

The National Agricultural
Law Center



*A research project from The National Center for Agricultural Law Research and Information
University of Arkansas School of Law • NatAgLaw@uark.edu • (479) 575-7646
www.NationalAgLawCenter.org*

An Agricultural Law Research Article

Food Law & Policy: An Essay

by

Peter Barton Hutt

August, 2005

Originally published in the Journal of Food Law & Policy:
1 J. FOOD L. & POL'Y 1 (2005)

FOOD LAW & POLICY: AN ESSAY

*Peter Barton Hutt**

INTRODUCTION

Food has been the driving preoccupation of humans since the dawn of evolution. Exactly when food processing began and when the original hunter-gatherers settled down to develop agriculture—or even the question of which of these occurred first—remain issues of scholarly pursuit and debate. It is clear, however, that these events occurred millennia before the advent of recorded history; therefore, we must rely on largely adventitious discoveries of archeological artifacts to advance our developing knowledge of these events.

Inevitably, the development of stable societies and organized agriculture required the establishment of rules to govern common behavior and shared expectations regarding the available food supply. These rules—the earliest manifestation of food law and policy—were undoubtedly first considered simply mutual understandings and communal practice. By the time of our earliest recorded history, in the clay tablets of ancient Samaria, these laws and policies had already been reduced to formal requirements and prohibitions that were enforced through severe penalties.

From these ancient clay tablets to the present, there is a vast unexplored treasure trove of food law and policy to be researched and documented in every part of the world. This task is as enormous and challenging as it is exciting and rewarding. Laws and policies never before uncovered or analyzed are waiting to be revealed and studied.

* Peter Barton Hutt is a senior counsel in the Washington, D.C. law firm of Covington & Burling, specializing in food and drug law. He teaches a full course on food and drug law at Harvard Law School during Winter Term and taught the same course at Stanford Law School during Spring Term 1998. Mr. Hutt is the co-author of the nation's leading food and drug law textbook (PETER BARTON HUTT AND RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS*, (2d ed. 1991)), serves on several journal editorial boards, and has published numerous papers on food and drug law and health policy. From 1971 to 1975 he served as Chief Counsel for the Food and Drug Administration, and he currently serves as legal counsel for numerous trade and industry groups connected to the food industry.

Until now, there has been no publication to serve as a focal point for this scholarly research. This new *Journal of Food Law & Policy* fills that void. Future research on food law and policy, from ancient times to the present, and spanning the entire world, now has a welcome home. This represents a propitious and long-overdue advance in scholarship, and the University of Arkansas School of Law must be congratulated for recognizing the importance of this field and seizing the opportunity to serve an unmet need.

THE BROAD SCOPE OF FOOD LAW AND POLICY

Because food provides the sustenance we must have to survive, food law and policy encompasses social, cultural, and personal beliefs and biases that cannot be ignored. For example, the current differences between the United States and Europe with respect to the marketing of cheese made from unpasteurized milk, the use of growth-promoting hormones in cattle, and the European distrust of genetically modified organisms in the food supply emanate more from a deep cultural divide than from any scientific disagreement.

Religious practice can be an equally potent consideration. The longstanding debate on whether the Jewish dietary laws were based on empirical evidence that some food contributed to human disease and therefore should be prohibited, or whether these laws were based simply upon ancient practice and superstition, will undoubtedly never be resolved. The complexity of the Jewish laws governing proper grace before partaking food, and requiring that agricultural land lay fallow every seventh year, aptly demonstrates the power of religion in our food law and policy.

Many erroneously assume that food law is limited to the governmental laws and regulations governing the marketing of food within a particular jurisdiction. For example, the United States Food and Drug Administration (FDA) has complex statutory requirements and prohibitions for all food products and food ingredients marketed in the United States. The United States Department of Agriculture (USDA) has equally complex requirements and prohibitions specifically governing meat, poultry, and egg products. A true understanding of food law and policy, however, extends far beyond these narrow confines. It includes, for example, issues relating to the ownership of agricultural property, the water rights needed to sustain agriculture, tax incentives to preserve family farms, agricultural research and education, governmental economic programs to prevent agricultural surplus and to stabilize agricultural prices, food distribution programs for school children and the poor, programs designed to provide nutri-

tion education and now to prevent obesity, and a host of other policies that impinge on food and agriculture.

Neither FDA nor USDA comprises the boundaries of the federal agencies that directly establish food law and policy. The Federal Trade Commission regulates food advertising. The Alcohol and Tobacco Tax and Trade Bureau (formerly the Bureau of Alcohol, Tobacco, and Firearms) specifically regulates alcoholic beverages. Drinking water is subject to regulation by the Environmental Protection Agency. The National Marine Fisheries Service of the Department of Commerce inspects fish. Postal fraud involving food is subject to legal action by the United States Postal Department. The Occupational Safety and Health Administration regulates worker health and safety in food plants and on the farm. The pesticides that are used to facilitate the growth of raw agricultural commodities are registered and regulated by the Environmental Protection Agency. The same proliferation of agencies that regulate the food industry at the federal level exists at the state level as well.

APPRECIATING THE HISTORICAL DEVELOPMENT OF FOOD LAW AND POLICY

There are many issues in food law and policy that have not changed throughout recorded history. One of the earliest clay tablets in ancient Samaria made it a crime for an innkeeper to provide a false measure of ale. A fundamental right established in the Magna Carta of 1215 was the guarantee of a uniform standard for weights and measures throughout England. Laws throughout the world, including the Federal Food, Drug, and Cosmetic Act (FDCA), maintain that tradition today.

In medieval London, each baker was required to write his name on each of his bread products so that a consumer could have recourse in the event of an adulterated product. Today, all food products sold in the United States, and in most of the world, are required to bear the name and address of the manufacturer or distributor, for precisely the same reason.

Laws prohibiting the adulteration and misbranding of food—although not written in those precise terms—can be found in every civilized country from ancient Greece and Rome to the present. At the outset, these laws were designed to protect the economic expectation of food purchasers. The Greek botanist Theophrastus, the Roman agriculturalist Cato, the Roman naturalist Pliny the Elder, the Greek botanist Dioscorides, and the Roman physician Galen, all describe common practices in ancient Greece and Rome of adulterating com-

mon food ingredients and food products. At that time, the legal prohibition against adulteration was based upon economic concern, not on safety grounds. (Indeed, the term “safety” was first used in food statutes within the past hundred years.) It was not until Frederick Accum published his landmark treatise on food adulteration in 1820 that food adulteration was identified as a safety, as well as an economic, issue.

Conflicts in the regulation of food between national and local jurisdictions have existed since the Middle Ages. In England, Parliament enacted food requirements for the entire country, the City of London enacted rules for local application, and each of the food trade guilds enforced standards for all members of that particular guild; the courts imposed judge-made common law as well. Throughout history, every European nation has established its own requirements regarding the food supply. Even after creation of the European Union, disparities among European food laws continue to exist at the individual country level. In the United States, food law was initially a matter of city, county, and state jurisdiction. It was not until the early twentieth century that federal food laws were first enacted. As a result, disparities between federal and state food requirements persist to this day.

International trade barriers and trade wars have similarly existed throughout history. Pliny the Elder told the amusing story that, in order to protect against foreign competition in the spice trade, the Arab countries spread rumors that cassia grew in shallow lakