people."[195]

Beginning in 1913, the Legislature required hotel and restaurant operators to obtain annual permits from the state Board of Health.[196] In 1967, the Legislature merged Board of Health functions into DHS (then called the Department of Health and Social Services) as part of a state government reorganization.[197] DHS currently licenses (issues annual permits for) restaurants, hotels and vending machine commissaries under s. 254.64, Wis. Stats. DHS also plays a key role in collecting health data and investigating food-borne disease outbreaks.

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[191] See chs. ATCP 60 and 80, Wis. Adm. Code. Many of the tests are required by the Interstate Pasteurized Milk Ordinance ("PMO"). The PMO also spells out lab certification requirements.
[192] See ch. ATCP 77, Wis. Adm. Code.
[193] See s. 97.30, Wis. Stats., and ch. ATCP 75, Wis. Adm. Code.
[194] See s. 254.64, Wis. Stats., and ch. HFS 196, Wis. Adm. Code.
[195] Ch. 366, Laws of 1876.
[196] Ch. 648, Laws of 1913.
[197] Ch. 75, Laws of 1967.

Local Agents

In 1983, the Legislature created a cooperative "local agent" program for retail food regulation.[198] Under that program, a participating city or county ("local agent") may license and inspect retail food establishments on behalf of DATCP.[199] A local agent may also license and inspect restaurants, hotels and vending machine commissaries on behalf of DHS.[200]

Local participation is voluntary. A participating local agent must enter into a contract with the cooperating state agency (local agents may contract with DATCP or DHS, or both, depending on the intended scope of the local program). Local agents must comply with applicable state rules.[201] The state agency must train local staff and monitor local regulation to ensure reasonable consistency and compliance with state standards.

Local agents may combine retail licenses and set their own license fees. Local license fees may be higher (and typically *are* higher) than state fees.[202] Local agents must pay part of their fee revenues to the contracting state agencies, to cover state costs for training, standardization and evaluation of local programs.

The local agent program is growing. DATCP has contracted with 36 local agents, and DHS has contracted with 50 local agents (DHS also uses local agents for other purposes). Local agents generally operate in the state's larger metropolitan areas. DATCP and DHS are responsible for inspection and licensing in areas that are not served by local agents.

Consistent Regulation

DATCP works closely with DHS and local governments to prevent duplicate licensing and inspection. Many grocery stores include restaurants, and vice-versa. DATCP and DHS coordinate so that grocery store–restaurant combinations are licensed and inspected by a single entity, *not* multiple entities. DATCP and DHS do not duplicate local agent licensing or inspection (but they retain jurisdiction to inspect if circumstances warrant).

DATCP and DHS have also adopted consistent (essentially identical) rules for grocery stores and restaurants. The rules are based on the federal Model Food Code published by FDA.[203] The Model Food Code addresses the following topics, among others:

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[198] 1983 Wis. Act 203.

[199] See s. 97.41, Wis. Stats.

[200] See s. 254.69, Wis. Stats. DHS already had authority to contract with local agents, but the 1983 legislation expanded local agent authority and authorized local agents to establish and collect their own license fees.

[201] See chs. ATCP 74 and 75 and chs. HFS 192 to 198, Wis. Adm. Code.

[202] DATCP fees are typically lower than DHS or local agent fees, because DATCP's food safety program is funded in part by general tax dollars. DHS and local food programs are, with limited exceptions, funded almost entirely by license fees. That is possible, in part, because there are more restaurants than grocery stores (restaurants offer a larger fee base).

[203] See ATCP 75 and HFS 196. See s. 227.14(1s), Wis. Stats., which authorizes DATCP and DHS to use the Model Food Code format.

- Potentially hazardous foods, including heating and cooling requirements.
- Construction and maintenance.
- Equipment and utensils.
- Management and personnel standards.
- Food sources.
- Receiving, handling, storing and displaying food.
- Delicatessen operations.
- Cleaning and sanitizing procedures.
- Food safety labels and consumer warnings.
- Mobile food establishments.
- Records and reports.

Food Law Enforcement

DATCP has broad statutory authority to administer Wisconsin's food safety laws. DATCP may take action against food law violators, regardless of whether they are licensed by DATCP. DATCP administers ch. 97, Wis. Stats. (food regulation), as well as related laws dealing with pesticides, animal feed, animal health, fair packaging and labeling, weights and measures, unfair and deceptive business practices, and commodity inspection and grading.[204] DATCP has a wide range of food regulatory tools including:

- ***Licensing.*** DATCP licenses over 30,000 dairy and food businesses (over 70,000 if you count registered livestock premises). DATCP may deny, suspend or revoke licenses for cause.[205] DATCP may also impose conditions on licenses.[206] License holders are entitled to a trial-type administrative hearing on the license action.[207] "Licenses" include permits, registrations, certificates, and like authorizations to do business.

- ***Rulemaking.*** DATCP may adopt rules that have the force of law.[208] Rules establish clear food safety standards for affected businesses. Rulemaking procedures must comply with ch. 227, Wis. Stats. All rules must be approved by the DATCP Board, and must undergo public hearings and legislative review. The statutory procedures are complex, so it now takes well over a year to adopt a rule. DATCP may adopt an emergency rule on short notice, but an emergency rule expires after 150 days (a legislative committee may extend it for up to 120 days). The emergency rule may expire before the "permanent" rule takes effect, leaving a regulatory "gap" that could affect public health and safety.

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[204] See, generally, chs. 93-100 and ch. 126, Wis. Stats. DATCP administers commodity grading programs for butter, cheese, eggs, grain and vegetables, among other things. DATCP regulates private graders (butter, cheese and eggs) or provides direct grading services upon request (grain and vegetables). DATCP charges fees to cover its costs. Grade standards for cheese, butter and eggs are found in chs. ATCP 81, 85 and 88, Wis. Adm. Code.

[205] See, for example, s. 93.06(7), Wis. Stats.

[206] See, for example, s. 93.06(8), Wis. Stats.

[207] See ch. 227, Wis. Stats., and ch. ATCP 1, Wis. Adm. Code.

[208] See, for example, food rulemaking authority provided in s. 93.07(1) and ch. 97, Wis. Stats. Other chapters provide extensive rulemaking authority related to animal health, feed, business practices, etc.

- ***Inspection and Sampling.*** DATCP may inspect facilities and records, take photographs, and collect samples for testing.[209]

- ***Subpoena and Investigative Authority.*** DATCP may conduct in-depth investigations, and may issue subpoenas and investigative demands to compel testimony and evidence.[210]

- ***Food Holding Orders and Condemnation Orders.*** DATCP may issue holding orders to prevent the sale or movement of suspect food while DATCP checks for law violations.[211] DATCP may condemn and order the disposal of adulterated food,[212] including unwholesome meat. DATCP may issue holding orders and condemnation orders without prior hearing (but subject to a follow-up right of hearing).[213]

- ***Voluntary Recalls.*** DATCP may not order a seller to "recall" food that the seller has already distributed. However, DATCP may issue a public consumer alert if the seller does not recall adulterated food voluntarily.[214]

- ***Administrative Injunctions (Special Orders).*** DATCP may prohibit the use of unsanitary equipment, facilities or procedures until the violation is remedied.[215] DATCP may also issue other special orders, including orders prohibiting unfair or deceptive business practices.[216]

- ***Civil Forfeiture Actions.*** DATCP may seek court-ordered civil forfeitures for food law violations.[217] Civil forfeiture actions are normally prosecuted by district attorneys at DATCP's request. DATCP is not authorized to issue summary "citations" or impose civil forfeitures by administrative order. But a respondent may stipulate to a court-ordered civil forfeiture in lieu of a license suspension or other administrative action by DATCP.[218] Civil forfeitures are paid to the county treasurer (for deposit to the state school fund), *not* to DATCP.

- ***Criminal Prosecution.*** Most food law violations are subject to criminal penalties.[219] District attorneys prosecute criminal cases based on DATCP investigations. In food cases, the state is not ordinarily required to prove criminal intent. However, criminal prosecution is typically reserved for serious or intentional violations.

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[209] See, for example, ss. 93.08(2), 97.12(1) and 97.42(7), Wis. Stats.
[210] See, for example, ss. 93.14-93.16, Wis. Stats.
[211] See, for example, ss. 97.12(2)(a) and (b) and 97.42(9)(b)1., Wis. Stats.
[212] See, for example, ss. 97.12(2)(c) and 97.42(9)(b)2., Wis. Stats.
[213] See ch. ATCP 1, Wis. Adm. Code.
[214] See, for example, s. 93.06(1)(f), Wis. Stats.
[215] See s. 97.12(3) and 97.42(9)(a), Wis. Stats. In appropriate cases, orders may be issued on a summary basis subject to a follow-up right of hearing.
[216] See s. 100.20(3), Wis. Stats.
[217] See, for example, s. 97.72(2), Wis. Stats. Civil forfeiture penalties were first provided for food law violations in 1985, as an alternative to criminal fines (see 1985 Wis. Act 229). Before that, court enforcement options were essentially limited to criminal prosecutions and injunction actions.
[218] DATCP often negotiates civil forfeiture consent judgments with defendants accused of food law violations.
[219] See, for example, s. 97.72(1), Wis. Stats.

- ***Court Injunction.*** DATCP may seek a court order enjoining food law violations.[220] Where necessary, DATCP may seek a temporary injunction pending hearing on a permanent injunction.

- ***Public Information.*** DATCP may collect and disseminate information, including information related to food safety problems and law violations.[221] DATCP may hold informational and investigative hearings, and may use its subpoena and investigative authority to compel the production of information.[222] DATCP may distribute information in many different ways including news releases, website postings, targeted correspondence and informational meetings.

[220] See, for example, s. 97.73, Wis. Stats.
[221] See, for example, s. 93.06(1)(f), Wis. Stats.
[222] See, for example, ss. 93.14-93.16, Wis. Stats.

4. The Future

Food regulation continues to evolve in response to a changing world. But the world is now changing at a breakneck pace, and food regulation faces some daunting new challenges. Here are just a few issues that will affect Wisconsin food regulation in the years to come:

Our Growing Dependency

We all get hungry every day, and a growing population demands ever more food. In 1839, when Wisconsin Territory enacted its first food safety law, there were fewer hungry mouths to feed:

- In 1839, Wisconsin Territory (including parts of what is now Minnesota) had only 30,000 food consumers. Today, Wisconsin has about *5.6 million* food consumers. Nearly a million more consumers may be added in the next 25 years.

- In 1839, the United States had only 17 million food consumers, compared to over *300 million* today. In 25 years, the U.S. may have nearly *400 million* food consumers.

- In 1839, the world had only about one billion food consumers, compared to over *6.5 billion* today. In 25 years, there may be over *8 billion* food consumers, and all of them will aspire to a higher living standard. The market for food is now a global market, driven by forces outside our control.

In 1839, most people in Wisconsin Territory still produced or gathered much of their own food directly from the land. Food production drew on previously untapped natural resources (including undeveloped land and virgin topsoil, now substantially diminished). The food chain was simple and short, and driven mainly by solar energy. There were few external inputs. Food consumers were also food producers, and they were self-sufficient to a considerable degree.

That does not mean that life was easy. In 1839, most families put in long days of physical toil just to put food on the table. They gathered their own fuel, grew their own crops, raised and slaughtered their own livestock, struggled against diseases, drought and pests, and prepared their food from scratch (*very* scratch). There were no tractors, trucks, supermarkets, refrigerators, freezers, gas ranges, micro-waves, hot running water or convenience foods. Choice was severely limited, and scarcity was common. There was little agricultural surplus to feed non-farm residents. The subsistence agriculture of 1839 would be wholly incapable of feeding today's large urban population.

But in the Wisconsin of 1839, as in most of human history, food production was mainly a local enterprise subject to local hazards. Most people had direct food production and processing know-how. Although there was some extended commerce in food, most people knew first-hand where their food came from, who produced it, and how it was produced. Consumers lived in close contact with the land and confronted, in a very personal way, the biological realities of food production.

Today, by contrast, we are utterly dependent on food produced elsewhere by strangers. Major U.S. cities typically have access to about one week's supply of food.[223] We rely on an intensive, large scale, highly industrialized, and highly efficient but impersonal system to bring food to our table. Much of our food comes from great distances – often from foreign sources. Few of us understand how, or under what conditions, it is produced.

This vast industrialized system provides us with historically cheap, plentiful and convenient food. Even with recent price increases, American consumers spend (on average) only about 13% of their disposable income for food[224] -- perhaps the lowest share of any country in the world. But it is hard to deny our growing ignorance and dependency.

Fossil Fuel Dependency

Our food supply depends, among other things, on fossil fuel. In 1918, one-fourth of all the crops grown in the U.S. went to feed horses and mules, which provided power for planting, cultivating, harvesting and transporting agricultural commodities.[225] Today, that work (and much more) is performed by machines running on fossil fuel (or on electricity generated from fossil fuel). Critical farm inputs, including nitrogen fertilizer and pesticides, are also made from fossil fuel. This infusion of fossil energy (a gift from past ages) has fueled an enormous increase in agricultural production, which has helped feed a burgeoning population.

Farming itself accounts for only about 20% of the energy used in the overall food system.[226] Considerably *more* fossil fuel is needed to dry, process, package, transport, refrigerate, freeze, store, heat and prepare the food we eat. Studies suggest that the overall U.S. food system (broadly defined to include farm, manufacturing, transportation, commercial and household activities related to food) now accounts for 10 to 17% of all U.S. energy use.[227]

Today, about 7 to 10 calories of fossil fuel energy are needed to provide just one calorie of food energy to our bodies.[228] We live (quite literally) on fossil fuel energy. The U.S., with less than 5% of the world's population, consumes roughly 25% of the world's annual fossil fuel production (food and non-food uses). We get about 60% of our oil from foreign sources.[229] Fossil fuel production is highly centralized, and vulnerable to price shocks and disruption. Growing world demand is creating intense competition for scarce supplies. And now, we realize, our ever-growing fossil fuel consumption is causing global warming.

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[223] Statement by Tom McGinn DVM, United States Department of Homeland Security, before the House Committee on Homeland Security, Subcommittee on Management, Investigations and Oversight, July 9, 2007. Available at *http://www.dhs.gov/xnews/testimony/testimony_1184092241513.shtm.*

[224] The Boston Globe, March 9, 2008.

[225] USDA, "Yearbook of Agriculture" (1960).

[226] Hendrickson, "Energy Use in the U.S. Food System: A Summary of Existing Research and Analysis," Univ. of Wisconsin, Center for Integrated Agricultural Systems (2004); Heller and Keoleian, "Life Cyle-Based Sustainability Indicators for Assessment of the U.S. Food System," Report No. CSS00-04, Center for Sustainable Systems, University of Michigan (2000).

[227] *Ibid*.

[228] *Ibid*.

[229] U.S. Department of Energy Statistics, 2005.

Food System Concentration

Concentrated Production

At nearly every level, and in nearly every way, the food industry is growing more concentrated. That concentration extends to farming. In 1870, nearly 70% of Wisconsin residents still lived on farms (or in small farm-related hamlets). The percentage dropped to 35% by 1920, to 10% by 1970, and to 2% by the start of the 21st Century. Farm families now comprise only about 8% of Wisconsin's *rural* population.[230]

It is startling to realize that in Wisconsin, "America's Dairyland," there are now far more prisoners than dairy farm operators. On June 30, 2006, Wisconsin had a state prison population of 21,440 (not counting local inmates held in county jails).[231] By comparison, Wisconsin has only about 14,000 dairy farms (*one-tenth* of the 140,000 dairy farms that existed in 1950). Even so, Wisconsin has far more dairy farms than any other state.

At the national level, less than one percent of the U.S. population now claims farming as an occupation (much less a *primary* occupation). Farm numbers dropped from 6.8 million in 1935 to 2.1 million in 2002, and many of those are small "hobby" farms.[232] Production is increasingly concentrated in large farms. In 2002, less than 2% (42,000) of the nation's farms accounted for *half* of the nation's farm product sales.[233] About 80 to 90% of U.S. cattle production is concentrated in less than 5% of the nation's feedlots.[234]

Large contractors control much of the nation's agricultural output, either directly or through production or marketing contracts. According to recent reports:[235]

- 4 companies controlled beef feedlots with a combined daily capacity of 1,926,000 head.
- 4 companies controlled 49% of U.S. on-farm pork production.[236]
- 4 integrated processors controlled nearly 59% of U.S. on-farm chicken production.
- 4 integrated processors controlled 55% of U.S. on-farm turkey production.
- One large farmer-owned cooperative marketed 33% of the nation's on-farm milk production.[237]

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[230] See *Wisconsin Bluebook (2003-04)*, p. 109.
[231] Wisconsin Bluebook (2007-08), p. 824.
[232] "Structure and Size of U.S. Farms: 2005 Family Farm Report/EIB-12, Economic Research Service, USDA, p. 6. Available at *http://www.ers.usda.gov/publications/EIB12/EIB12c.pdf*.
[233] Ibid., at p. 10.
[234] Statement by U.S. Senator Richard Burr, August 16, 2007.
[235] Except as otherwise noted, figures are from Hendrickson and Heffernan, "Concentration of Agricultural Markets," University of Missouri Department of Rural Sociology (April, 2007). Available at *http://www.nfu.org/wp-content/2007-heffernanreport.pdf.*
[236] Hendrickson and Heffernan, "Concentration of Agricultural Markets," University of Missouri Department of Rural Sociology (January, 2005). Available *at http://www.foodcircles.missouri.edu/CRJanuary05.pdf.*
[237] Ibid.

Concentrated Processing

Food processing is also dominated by a small number of companies. According to a 2007 report:[238]

- 4 companies processed nearly 84% of all U.S. beef.
- 4 companies processed 66% of all U.S. pork.
- 4 companies processed nearly 59% of U.S. chicken (2 companies processed 47%).
- 4 companies processed 55% of U.S. turkeys.
- 3 companies controlled 55% of U.S. flour milling.
- 4 companies controlled 80% of U.S. soybean crushing (3 companies controlled 71%).
- 4 dairy processors had combined sales of nearly $22 billion.

Concentrated Inputs

Modern agriculture relies heavily on key inputs such as high-performance livestock and crop genetics, fertilizer, pesticides and feed. With artificial insemination, a single prized bull can now father a million offspring. A small number of companies can now shape the genetics of whole crop and livestock sectors, potentially limiting genetic diversity.[239] Concentration, often spurred by new technology, is growing in many input markets. According to recent reports:[240]

- 2 companies controlled 60% of U.S. corn and soybean seed production.
- One company, Monsanto, controlled 90% of the world market for genetically engineered seed (now widely used in the U.S.).[241] Monsanto's genetically engineered "Roundup-ready" seed allows even more use of the company's popular Roundup herbicide.
- One company controlled 50-60% of U.S. commercial fertilizer sales.
- 4 companies controlled 34% of U.S. commercial feed production facilities.

Retail Concentration

Food *retail* concentration is growing at a breathtaking pace. In 2005, five companies accounted for 48% of all supermarket grocery sales in the U.S. – up from 27% in 1997.[242] Wal-Mart, the nation's largest food retailer, increased its food sales by nearly 49% in the short period from 2004 to 2006.[243] A 2003 study projected that Wal-Mart would soon control 35% of the retail grocery market.[244]

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[238] Hendrickson and Heffernan (April 2007). Beef processing may become even more concentrated if the giant Brazilian meatpacker JBS completes its proposed buyouts of Smithfield Foods and National Beef Co. "Dealmaking Sweeps U.S. Beef Market," Dow Jones Newswires (March 6, 2008). The U.S. Justice Department has filed an anti-trust suit challenging the proposed National Beef buyout, but not the Smithfield buyout (DOJ press release, October 20, 2008).

[239] See, for example, Notter, "The Importance of Genetic Diversity in Livestock Populations of the Future," Journal of Animal Science 1999, 77:61-69.

[240] Except as otherwise noted, figures are from Hendrickson and Heffernan (January 2005).

[241] Financial Times, Nov. 16, 2006.

[242] Hendrickson and Heffernan (April 2007).

[243] Ibid.

[244] Retail Forward, "Wal-Mart Food: Big, and Getting Bigger," September, 2003.

Nearly half of the nation's retail food dollars are now spent in restaurants (compared to 25% in 1955), and more than half of those dollars are now spent at large restaurant and fast-food chains.[245] Chains continue to increase their restaurant market share at the expense of local independent restaurants.

Physical Concentration

The concentration of ownership parallels a physical concentration of production, processing and distribution facilities. Farms, feedlots, processing plants, distribution facilities and retail stores are larger. Processing is highly industrialized and automated. Production and processing know-how is confined to a relatively small number of experts who manage complex, highly automated (and energy dependent) systems. Agricultural inputs, farm commodities and foods are transported over great distances.

Effects of Concentration

Food system concentration is driven by market realities, including changing technology, capital demands, and economies of scale. But it can have costs and consequences that are not factored into ordinary market calculations:

- Centralized and mono-cultural systems may make the food chain more vulnerable to a variety of threats, including disease, bio-security, fuel disruption and terror threats.
- Problems at one location may quickly spread to many distant locations.
- Small failures and dislocations in complex systems may have widespread consequences for a whole society.
- Concentrated market power may adversely affect farmers, small businesses, consumers and democratic institutions. Monopoly power may perpetuate and extend itself, regardless of economic efficiency.
- Concentration at one level (such as retail) may reshape the entire food chain, right down to the farm level.
- A concentrated industry may be less responsive to state citizen interests, and less susceptible to state regulation. Global corporate interests may differ from Wisconsin interests.
- Concentration may create pressure for national and international uniformity, sometimes at the expense of state law and policy.

Global Sourcing of Food

Much of our food now comes to us from foreign sources. Imported food must, in theory, meet the same standards as domestic food. But it is produced and processed outside the direct purview of U.S. inspectors (much less Wisconsin inspectors). The federal government inspects only a tiny fraction of all food import shipments.

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[245] Nation's Restaurant News, December 19, 2005. Available at *http://findarticles.com/p/articles/mi_m3190/is_51_39/ai_n15967678.*

Food imports are not a new phenomenon (after all, bananas do not grow well in Wisconsin). But the lowering of trade barriers has helped fuel an explosion of imported food and food ingredients. Food imports more than doubled in the last decade, to $79.9 billion.[246] Food comes from a wide range of countries, including many countries that have weak food safety regulation. Some of the import growth is driven by specialized market demand, but much is also driven by general price competition for standard commodities and ingredients.

Meat and Poultry Imports

USDA regulates imports of meat, poultry and eggs. USDA does not inspect the slaughter or processing of imported meat, as it does for domestic products. However, imported meat must originate from USDA-certified nations and exporting establishments.[247] Foreign meat regulation does not have to meet U.S. standards, but it must provide "equivalent" food safety protection. USDA evaluates foreign sources by document reviews and random statistical sampling of imported products. USDA may also conduct occasional on-site audits of some establishments.

It is ironic that meat produced in foreign countries (beyond the reach of U.S. inspection) can be sold throughout the U.S., while wholesome Wisconsin meat produced under continuous state inspection cannot. Until now, only federally-inspected meat establishments could produce meat for interstate commerce.[248] But under recent law changes, small state-inspected meat establishments (25 or fewer employees) will soon be able to ship their meat products to buyers in other states.[249]

Other Imported Food

FDA regulates food and feed imports other than meat, poultry and eggs. Under the federal Bioterrorism Act of 2002,[250] foreign and domestic facilities must register with FDA if they manufacture, process, pack, or hold food or feed for consumption in the U.S.[251] As of July 3, 2007, FDA had registered 322,744 facilities, including 188,946 *foreign* facilities and 133,798 *domestic* facilities.[252]

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[246] "Globalization in Every Loaf," New York Times, June 16, 2007, citing the U.S. International Trade Commission.

[247] See USDA website at http://www.fsis.usda.gov/regulations_&_policies/Import_Information/index.asp.

[248] The prohibition against interstate sales of state-inspected meat has not been applied to state-inspected meat from captive game animals or captive game birds.

[249] See Title XI of the Federal Food, Conservation and Energy Act of 2008 (otherwise known as the 2008 Farm Bill), Public Law 110-246, enacted June 18, 2008. The new interstate shipment authorization will not take effect until USDA adopts implementing rules (the act directs USDA to adopt rules within 18 months). Meat establishments with more than 25 employees are still precluded from shipping meat in interstate commerce unless they are federally inspected. State-inspected plants with 25-35 employees may sell in interstate commerce for an initial "grace period" of 3 years, but must transfer to federal inspection if they want to continue interstate sales beyond that "grace period."

[250] P.L. 107-188.

[251] See FDA rules at 21 CFR 1, subpart H.

[252] See FDA website document "Registration of Food Facilities -- Compliance Information (July 3, 2007) at *http://www.cfsan.fda.gov/~furls/ffregsum.html.*

Over 170 different countries have registered facilities. In mainland China alone, there are over 17,000 FDA-registered facilities. Registrants must provide basic identification (including plant locations), and must identify the types of food produced.[253] But registrants are not required to provide food safety information, and FDA does not inspect or regulate food processing operations (much less farm operations).[254]

Under the Bioterrorism Act of 2002, importers must also notify FDA before importing food or feed shipments to the U.S.[255] Notice must describe the import shipment, including the food type and quantity, food source, food manufacturer, import destination and estimated import date.[256] FDA inspects a very small percentage of import shipments (the agency conducts lab tests on less than one percent of shipments).[257]

FDA attempts to target its testing based on risk priorities, but the sheer number of shipments and possible contaminants limits the practical efficacy of surveillance testing. Domestic recipients of import shipments must keep import records,[258] and may be held accountable for imported food that they distribute in this country.

Processed Food Ingredients

Many food commodities from foreign sources are used as generic ingredients in processed foods. A single processed food may include ingredients from many different domestic and foreign sources. Processors are responsible for the ultimate product, which must meet U.S. food safety and labeling standards. However, the sheer number of potential ingredients and sources limits the feasibility of country-of-origin labeling. Contaminant testing and trace-back may also be difficult (as illustrated by recent problems with contaminated pet food ingredients from China).

Country-of-Origin Labeling

It is not always possible to tell, from a food label, whether food originates from a domestic or foreign source. Congress enacted "country of origin labeling" (COOL) requirements in 2002,[259] but later postponed those requirements for everything except seafood.[260] Revised COOL requirements finally took effect on September 30, 2008. Those requirements now apply to the following foods sold in grocery stores:

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[253] See FDA website document, "What You Need to Know About Registration of Food Facilities," referenced at *http://www.cfsan.fda.gov/~dms/fsbtbook.html.*

[254] Last year, FDA inspected only about 100 of the nearly 190,000 foreign food plants that ship food to the U.S. (a rate of one inspection every 1,900 years). "For F.D.A., a Major Backlog Overseas," New York Times, January 29, 2008.

[255] See FDA rules at 21 CFR 1, subpart I.

[256] See FDA website document, "What You Need to Know About Prior Notice of Imported Food Shipments," referenced at *http://www.cfsan.fda.gov/~dms/fsbtbook.html.*

[257] "Globalization in Every Loaf," New York Times, June 16, 2007.

[258] See FDA website fact sheet at *http://www.cfsan.fda.gov/~dms/fsbtac23.html.*

[259] The legislation was included in the Farm Security and Rural Investment Act of 2002, more commonly known as the 2002 Farm Bill.

[260] P.L. 108-199, P.L. 109-97. Seafood requirements (fish and shellfish) took effect in 2005.

- Seafood.
- Beef, pork, lamb, chicken and goat meat.
- Fruits and vegetables (fresh and frozen).
- Peanuts, pecans, macadamia nuts and ginseng.

COOL does *not* apply to *processed* foods made from covered ingredients, or to meals served in restaurants. USDA is adopting rules to interpret and implement COOL.

Impact on State Food Safety Programs

Food import regulations are affected, to a considerable degree, by international trade negotiations. States do not play a significant role in trade negotiations, or in the initial regulation of imports. But they often play a key role in "after-the-fact" responses to food safety problems involving imported food. The cost burden for "after the fact" responses may fall heavily on the states, because states conduct more than 80% of all U.S. food safety inspections and tests.

Bio-Security and Emergency Response

Disease Threats

The security of the food system has been a growing concern, especially since the terrorist attack on September 11, 2001. The food system is vulnerable to a number of threats, and terrorism is just one of them. Disease is one of the foremost threats:

- Some food-borne diseases such as E. coli, Salmonella, Listeria, Campylobacter, hepatitis A and botulism pose acute (potentially fatal) threats to human health. According to the Centers for Disease Control, food-borne diseases account for 76 million bouts of illness, 325,000 hospitalizations and 5,000 deaths in the U.S. each year.[261] Disease outbreaks can undermine consumer confidence and devastate large sectors of the food industry, as illustrated by nationwide outbreaks of E. coli in 2007 (spinach) and salmonella in 2008 (blamed on tomatoes, then imported peppers). DATCP coordinates state emergency responses with the Wisconsin Department of Health Services (DHS) and federal authorities. Wisconsin has one of the best programs in the nation for detecting and reliably reporting disease outbreaks, according to a Scripps-Howard News Service study published in November 2006.[262]

[261] United States Department of Health and Human Services, Centers for Disease Control, website at *http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#howmanycases.*

[262] *See http://www.healthjournalism.org/news/2007/fatalfood.htm*. The Scripps-Howard study looked at over 6,000 food related disease outbreaks reported by all 50 states to the Centers for Disease Control and Prevention between 2000 and 2004. Effective reporting relationships, excellent lab testing, and strong state-local cooperation were cited as reasons for Wisconsin's success. Wisconsin was one of the first states to spot the recent nationwide E. coli outbreak traced to spinach, based in part on DHS health incident reporting and DATCP lab testing.

- Other diseases pose a grave threat to the food system, even though they are not transmissible to humans. For example, an outbreak of foot-and-mouth disease could shut down much of Wisconsin's vast dairy and livestock industry. The 2001 foot-and-mouth outbreak in the United Kingdom illustrated the danger. Millions of livestock were killed, and the crisis cost Britain as much as *$15 billion* (8 billion British pounds).[263] Images of bulldozed and burned animal carcasses flooded the media worldwide. Despite lessons learned from 2001, Britain was again rocked by foot-and-mouth outbreaks in 2007.

- Some diseases, such as tuberculosis and influenza, recognize no boundaries between wild animals, domestic livestock and human beings. Some of these diseases may be food-borne. But even if not food-borne, they can cause tremendous damage to livestock industries and food systems. Wild animals (initially infected from wild or domestic sources) can roam freely and spread disease to other wild animals and domestic livestock, complicating disease control. Some states, including Michigan and Minnesota, have recently found tuberculosis in cattle *and* surrounding wild deer populations. Avian influenza, including pathogenic strains dangerous to humans, may also be spread between wildfowl and domestic poultry.

- Diseases such as BSE ("mad cow disease") can move upward through the food chain, from animal feed to livestock to humans. BSE can spread fear among consumers, and can devastate key livestock industries and export markets. Wisconsin has conducted more BSE surveillance tests than any other state. To date, Wisconsin has tested well over 100,000 cattle without any disease findings (about 20% of all cattle tested in the U.S.). But a positive BSE finding could have a far-reaching impact on Wisconsin's livestock and food industry.

- Johne's disease incubates slowly, and is hard to detect. But it is widespread among cattle, and has a tremendous impact on milk production and farm profitability. In Wisconsin's dairy cattle industry alone, the disease is costing an estimated $54 million *each year* in weight loss and reduced milk production. Dairy farmers with infected herds may be losing as much as $235 a year for every animal in their herd, and the dairy processing industry is losing much-needed milk production.[264] But livestock operators have been slow to test, and slow to demand herd test information on cattle they purchase,[265] so the disease continues to spread. Some researchers have hypothesized a milk-borne link to Crohn's disease in humans, but no link has been proven.

- Exotic diseases and pests, which are appearing with greater frequency because of global trade, can affect food production. Once established, they may be hard or impossible to eradicate.

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[263] See United Kingdom official inquiry report at *http://archive.cabinetoffice.gov.uk/fmd/fmd_report/report/index.htm.* Researchers at Kansas State University recently predicted that a foot-and-mouth outbreak in Kansas could cost that state $1 billion. Kansas State University, PRNewswire, November 27, 2007.

[264] See DATCP website at *http://www.datcp.state.wi.us/ah/agriculture/animals/disease/johnes/index.jsp*.

[265] Under Wisconsin law, a seller impliedly warrants that cattle are free of Johne's disease unless the seller tests the source herd and discloses its risk classification, or discloses that the source herd is at high risk for Johne's disease because it has not been tested (see s. 95.195, Wis. Stats., and ss. ATCP 10.16 and 10.18, Wis. Adm. Code).

Accidents and Toxic Contamination

Accidents pose another important threat to the food supply. Emergency authorities train for major incidents, such as Chernobyl-type failures of nuclear power plants, which could devastate whole agricultural regions for decades. But more "mundane" accidents can also have major consequences – especially in highly centralized production and distribution systems.

An early example occurred in 1973, when a single Michigan warehouse accidentally substituted an industrial chemical (PBB) for an animal feed additive. The contaminant was mixed with feed, redistributed and consumed by animals throughout the state. There was widespread livestock illness and, ultimately, contamination of human food including meat, dairy products and eggs. The contaminant was eventually found in human tissue and in the milk of nursing human mothers who had consumed contaminated products.

As a result of the Michigan PBB incident, over 538 Michigan farms were quarantined, and over 23,000 cattle, 5,000 swine and sheep, 1.5 million chickens, 2,600 lbs. of butter, 34,000 lbs. of dry milk products, 1,500 cases of canned evaporated milk, 18,000 lbs. of cheese, 5 million eggs and 865 million tons of feed were destroyed.[266] Canada banned beef imports from Michigan for over 15 months, and there were questions related to long-term human health effects. Damage claims totaled many millions of dollars.

Following the Michigan PBB incident, DATCP led the nation in creating an emergency "toxic response" program to respond to unexplained animal deaths and toxic emergencies. A toxic response team coordinates rapid multi-disciplinary responses within DATCP, and with other agencies as necessary. Among other things, the team works to limit potential food contamination. DATCP handles a number of significant toxic response incidents every year (some caused by intentional criminal acts). But, to date, none of those events has risen to the level of a major statewide catastrophe.

Disaster Planning and Emergency Response

It is difficult for human beings to contemplate, much less plan for, truly catastrophic events. DATCP works with Wisconsin Emergency Management and others to coordinate emergency response plans. But plans can fall short in a variety of ways, as Hurricane Katrina showed.

For example, animal disease control plans may make unrealistic assumptions about voluntary compliance with disease control directives (especially when compliance may entail financial losses).[267] Plans may also underestimate the sheer time and effort required to diagnose, identify, trace, quarantine, test, condemn, destroy and safely dispose of large numbers of diseased and potentially diseased animals. Disease may spread from multiple locations at unexpected rates.

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[266] Statement by Sam D. Fine, FDA, before the Subcommittee on Conservation and Credit, Committee on Agriculture, U.S. House of Representatives, April 30, 1976.

[267] Under its chronic wasting disease control program, DATCP has been forced to litigate over 20 quarantine and condemnation orders challenged by farm-raised deer owners. Some owners continued to challenge condemnation orders even after multiple tests (in one case at least 20 tests!) confirmed CWD in their herds. DATCP ultimately prevailed in all of the cases, but litigation tied up staff resources and delayed the elimination of diseased herds.

Staff shortages may also limit, in a very fundamental way, government's ability to put knowledgeable disease control personnel "on the ground" in a disease emergency. In a foot-and-mouth outbreak, DATCP would be able to field only a small handful of trained veterinarians for the entire state. That lack of readily available resources could have grave consequences.[268] The United States Department of Agriculture would help, but USDA could also be overwhelmed if the disease spread quickly to several states (as it easily could).[269]

The challenge is to have adequate response capacity for large-scale emergencies, without having underutilized staff during "normal" times. DATCP has attempted to recruit and train private veterinarians (a volunteer "vet corps") to assist in emergencies. But under current arrangements, those veterinarians would have limited emergency authority. For example, they would not be authorized to do compulsory inspection or testing, or to issue quarantine or condemnation orders.[270]

Identifying Food Sources

Food comes from the earth, not just from a store. Disease organisms and adulterants introduced in the early stages of food production and processing can affect the safety of the final food product. In many cases, it is possible to retrace food shipments to the wholesale level but not the farm level.[271] Prompt identification of farm sources may be critical in a food safety emergency. In an animal disease emergency, such as a foot-and-mouth outbreak, identification of surrounding livestock premises may also be critical for disease control.

Livestock often move from farm to farm without any formal record of movement.[272] Animals from many different farms may be assembled, commingled and shipped in re-sized lots to multiple destinations.[273] In Wisconsin, thousands of animals move every day. If disease is found in live animals or meat, it may be difficult to track down the ultimate source. It may also be difficult to locate and contact other livestock premises that may be affected. That may cause a bad situation to get much worse.

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[268] An official inquiry into the 2001 foot-and-mouth epidemic in Britain concluded that faster information, faster deployment of critical skills, and faster action on the ground to slaughter infected and suspect animals, would have limited the scale of the disaster. See *http://archive.cabinetoffice.gov.uk/fmd/fmd_report/report/index.htm.*

[269] A U.S. emergency simulation suggested that within 4 days of a foot-and-mouth outbreak in a small Texas herd, the highly contagious virus would have spread through 15 Texas counties and Mexico and, within one week, to 27 states. The simulation showed the difficulty in detecting the disease quickly, tracking down exposed animals, and assembling veterinarians and others to contain the epidemic.

[270] A more ambitious "vet corps" program could keep trained veterinarians on retainer, for possible activation in an emergency. The veterinarians would be paid for their emergency service, and would be trained and authorized to exercise governmental powers in an emergency. However, a program of that sort would entail a considerably larger budget, and considerably more training, planning, contract negotiation and insurance coverage.

[271] Milk and dairy products are an exception. DATCP rules require dairy plants to keep individual records of milk shipments from farms. *See* chs. ATCP 60 and 80, Wis. Adm. Code.

[272] Documentation is required for *interstate* livestock movement and for *some* interstate movement (see ch. ATCP 10, Wis. Adm. Code).

[273] Animal markets, dealers and truckers are required to keep records (see chs. ATCP 10 and 12, Wis. Adm. Code), but those records may not ensure swift and accurate animal traceback in all cases.

Wisconsin led the nation in creating a mandatory livestock premises registration program to locate all livestock premises in the state.[274] Nearly 60,000 Wisconsin livestock premises have been registered to date (about 1/6 of all premises registered *nationwide*).[275] Among other things, Wisconsin has now identified and located nearly 13,000 poultry premises in the state. The poultry information could be critical in an avian influenza outbreak, which in its most pathogenic form could pose a mortal threat to humans as well as birds.

Although premises registration is mandatory, Wisconsin has relied mainly on voluntary compliance by livestock operators. Most operators have complied, but a significant number have not (some cite religious or philosophical reasons). Lack of registration could delay emergency response efforts, to the detriment of other livestock producers and the general public.

Premises registration provides a foundation for voluntary identification and tracking of individual animals. There is no law *requiring* identification of individual animals, except in certain situations.[276] But livestock and meat buyers, both here and abroad, are demanding better documentation and trace-back capacity for disease control, food safety and marketing reasons. Sellers who cannot provide the necessary documentation may be excluded from key markets. On the other hand, the United States continues to expand imports of meat and animal products from countries that have little, if any, on-farm tracking of livestock.

The Animal Food Chain

Wisconsin has a large rendering and animal food processing industry. The industry collects and processes animal carcasses and by-products, and produces useful non-food products such as grease, tallow, blood meal, bone meal and animal feed. This is an important waste recycling function, alleviating what would otherwise be a major waste disposal challenge.

Wisconsin licenses and regulates rendering plants, animal food processors, carcass collectors and grease processors,[277] as well as commercial feed manufacturers.[278] These closely-related programs protect human and animal health, and provide an important backup for the meat inspection program.[279] Regulation prevents the sale of inedible by-products as human food. It also prevents animal feed adulteration that could harm animals and, ultimately, humans.

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[274] See s. 95.51, Wis. Stats., and ch. ATCP 17, Wis. Adm. Code. Wisconsin is one of few states with mandatory livestock premises registration. The U.S. Department of Agriculture has retreated from its initial proposal to mandate a nationwide system of premises registration and animal identification. Federal funding cuts could also affect Wisconsin's existing premises registration program.

[275] See *http://animalid.aphis.usda.gov/nais/premises_id/update.shtml)*. Livestock premises registration information is confidential. But DATCP may use and share the information when necessary to protect public health, safety or welfare.

[276] See ch. ATCP 10, Wis. Adm. Code. Identification is often required for animals imported to Wisconsin, and for animals handled by livestock markets, dealers and truckers. In some limited cases, it may also be required for animals moved within the state.

[277] See s. 95.72, Wis. Stats., and ch. ATCP 57, Wis. Adm. Code. Wisconsin also regulates animal markets, animal dealers and animal truckers to control the movement and disposition of diseased animals. See ss. 95.68, 95.69 and 95.71, Wis. Stats., and chs. ATCP 10 and 12, Wis. Adm. Code.

[278] See s. 94.72, Wis. Stats., and ch. ATCP 42, Wis. Adm. Code.

[279] DATCP recently updated its rules for rendering and animal food processing plants (ATCP 57). The new rules are scheduled to take effect on December 1, 2008.

"Mad cow disease" (BSE) has forcefully revealed the connection between animal feed and human health. Wisconsin enforces federal BSE regulations that restrict the use of animal carcass materials in feed intended for related species.[280] Wisconsin has also conducted more BSE surveillance tests than any other state.[281] As of January 1, 2007, Wisconsin had tested well over 100,000 cattle without any disease findings (about 20% of all cattle tested *nationwide*, and more than the total number tested in all of Canada).

New FDA rules, scheduled to take effect in April 2009, will tighten current animal feed regulations.[282] The new rules will ban certain cattle materials from *all* animal feed and pet food, not just ruminant feed. DATCP will enforce the new federal regulations on behalf of FDA when they take effect.

Food and Consumer Choice

We food consumers have many options. Companies, industries and regional economies may rise and fall based on the choices we make. Our choices depend on many factors including price, taste, convenience, "image," habit, brand identification, and perceived safety and nutritional value. Our perceptions are not always accurate, and our choices are not always purely rational. Our eating habits can be shaped in many ways, often while we are still children.

Food marketers understand this. The food and beverage industry is the second leading advertiser in the U.S. economy, next to the auto industry.[283] Food ads are the top category of television ads seen by children.[284] Most food advertising is devoted to highly processed food, snacks, soft drinks and alcoholic beverages.[285] Advertising often promotes processed foods and beverages that have higher fat and sugar content than traditional foods.[286] According to Consumer Reports, some breakfast cereals marketed to U.S. children are more than half sugar by weight.[287]

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[280] DATCP enforces federal feed restrictions under contract with FDA. New FDA regulations, issued in April 2008 and scheduled to take effect in April 2009, ban certain cattle materials from *all* animal feed (not just cattle or ruminant feed).

[281] BSE surveillance tests were conducted at meat establishments, rendering plants and animal food processing plants. DATCP supervised surveillance testing, in cooperation with USDA.

[282] FDA Docket No. 2002N-0273, Federal Register: April 25, 2008 (Volume 73, Number 81). The new rules amend current FDA rules under 21 CFR 589.

[283] Gallo, "Food Advertising in the United States," chapter 9 of *America's Eating Habits; Changes and Consequences*, United States Department of Agriculture, Economic Research Service, Agriculture Information Bulletin No. (AIB750), May 1999, at p. 174. Available at *http://www.ers.usda.gov/publications/aib750/.*

[284] Kaiser Foundation, "Food for Thought: Television Advertising to Children in the United States," (March 2007), available at *http://www.kff.org/entmedia/7618.cfm*. Advertisers also use "advergames" and other internet marketing techniques to reach children. See Kaiser Foundation, "It's Child's Play: Advergaming and the Online Marketing of Food to Children" (July, 2006), available at *http://www.kff.org/entmedia/7537.cfm.*

[285] Gallo, at p. 177.

[286] Much of the sugar in the American diet comes from soft drinks. In 1945, Americans drank 4 times more milk than soft drinks. By 1997, Americans drank 2.5 times more soft drinks than milk. Gallo, at p. 142 (Figure 4).

[287] "Consumer Reports: Some Cereals Marketed to Children are More than 50 Percent Sugar," Wall Street Journal, Market Watch, October 1, 2008.

Perhaps not surprisingly, we face a rising epidemic of obesity and related conditions such as diabetes, high blood pressure and heart disease. Medical authorities tell us that we consume too much sugar, too much fat, too much highly processed food, and just plain *too much* food for our sedentary lifestyles. The U.S. Surgeon General has identified overweight and obesity as the fastest growing cause of disease and death in America. Our food may be "safe" in the traditional sense, yet our consumption may be systematically undermining our long term health.

In 1981, the Federal Trade Commission abandoned efforts to regulate advertising of high-sugar foods to children.[288] But today's public health crisis has prompted renewed concern over food advertising practices, including advertising aimed at children.[289] In response to that concern, cereal maker Kellogg recently announced that it would reduce the sugar content of children's cereal and curtail advertising of high-sugar cereal to children.[290]

Although the food industry shapes consumer choices, consumers also shape the food industry. What we choose to eat affects *what* is produced, *where* it is produced, and *how* it is produced. Sometimes we react spasmodically, in response to food scares or diet fads that can make or break entire food industries almost overnight. But in other cases, our choices may be more deliberate.

Consumers, and particularly affluent consumers for whom price is less critical, can "cast their votes" in support of foods, production methods or causes that they favor. For example, some consumers may be willing to pay a premium for foods that are locally produced, environmentally-friendly, humane to animals, produced under fair labor standards, or produced by traditional artisan methods.

The growing market for "organic" foods is just one example. "Organic" sales grew by about 20% per year from 1990 to 2000.[291] "Organic" marketing has gone mainstream, as major food manufacturers and retailers have recognized its profit potential. Today, "organic" food is often produced, processed and marketed on an industrial scale. About half of the $7.8 billion spent on "organic" food in 2000 was purchased in conventional retail outlets.[292]

What does "organic" mean, and what *should* it mean? USDA has published extensive rules defining "organic" food production practices, and regulating use of "organic" labels.[293] Those rules are the subject of continuing controversy. On one hand, overly strict rules might unduly limit the use of "organic" food labels. On the other hand, watered-down rules might lead to abuse of the "organic" label and make the label meaningless or misleading.

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[288] Federal Trade Commission. Children's advertising: termination of rulemaking proceeding. Federal Register 1981; 46:48710-48714.

[289] See, for example, "Perspectives on Marketing, Self-Regulation and Childhood Obesity: A Report on a Joint Workshop of the Federal Trade Commission and the Department of Health and Human Services" (April 2006), available at *www.ftc.gov/os/2006/05/PerspectivesOnMarketingSelf-Regulation&ChildhoodObesityFTCandHHSReportonJointWorkshop.pdf.*

[290] New York Times, June 14, 2007.

[291] Dimitri and Green, "Recent Growth Patterns in the U.S. Organic Foods Market," United States Department of Agriculture, Economic Research Service, Agriculture Information Bulletin No. (AIB777), September 2002, at p. 2. Available at *http://www.ers.usda.gov/publications/aib777/.*

[292] Ibid., at p. 2.

[293] 7 CFR 205.

Wisconsin is a national leader in organic food production.[294] Wisconsin has more organic dairy and livestock operations than any other state, and ranks second in total number of organic farms. The number of Wisconsin organic farms has grown by more than 90% in the last 5 years, while the number of organic processors and distributors has grown by 31%.

Wisconsin is also playing a role in the emerging "local foods" movement. More consumers are looking for fresh, locally-produced food – at the grocery store, in restaurants, at farmers markets, and in direct farm-to-consumer transactions. "Local food" sales currently represent a fairly small share of overall food sales, and there are constraints related to seasonality, cost, range of choice, and available distribution networks. But "local food" purchases can keep dollars in the community, strengthen community ties, increase consumer understanding of food production, and provide a "win-win" solution for consumers and local food producers.

Genetic Engineering

Genetic engineering (recombinant DNA technology) has already changed food production methods, and is increasingly changing the food we eat. The Grocery Manufacturers of America estimate that 70 to 75% of all processed foods available in U.S. grocery stores may already contain ingredients from genetically engineered plants.[295]

Breads, cereal, frozen pizzas, hot dogs and soda are just a few of the processed foods affected. Major U.S. food crops, such as corn and soybeans, are now produced in large part from genetically engineered plant varieties. Corn and soybeans are used to produce a wide array of processed foods.

Genetic engineering has been used to change the agronomic characteristics of food plants (for example, to improve pest resistance or increase pesticide compatibility). But it is also being used to alter the traits of food products themselves.[296] Scientific advances are expected to accelerate over the next decade, leading to the development and commercialization of a greater number and variety of genetically engineered crops, livestock and food products.[297]

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[294] "Wisconsin Organic Agriculture Facts," DATCP publication (July 2007).

[295] See "Genetic Engineering: The Future of Foods?" *FDA Consumer Magazine* (November-December, 2003). Available at *http://www.fda.gov/fdac/features/2003/603_food.html.*

[296] See Notice of Proposed FDA Rule Related to Premarket Notice of Generically Engineered Foods, Federal Register: January 18, 2001 (Volume 66, Number 12). Available at *http://www.cfsan.fda.gov/~lrd/fr010118.html.*

[297] "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (Guidance for Industry)," FDA Center for Food Safety and Applied Nutrition, June 2006. Available at *http://www.cfsan.fda.gov/~dms/bioprgu2.html*.

Official reviews have found no significant food safety problems related to genetically engineered foods marketed to date (they emphasize that genetic engineering is like traditional plant or animal breeding, except that it is more specifically targeted).[298] However, genetic engineering in food production remains controversial, and the controversy is not limited to food safety. A classic controversy involved the use of synthetic bovine growth hormone ("rBST") in milk production. For several years, this was a major public issue in Wisconsin and in other states.

The rBST Controversy

Monsanto began to develop rBST in the 1980's, as a way to increase milk production per cow. Monsanto produced rBST with recombinant DNA technology, which was then still relatively new. In 1993, FDA approved rBST as a new animal drug for injection into dairy cows. FDA determined that rBST was safe for use in milk production, and had no human health impact.

However, rBST opponents argued that there were potential health risks, and that consumers in any case had a "right to know" how their milk was produced. They argued that large "factory" farms would benefit from rBST to the economic detriment of traditional "family" farms, and that rBST injections were harmful or inhumane to dairy cows. They called for mandatory rBST labeling of milk and dairy products, so that consumers could exercise "freedom of choice."

Others opposed mandatory labeling, saying that it would create an unfair impression of health risks and would discourage legitimate use of an effective product. Some went further to say that "rBST-free" claims were inherently deceptive, and should be banned. They noted that bovine growth hormone occurs naturally in milk, that no analytical test can distinguish between the natural and synthetic hormone, and that no test can prove whether rBST has been used in milk production.

The Legislature did not require mandatory labeling,[299] but allowed certain "rBST-free" claims that were substantiated according to DATCP rules.[300] Sellers must substantiate "rBST-free" claims with farmer affidavits and must disclose, in connection with each claim, that no significant difference has been shown between milk produced with or without the use of rBST.

Until recently, only a few dairy processors were making "rBST-free" claims on their product labels. But major U.S. food retailers, including Wal-Mart and Kroger, are showing new interest in "rBST-free" labeling. Their marketing strategies could have a substantial impact on dairy processors and farmers.

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[298] "Genetic Engineering: The Future of Foods?" *FDA Consumer Magazine* (November-December, 2003). Available at *http://www.fda.gov/fdac/features/2003/603_food.html.*

[299] In 1996, the U.S. Second Circuit Court of Appeals struck down Vermont's mandatory rBST labeling law. The Court held that there was an insufficient state interest to justify a mandatory labeling requirement, given the lack of evidence that rBST caused health problems. *International Dairy Foods Association et al. v. Amestoy and Graves, 92 F. 3d 67 (1996).*

[300] See s. 97.25, Wis. Stats., and ch. ATCP 83, Wis. Adm. Code.

Regulation of Genetically Engineered Food

The rBST case is one example of a more general debate related to genetically engineered foods, food production methods, and "consumer right to know." On a global level, for example, some countries have imposed trade embargoes and mandatory labeling requirements on foods and food commodities produced by recombinant DNA technology. Some restrictions are related to global trade negotiations and protection of domestic industries, but they are typically characterized as consumer protection regulations.

In the U.S., genetically engineered foods do not necessarily require government pre-approval (pre-approval *may* be required in certain cases, depending on the nature of the genetic modification or product use).[301] Manufacturers are responsible for ensuring that genetically engineered food products are safe,[302] and FDA may take action against unsafe products. An important FDA concern relates to the possible introduction of allergens.[303]

FDA has published safety guidelines for genetic engineering of food plants, but has not adopted the guidelines as rules.[304] The FDA guidelines are part of a broader federal framework for the review of new genetically-engineered organisms.[305]

FDA encourages, but does not require, manufacturers to notify and consult with FDA before marketing foods from genetically engineered plants.[306] To the best of FDA's knowledge, manufacturers have consulted with FDA on all genetically engineered foods marketed to date.[307] But a much larger number of genetically engineered foods will be marketed in the future.[308]

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[301] For example, new animal drugs and pesticides require government pre-approval. See Notice of Proposed FDA Rule Related to Premarket Notice of Generically Engineered Foods, Federal Register: January 18, 2001 (Volume 66, Number 12). Available at *http://www.cfsan.fda.gov/~lrd/fr010118.html*.

[302] See "Genetic Engineering: The Future of Foods?" *FDA Consumer Magazine* (November-December, 2003). Available at *http://www.fda.gov/fdac/features/2003/603_food.html.*

[303] See "Bioengineered Foods: Will They Cause Allergic Reactions?" *Food Allergy News* (October-November 1997). Available at *http://www.cfsan.fda.gov/~dms/pubalrgy.html.*

[304] FDA Statement of Policy: Foods Derived from New Plant Varieties (57 FR 22984, May 29, 1992). The Codex Alimentarius Commission has adopted international guidelines that are consistent with the FDA guidelines. See "Genetic Engineering: The Future of Foods?" *FDA Consumer Magazine* (November-December, 2003). Available at *http://www.fda.gov/fdac/features/2003/603_food.html.*

[305] See Coordinated Framework for the Regulation of Biotechnology Products (51 FR 23302, June 26, 1986).

[306] "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (Guidance for Industry)," FDA Center for Food Safety and Applied Nutrition (June 2006*)*, available at *http://www.cfsan.fda.gov/~dms/bioprgu2.html*. FDA proposed pre-market notification *rules* in 2001, but never adopted the proposed rules. *See* Notice of Proposed FDA Rule Related to Premarket Notice of Generically Engineered Foods, Federal Register: January 18, 2001 (Volume 66, Number 12). Available at *http://www.cfsan.fda.gov/~lrd/fr010118.html.*

[307] See "Genetic Engineering: The Future of Foods?" *FDA Consumer Magazine* (November-December, 2003). Available at *http://www.fda.gov/fdac/features/2003/603_food.html.*

[308]Notice of Proposed FDA Rule Related to Premarket Notice of Generically Engineered Foods, Federal Register: January 18, 2001 (Volume 66, Number 12). Available at *http://www.cfsan.fda.gov/~lrd/fr010118.html.*

Genetic engineering can also be used to introduce transgenic traits into food animals. Most transgenic modifications are treated as "new animal drugs" that require pre-market approval by FDA (the "drug" is merely introduced by genetic alteration, rather than by traditional methods such as injection).[309] Once a transgenic trait has been introduced into individual animals, a population of transgenic animals can be produced by breeding or, in some cases, by cloning the transgenic animals.

FDA recently evaluated the safety of meat and milk produced from cloned animals. FDA asked companies to refrain from introducing cloned animals or their products into the food chain until the evaluation was completed (the companies complied, according to FDA).[310] On January 15, 2008, FDA issued a final risk assessment finding that meat and milk from clones of adult cattle, pigs and goats, and their offspring, are as safe to eat as food from conventionally bred animals.[311] That action effectively removed the last U.S. regulatory barrier to the marketing of meat and milk from cloned cattle, pigs and goats.

Mandatory labeling of genetically engineered food is not ordinarily required in the U.S. unless the genetically engineered food differs in significant ways from its conventional counterpart (for example, if the genetic modification reduces nutritional value or introduces a known allergen).[312] However, sellers may voluntarily represent that their products are produced with *or without* recombinant DNA technology if the representations are true.[313] Sellers must be able to substantiate the representations.

Genetic engineering presents new issues related to "property rights" in seed, plants, animals and food varieties. It may also present new environmental, social and market issues. Even if these are not "food safety" issues as such, they may have considerable bearing on public perception and policy related to the production and sale of genetically engineered food.

Because of the scope and technical complexity of genetic engineering issues, regulation is largely concentrated at the federal level.[314] State governments generally play a subordinate role. But as the rBST issue showed, states may be drawn into the public policy debate.

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[309] "A New Kind of Fish Story: The Coming of Biotech Animals," *FDA Consumer Magazine* (January-February 2001). Available at *http://www.cfsan.fda.gov/~dms/fdbiofsh.html.*

[310] "Cloning: Revolution or Evolution in Animal Production," FDA Consumer Magazine (May-June, 2003). Available at *http://www.fda.gov/fdac/features/2003/303_clone.html.*

[311] See FDA documents at *http://www.fda.gov/cvm/cloning.htm.*

[312] See "Genetic Engineering: The Future of Foods?" *FDA Consumer Magazine* (November-December, 2003). Available at *http://www.fda.gov/fdac/features/2003/603_food.html.*

[313] See "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering," FDA Center for Food Safety and Applied Nutrition (January 17, 2001).
Available at *http://www.cfsan.fda.gov/~dms/biolabgu.html.*

[314] However, see s. 146.60, Wis. Stats.

Animal Welfare

Humane Treatment of Animals

Animal welfare is a growing issue in food production. Recently, dramatic video footage showing inhumane treatment of "downer" (non-ambulatory) cattle in a California meat plant prompted the largest meat recall in the nation's history.[315] The incident resonated with consumers nationwide, and raised food safety as well as animal welfare concerns. USDA ordered the recall of 143 million pounds of beef produced by Weston/Hallmark Meat Co., and promised to tighten surveillance nationwide.

Federal regulations currently prohibit the slaughter (for food) of animals that are "down" when presented for *ante mortem* inspection. Up to now, those regulations have allowed the slaughter of animals that go "down" *after* inspection because of an acute injury (*not* because of a disease), provided that a USDA inspecting veterinarian determines that the animal is safe for food use.[316] However, USDA is currently proposing tougher rules that will flatly prohibit the slaughter of "downer" animals for food, regardless of when or why the animals go "down."[317] When USDA adopts the new rules, DATCP will also implement those rules under Wisconsin's meat inspection program.

Wisconsin law prohibits cruelty to animals.[318] Animals must be transported in a humane manner[319] and must be slaughtered by humane methods.[320] Persons receiving, transporting or holding animals for slaughter must do so in a humane manner.[321] Animal markets, dealers and truckers must handle animals in a humane manner, and must have adequate facilities and equipment to do so.[322]

Animal custodians must provide animals with sufficient food, water, shelter and waste removal to maintain animal health and minimize health hazards.[323] But in the case of farm animals, the law does not impose shelter requirements or standards "more stringent than normally accepted husbandry practices in the particular county where the animal or shelter is located."[324]

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[315] "USDA Orders Largest Meat Recall in Nation's History," Washington Post, February 18, 2008.

[316] 9 CFR 309. "Downer" animals must be handled in a humane manner, regardless of whether they are slaughtered for food.

[317] Federal Register, Vol. 73, No. 169 (August 29, 2008).

[318] See s. 951.02, Wis. Stats.

[319] See s. 951.05, Wis. Stats.

[320] See s. 95.80, Wis. Stats., and s. ATCP 55.07(11), Wis. Adm. Code. Wisconsin regulations also parallel federal regulations related to the slaughter of "downer" animals for food (Wisconsin regulations must be at least "equal to" federal regulations). See, generally, ch. ATCP 55, Wis. Adm. Code.

[321] See s. ATCP 55.07(11), Wis. Adm. Code.

[322] See ch. ATCP 12, Wis. Adm. Code.

[323] See ss. 951.13 and 951.14, Wis. Stats.

[324] See s. 951.14(intro.), Wis. Stats.

Animal cruelty laws are found in ch. 951, Wis. Stats., which is part of the general criminal code. District attorneys and local law enforcement agencies are generally responsible for enforcing criminal code provisions, with possible assistance from certified local humane officers.[325]

DATCP is not directly responsible for enforcing the criminal code. However, DATCP trains and certifies local humane officers, and provides veterinarian consultation to local humane officers as needed.[326] DATCP also administers humane treatment standards related to slaughter establishments, animal markets, animal dealers, animal truckers, and rendering establishments.[327]

Emerging Animal Welfare Issues

Beyond traditionally defined "animal cruelty," there is a larger national and international debate related to acceptable animal husbandry practices in food production. For example, there is considerable debate over animal confinement practices in highly industrialized livestock and poultry operations, and a related debate over routine antibiotic feeding to maintain the health of closely confined animals. Some of these issues have human health dimensions, such as antibiotic resistance and the concentration of pathogens transmissible to humans.[328]

For better or worse, major food processors and retailers exercise powerful influence over animal welfare practices in food production. Extreme animal confinement practices may give some suppliers a production cost advantage. But animal welfare has become an important issue for many consumers, and food businesses that care about their image will need to pay attention.

For example, the Quick Service Restaurant Industry (at the initiative of McDonald's) has now set animal handling standards for its meat suppliers, and is auditing the suppliers' animal handling practices. In January 2007, Smithfield Foods (the world's largest pork production contractor) announced a 10-year phase-out of "gestation crates" that narrowly confine pregnant females so that they cannot turn around. In September 2006, Ben and Jerry's Ice Cream announced that it would phase out its use of eggs from hens raised under intense confinement in "battery cages." And in July 2007, the Wendy's fast-food chain announced that it would give preference to pork and chicken suppliers that meet certain humane standards.

These examples suggest that major food companies have considerable direct or indirect control over livestock production practices, and that they are becoming increasingly sensitive to their animal welfare image. Emerging animal welfare standards may affect the shape of the livestock industry itself, reducing the competitive advantage that might otherwise accrue to highly mechanized livestock operations using extreme confinement practices.

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[325] See ch. 173, Wis. Stats. Certified humane officers may conduct investigations, issue abatement orders, take custody of animals, and manage the disposition of animals as provided in ch. 173, Wis. Stats. Local governments may appoint certified humane officers, but are not required to do so.

[326] See ss. 93.07(11) and 173.27, Wis. Stats., and ch. ATCP 15, Wis. Adm. Code.

[327] See chs. ATCP 12, 55 and 57, Wis. Adm. Code.

[328] See, for example, United Nations Food and Agriculture Organization, "Industrial Livestock Production and Global Health Risks" (September 17, 2007). See also the Pew Commission on Industrial Farm Animal Production, "Putting Meat on the Table: Industrial Farm Animal Production in America" (April 29, 2008).

Health Claims

Substantiating Health Claims

Food is, by its very nature, a source of life, health and nutrition. But some sellers make specific health claims for foods and dietary supplements, and in some cases those claims may be false or deceptive. The number and variety of health claims has grown dramatically in recent years.

State and federal law prohibit deceptive advertising and labeling claims (direct or implied), including deceptive health claims.[329] Sellers must have substantiation for health claims before they make the claims (after-the-fact justification does not suffice). The nature and extent of substantiation may depend on a variety of factors, but the substantiation must be scientific (it may not consist solely of personal endorsements, for example). The substantiation must support the claims that are made.

Dietary Supplements

FDA regulates dietary supplements (such as vitamins, herb supplements, etc.) under a different set of regulations than those covering drugs and "conventional" foods.[330] Before marketing a dietary supplement, a manufacturer must ensure that the supplement is safe. But the manufacturer does not ordinarily have to notify FDA or get FDA pre-approval unless the supplement includes "new dietary ingredients."

Dietary supplements must be labeled as "supplements" and must bear descriptive product names. A product label must include the name and address of the manufacturer, a complete list of ingredients, and the product net contents. Labeling must be truthful, and must disclose significant safety risks.

New FDA rules establish "good manufacturing practice" standards for dietary supplements, to ensure consistent product content.[331] Beginning in 2008, manufacturers must also report serious adverse health events to FDA.

Disease Prevention Claims

A label may not claim that a food or dietary supplement reduces the risk of a specific disease or health condition unless one of the following applies:[332]

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[329] For a discussion of federal law, see Federal Trade Commission Policy Statement on Food Advertising, *http://www.ftc.gov/bcp/policystmt/ad-food.htm*. See also Peeler and Cohn, "The Federal Trade Commission's Regulation of Advertising Claims for Dietary Supplements," *Food and Drug Law Journal (Vol. 50, 1995).*

[330] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

[331] See FDA news release, dated June 22, 2007, at http://www.fda.gov/bbs/topics/NEWS/2007/NEW01657.html

[332] See FDA guidance at *http://www.cfsan.fda.gov/~dms/hclaims.html* and *http://www.cfsan.fda.gov/~dms/hclmgui3.html*.

- FDA specifically authorizes the claim.[333] FDA may authorize a claim if there is "significant scientific agreement" supporting the claim.

- The claim is based on an authoritative statement of the National Academy of Sciences or a U.S. government scientific body, and the labeler gives FDA prior notice of the claim.[334]

- The claim is a "qualified health claim" and the labeler gives FDA prior notice of the claim. The claim must be adequately qualified to disclose that the scientific evidence supporting the claim does not meet the usual standard of "significant scientific agreement."

Third-Party Claims

Food consumers rely on food product labels and advertising. But they also rely on information from other sources, including published research, news reports, diet advocates and personal acquaintances. The internet has become an important vehicle for food-related communications of all sorts. Some of the information is reliable, and some is not.

Third-party research and communications are forms of "free speech" that are generally outside the realm of food regulation. But if third-party research or communications are used or orchestrated as part of a deceptive advertising or promotional scheme by a food seller, they are subject to regulation under state and federal law. Partly because of the internet, this has become a significant new issue in sales promotion and food regulation.

Information Sharing and Security

Shared information is important for food safety. By working together and sharing information, government and business can do a better job of preventing and responding to food safety problems.[335] Information can also warn consumers of food safety threats, and create powerful compliance incentives for business. Information technology makes it possible to analyze, portray and publish information in powerful new ways.

But information sharing has its limits and its risks. Businesses worry about disclosing proprietary information, and individuals worry about personal privacy. Businesses may be reluctant to share information if they fear that it will be disclosed to competitors or the general public.[336] Unfair or inaccurate publicity may also cause great harm to legitimate businesses. Public information must be timely and informative, but it must also be fair and accurate.

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[333] A labeler may petition FDA for authorization, pursuant to the Nutrition Labeling and Education Act of 1990, P.L. 101-535 (1990).

[334] See the Food and Drug Administration Modernization Act of 1997, P.L. 105-115 (Nov. 21, 1997).

[335] For example, DATCP participates in an agroterrorism evaluation program (Strategic Partnership Program Agroterrorism Initiative) with participating companies and other government agencies including the U.S. Department of Homeland Security, USDA, FDA and the FBI.

[336] DATCP can, if necessary, compel the production of relevant information (see, for example, ss. 93.14-93.16, Stats.). But effective information sharing depends, to a considerable degree, on voluntary cooperation.

Open Records Law

Information in DATCP's possession may be open to public inspection, even if DATCP does not affirmatively publish that information. Information collected or prepared by a state agency is generally open to public inspection unless the information is specifically protected by law or unless the *public* interest in nondisclosure clearly outweighs the presumptive public interest in disclosure.[337] Information technology has expanded the potential scope of "open records" requests. Confidential information is sometimes connected to non-confidential information, complicating "open records" compliance.

Protected Information

Some information is specifically protected from disclosure by law. For example, DATCP is generally required to protect social security numbers, food processor financial statements, dairy plant producer lists, milk producer quality test data, Johne's disease test information, livestock premises registration information (other than premises ID numbers), and agricultural statistical data obtained from individual survey respondents.

DATCP must also protect bona fide "trade secrets,"[338] and may protect other business information where appropriate under the Open Records Law "balancing test."[339] But a business *claim* of confidentiality does not automatically qualify business information as a "trade secret" or exempt it from disclosure.[340]

In some cases, even if DATCP believes that information is confidential, a court may come to a different conclusion and order DATCP to release the information. Certain information may also be shared with cooperating agencies, even though it is protected from disclosure to the general public.[341]

Information Security

Information security is a growing challenge in an electronic age. In former times, a locked file drawer might suffice. But now, agencies must be concerned with "firewalls" and electronic access from anywhere in the world. Large volumes of information can be searched and transferred at the speed of light. Security systems do not always keep pace with security threats. Government "outsourcing" of information management may aggravate some security risks.

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[337] See Wisconsin Open Records Law, subch. II of ch. 19, Wis. Stats.

[338] See s. 134.90, Wis. Stats.

[339] For example, DATCP has denied public requests to inspect detailed blueprints of dairy and food processing facilities (partly for security reasons). DATCP concluded, under the Open Records Law, that the public interest in nondisclosure outweighed the presumptive public interest in disclosure.

[340] If a business reasonably claims that records are confidential, but DATCP concludes that disclosure is required under Wisconsin's Open Records Law, DATCP will typically notify the business before releasing the records. The business may seek a court order enjoining the proposed release, if it believes it has legal grounds to do so.

[341] Wisconsin Attorney General's opinion to DATCP (informal written opinion), April 28, 1986.

Walking the Tightrope

In the years to come, there is likely to be growing tension between the competing demands of information sharing and information security – between privacy protection and the "public right to know." That tension will be felt in the food safety realm, as in other realms.

Changing Food Technology

Technology Changes Regulation

Food technology is changing food regulation. Traditional food regulation was based on prescriptive sanitation standards and visual inspection. But traditional methods may not be adequate to deal with complex and rapidly changing technological systems. In some cases, traditional methods may add costs and constraints that do not enhance food safety. Rigid design standards may limit food safety innovations and efficiency.

Food regulation is increasingly shifting toward a HACCP-type approach, which gives food businesses more flexibility and responsibility to implement specially tailored food safety systems, subject to certain basic performance criteria.[342] Businesses must analyze key hazards, identify critical control points, create and document systems to prevent food safety risks, and monitor and record the effectiveness of those systems. Businesses are increasingly responsible for conducting their own food safety testing, and for taking effective action to monitor and control food quality.

DATCP's role is shifting accordingly. DATCP may be less engaged in routine visual inspections and more engaged in auditing food safety systems (which may require a higher level of expertise). DATCP may be less engaged in direct testing, and more engaged in review of industry testing. Standards may be more performance-based and less narrowly prescriptive. Improved analytical testing protocols may provide more objective data related to food safety. In some situations, remote sensing technology may supplement or replace traditional regulatory information-gathering.

Limits to Change

All of this has its limits, however. For example, small food businesses may find it hard to implement HACCP-based systems, and may need more standardized regulation. Analytical testing may not always be adequate to detect real food safety threats. In some cases, rigid federal standards may limit flexibility. And in some cases, "one-size-fits-all" regulation may simply be more effective and efficient. But one way or another, the regulatory system must adapt to fast-moving changes in food industry technology and practices.

[342] The HACCP ("hazard analysis-critical control point") approach is mandated under federal and state meat inspection programs. State law incorporates federal HACCP requirements by reference (see s. 97.42(4m), Wis. Stats.).

Dairy Regulatory Reform

Competitive Pressure

Wisconsin has just over 12,000 Grade A dairy farms and just over 2,000 Grade B farms. The number of dairy farms has declined, as farms have grown in size and productivity. Today, Wisconsin's 14,000 dairy farms produce about as much milk as the 140,000 dairy farms that existed in the state in 1950.

Wisconsin still has far more dairy farms than any other state. For example, California (now the nation's highest producing dairy state) has just over 2,000 dairy farms. California dairy farms are, on average, much larger and more industrialized than Wisconsin farms (the average California herd has 908 cows, compared to 85 cows in Wisconsin). California milk production has increased faster than Wisconsin milk production, and California farms have a lower average cost of production, but California cows are by no means "happier" than Wisconsin cows.

Wisconsin dairy processors face strong competitive pressure from California and other states, especially in the critical national cheese market (85-90% of Wisconsin milk is used for cheese). The overall national cheese market is growing, but Wisconsin has been losing market share for decades. Milk procurement costs are a major factor.

Compared to California processors, Wisconsin processors pay a consistently higher average milk price to dairy farmers.[343] That is good for Wisconsin farmers (at least in the short run), but it puts Wisconsin processors at a competitive disadvantage. A continued decline in market share could have serious long-term economic ramifications for the Wisconsin dairy industry -- including milk producers as well as processors.

Inspection Costs

Dairy *inspection* costs may also affect Wisconsin's competitive position, but to a much smaller degree. The Interstate Pasteurized Milk Ordinance ("PMO") generally requires twice-a-year inspections of Grade A dairy farms, even when routine testing indicates that those farms are producing high quality milk.

The PMO mandate is more costly for Wisconsin than for other states, because Wisconsin has many more dairy farms. The PMO mandate also limits DATCP's flexibility to allocate resources based on risk. DATCP is forced to use 30% of its food safety inspection staff for grade A dairy farm inspections, even though other facilities typically pose higher food safety risks.

[343] For example, in April 2007 Wisconsin farmers received an average milk price of $17.20 per hundredweight while California farmers received an average of $15.20 per hundredweight (see Wisconsin Agricultural Statistics Service *Agricultural Highlights* Bulletin for May 2007). That represents a procurement cost difference of more than 10%.

Wisconsin dairy processors pay license fees to cover about 60% of dairy farm inspection costs (state inspection helps ensure the quality of the processor' milk supply). That is an added cost for dairy processors, but it represents only a tiny share of their *overall* costs. The industry-wide inspection fee total is less than *one one-thousandth* of the amount that Wisconsin processors pay for milk.[344] If Wisconsin processors paid the same milk price as California processors, they would save more than 100 times the amount of their current inspection fee burden.

Performance-Based Inspection

Although the PMO generally requires twice-a-year inspections of Grade A dairy farms, it gives states some latitude to adjust inspection intervals based on farm performance. Wisconsin has implemented a performance-based system, within limits specified by the PMO (Wisconsin is one of few states to do so). Most Wisconsin Grade A farms are inspected twice a year, but inspection intervals may range from once-a-year to 4-times-a-year based on performance.[345]

A performance-based inspection system makes sense, but the current system is constrained within narrow limits specified by the PMO. Less frequent inspection of some farms is offset by more frequent inspection of others, and inspection logistics are more complicated and costly. So there has been no net reduction in inspection costs.

DATCP is working with the University of Wisconsin to evaluate other possible approaches to performance-based inspection that could generate real savings. But changes to the current inspection program, if any, will require nationwide changes in the PMO. Wisconsin cannot make unilateral changes that violate the PMO.

A Changed Industry

At the state level, law changes may also be needed to keep pace with changing dairy industry organization. The current regulatory framework is still based, in some ways, on the historical model of the local processing plant that collects milk from nearby farmers ("patrons") who supply milk to the same plant for years. The processing plant pays farm license fees, tests farm milk shipments, and reports farm milk test results for its farm "patrons."

The current reality is more complex: milk "handlers" often collect farm milk over a wide area, and transport that milk over large distances to many different processors. Some farmers haul their own milk (often to more than one processor), while others process their own milk on the farm. Farmers often ship milk to processors in other states, and vice versa. Farm milk is marketed and processed under many different contract and ownership arrangements. These changes complicate licensing, sampling, testing and reporting responsibilities. Law changes may be needed to keep pace with a changing industry.

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[344] In 2005, processors paid approximately $3.5 *billion* for milk produced on Wisconsin farms. In FY 2005-06, Wisconsin processors paid about $2.5 million in license and milk procurement fees (mostly to fund dairy farm inspection). Milk procurement costs are thus more than a thousand times larger than inspection costs. Inspection costs comprise an even *smaller* share of *overall* processor costs (overall costs include labor, buildings, equipment, debt service, overhead, taxes and other costs in addition to milk procurement costs).

[345] See s. ATCP 60.245, Wis. Adm. Code, which mirrors the PMO.

Federal Preemption of State Food Laws?

In recent years, there have been several efforts in Congress to pass federal food "uniformity" legislation. Major food industry groups, including the Grocery Manufacturers of America, have supported the legislation. The latest version, called the "National Uniformity for Food Act of 2005" (H.R. 4167) gathered substantial Congressional support, but did not come to a final vote.

The legislation was billed as food labeling reform, designed to limit inconsistent labeling requirements in different states. But it actually went much further, to preempt state food safety laws that were not identical to federal laws. Under the proposed legislation, states with non-identical laws would need to petition the federal government for exemptions. The legislation was opposed by a broad coalition including the Consumers Union, the National Association of State Departments of Agriculture, the Association of Food and Drug Officials, and at least 39 state Attorneys General.

Food safety regulation originated in the states, and states like Wisconsin have long regarded food safety as a critical state responsibility. State laws also reflect important regional variations in food production and processing. More than 80 percent of all food safety inspection and testing is performed at the state level. Federal food safety inspections have actually fallen by 78% in the past 35 years.[346] FDA inspects domestic food manufacturers (on average) only about once every 10 years, and almost *never* inspects retail food establishments or farms.

With the consolidation of food businesses on an interstate and international scale, there is strong pressure for national and even international standardization of food laws. Large multi-state and multi-national companies seek consistency and predictability, and wish to avoid a "patchwork" of inconsistent state regulations. But complete standardization of food laws could limit a state's authority to protect its citizens.

State governments are already under strong pressure to avoid needlessly inconsistent regulation. Many Wisconsin food safety regulations are already closely patterned on federal regulations or models, and DATCP is currently participating in a "pilot" program with FDA to standardize state food safety operations based on federal minimum standards. But Wisconsin history also shows the value of state leadership and independent state authority. Federal law should not prevent or discourage Wisconsin from taking effective action to protect its citizens from real food safety hazards.

[346] "FDA Science and Mission at Risk," Report prepared for the FDA Science Board by the Subcommittee on Science and Technology (November, 2007), at p. 21. FDA domestic inspections fell from about 35,000 in 1973 to about 8,000 in 2006. "For F.D.A., a Major Backlog Overseas," New York Times, January 29, 2008.

Interstate Meat Sales

Under federal law, state meat inspection programs must be at least "equal to" the federal program. Wisconsin's program meets that standard and is, by some measures, superior to the federal program. Yet, until now, federal law has prohibited state-inspected meat establishments from selling their products in interstate commerce (only federally-inspected establishments could sell across state lines).

Ironically, meat produced in foreign countries (beyond the reach of U.S. inspection) could be sold throughout the U. S. while wholesome Wisconsin meat produced under continuous state inspection could not. In theory, Wisconsin meat establishments could opt for federal inspection. But federal inspection was mainly designed for large industrialized meat establishments, and was not well suited to small specialty meat operations.

Wisconsin and other states finally succeeded in getting the federal law changed. The law change will allow small state-inspected meat establishments (25 or fewer employees) to ship their meat products to other states.[347] Larger plants, and plants currently under federal inspection, will still need to be federally inspected if they want to sell across state lines.[348] USDA must adopt rules to implement the law change by 2010. State-inspected plants may not sell across state lines until those rules are in effect.

Retail Food Regulation

Many food contamination problems originate at retail establishments. The rapid growth of "ready-to-eat" and delicatessen food has increased the risks. Risk assessments suggest that Wisconsin should focus more resources on *retail* food safety, but state inspection resources are severely limited.

DATCP licenses grocery stores, while the Department of Health Services (DHS) licenses restaurants. In metropolitan areas, local governments often license and inspect those establishments for DATCP and DHS (local participation is voluntary). Local agents may charge their own fees, which are often higher than state fees. DATCP and DHS must train, monitor, evaluate and assist local agents.

The local agent program is growing. DATCP currently contracts with 36 local agents, compared to 21 local agents in 2000.[349] Local agents now license about *half* of all the retail food establishments licensed in the state. Although local agents now serve many metropolitan areas, DATCP still needs to inspect in areas not served by local agents. DATCP must also devote more staff to training, evaluating and assisting local agents. State oversight ensures consistent statewide regulation, which is important for competitors as well as consumers.

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[347] See Title XI of the Federal Food, Conservation and Energy Act of 2008 (otherwise known as the 2008 Farm Bill), Public Law 110-246, enacted June 18, 2008.

[348] State-inspected plants with 25-35 employees may sell in interstate commerce for an initial "grace period" of 3 years, but must transfer to federal inspection if they want to continue interstate sales beyond that "grace period."

[349] DHS currently contracts with 50 local agents (DHS uses local agents for other health-related programs, in addition to restaurant inspection).

DATCP and DHS have coordinated their programs, and adopted uniform rules, to avoid duplicate licensing and inspection. A retail establishment is licensed and inspected by a single government entity (DATCP, DHS or a local agent), *not* multiple entities. That is true even when the establishment includes both a grocery store *and* a restaurant.

Food Safety Staff and Funding

Staff Reductions

Today, DATCP has fewer than 580 authorized staff for *all* of its programs (not just food-related programs). That represents a nearly *30% reduction* from 1980, when DATCP had 800 staff. Yet DATCP now administers many more programs than it did in 1980. DATCP relies heavily on an experienced but aging workforce (43% of DATCP's current workforce is over age 51).

A similar trend applies to *food safety* staffing. Since 1990, DATCP has taken on added food safety responsibilities even as its food safety staff size has declined by 17% (from 118 to 98).[350] Staffing for food-*related* programs, such as animal health, has also declined. DATCP now has only about 37 regular staff for its *entire* animal health and disease control program.[351]

About half of DATCP dairy and food safety staff are field inspectors. Those 50 or so inspectors perform about 27,000 food and dairy inspections each year (not counting meat inspections). Wisconsin has more regulated facilities per inspector than other compared states (for example, Wisconsin currently has 445 facilities per inspector, while California has only 88 facilities per inspector).[352]

As state food safety staffing has declined, so has federal staffing. Between 2003 and 2007, FDA food safety inspections fell by 47% and FDA tests of domestically-produced food fell by 75%.[353] Over the past 35 years, FDA food safety inspections have fallen by 78%.[354] FDA inspects domestic food manufacturers, on average, only about once every 10 years.[355] FDA almost *never* inspects retail food establishments or farms.[356]

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[350] The cited figures include food and dairy staff, but *not* meat inspection staff. Meat inspection staffing, which is largely dictated by slaughter inspection requirements, fell by 5% over the same period (from 96 to 87).

[351] This does not count temporary project staff funded (for now) by federal dollars.

[352] Wisconsin Legislative Audit Bureau letter report, Food and Dairy Safety Program Funding (January 2008), pp. 11-12.

[353] See Wisconsin State Journal, February 27, 2007, p. 1.

[354] "FDA Science and Mission at Risk," Report prepared for the FDA Science Board by the Subcommittee on Science and Technology (November, 2007), at p. 21. FDA domestic inspections fell from about 35,000 in 1973 to about 8,000 in 2006. "For F.D.A., a Major Backlog Overseas," New York Times, January 29, 2008.

[355] "FDA Science and Mission at Risk," Report prepared for the FDA Science Board by the Subcommittee on Science and Technology (November, 2007), at p. 21.

[356] *Ibid.*

Federal inspection of food imports and importing establishments is extremely limited.[357] In 2007, FDA inspected only about 100 of the nearly 190,000 foreign food plants that ship food to the U.S. (a rate of one inspection every 1,900 years).[358] As federal budgets are squeezed, federal financial support for state programs (including food safety, meat inspection, disease control, and livestock premises registration) may also be affected.

Funding Deficits

For many years, Wisconsin funded nearly all of its food safety and disease control operations with general tax dollars (GPR). But starting in the 1980's, the state began funding more of those operations with industry license fees. License fees now fund about 60% of DATCP's dairy and food safety operations (not counting meat inspection) and 19% of its animal disease control operations.[359]

Recent state budgets reduced the GPR funding share and transferred a substantial amount of food safety license fee revenue to the state general fund (to help remedy state budget deficits). DATCP averted an imminent food safety funding crisis by increasing license fees.[360] But DATCP projects another budget shortfall at the end of the next biennium, if nothing else is done.

Ironically, budget cuts for high-risk food safety and disease control programs have produced negligible savings for the state budget as a whole, because the state spends an infinitesimally small share of its tax revenues on these critical programs. In FY 2006-07, the state GPR budget for *all* of DATCP's food safety and disease control program operations (including *all* food, dairy, animal health *and* meat inspection operations) represented only about 0.00064 (considerably less than one one-thousandth) of the total state GPR budget.

Across-the-board state budget cuts have a disproportionate impact on small programs (like food safety and disease control) that are already under-funded. Past successes may tempt us to take food safety and disease control for granted, and minimize their budget priority. But that could be a mistake of historic proportions.

The Role of State Government

Wisconsin has a long and proud food safety tradition. But in the face of new regulatory challenges and resource limitations, we must ask some basic questions:

- Are food safety and security still important responsibilities of state government? Who will protect food consumers if state government does not?

- What is state government's appropriate role?

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[357] "U.S. Food Safety Strained by Imports," New York Times, April 23, 2007.
[358] "For F.D.A., a Major Backlog Overseas," New York Times, January 29, 2008.
[359] Fees vary, based on business size and type.
[360] See DATCP rulemaking docket files 05-R-07 (Food License and Dairy Fees) and 07-R-02 (Animal Health Fees).

- How can farmers, business, consumers and government work together to enhance food safety and security?

- Are we equipped to handle new, and more daunting, disease and bio-security threats?

- Have industry consolidation, global sourcing and complex technology moved food safety beyond the practical reach of state government? Is government at *any* level capable of effective regulation?

- What is the appropriate role of federal, state and local regulation? How can we best coordinate federal, state and local efforts?

- Do traditional regulatory methods still work? Are we spending too much valuable time on routine (albeit legally mandated) inspections? Are we using current tools to best advantage? Are other tools, including information tools, available?

- How do we simultaneously, and fairly, regulate giant global corporations and local "mom and pop" food businesses?

- Should we still try to set minimum food safety standards? Or should we let the market operate without any standards, and hope for the best? How do we ensure that minimum standards are actually being met?

- Although traditional "food safety" remains a key concern, do we need to think more comprehensively about food system security, sustainability and impacts? How do we work with others to address those concerns?

- Does state government have a preventive, problem-solving role? Or are we simply "first responders" who try to clean up after the wreck?

- Does the food industry still have a collective interest in food safety? Can the industry play a progressive leadership role, as Wisconsin's emerging dairy industry did in the late 19th Century?

- Should Wisconsin strive to be a leader and innovator, as it has been in the past?

- Is state government serious about food safety? Do we actually have the knowledge, tools, staff and resources to do the job?

5. Conclusion

Wisconsin now has 5.6 million food consumers. We all get hungry every day. We want, and expect, a secure and steady supply of safe and affordable food. But we are no longer capable of producing that food ourselves. We rely on complex industrialized systems to produce and deliver the food we need at a price we can afford. Those systems are driven by large infusions of fossil fuel.

In the 21st Century we are utterly dependent on food produced elsewhere, by others. Without food systems to sustain us, our life expectancy would be measured in weeks. Major cities have ready access to only about one week's supply of food. Most of our food travels hundreds or thousands of miles, through complex production and distribution networks. Food safety, food security and consumer protection have never been more important.

Wisconsin has a proud tradition of food safety, but that tradition is being tested in many ways. With limited resources, Wisconsin faces new food safety and security challenges and a profoundly changing marketplace. Although our food is arguably cheaper, more convenient and safer than ever, we are engaged in an increasingly precarious "high wire" act. Food safety and disease control programs are under considerable stress. Like a bridge, they can appear to operate normally until they collapse.

The food systems that keep us alive are now highly concentrated, and they are dominated by interstate and global enterprises. Wisconsin food businesses face relentless interstate and global competition. The experience is like that of traditional main street merchants, as they awaken to the new reality of a Wal-Mart on the outskirts of town.

Although the food business is changing, it is still critically important to Wisconsin's economic well-being. The dairy business alone contributes $20 billion to the state's economy.[361] Wisconsin exports about 85% of its dairy products to other states, and those exports help balance the state's growing imports of oil and gas, cars, computers, clothing, building materials, electronics, entertainment, coffee, and thousands of other items. Overall, Wisconsin's agriculture and food industries contribute $51.5 billion to the state's economy, and provide jobs for nearly half a million Wisconsin residents.[362]

What consumers have lost in frontier independence, they have gained in choices. Today, a typical supermarket contains about 45,000 products.[363] Consumers here and elsewhere have a wide array of options from all over the globe. Their perceptions and choices can make or break individual businesses, industries and regions. To succeed against strong competition, Wisconsin must deliver what consumers want and need.

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[361] See Deller, "Wisconsin and the Agricultural Economy," University of Wisconsin-Madison, Department of Agricultural and Applied Economics, Staff Paper No. 471 (March, 2004). Available at *http://www.uwex.edu/ces/ag/wisag/*.

[362] *Ibid*.

[363] Food Marketing Institute, "Supermarket Facts" (Industry Overview 2006). Available at *http://www.fmi.org/facts_figs/superfact.htm*.

Consumers are concerned, among other things, about food safety and quality. On these points, Wisconsin has a marketing advantage. "Wisconsin" means wholesomeness, tradition, integrity, craftsmanship and uncompromising quality. But that "brand" image – painstakingly developed over more than 150 years – can be damaged or lost, almost overnight, in a single high-profile food crisis or disease outbreak. It can also be frittered away, over time, in many small ways.

Our food systems are complex and fragile. Problems originating at a single business can cause widespread harm to consumers *and* other businesses. Diseases and other hazards can wreck whole industries, and tarnish the image of an entire state. From both a consumer *and* a business perspective, food regulation remains an important *collective* enterprise for Wisconsin. Farmers, consumers, business and government – we are all in this together.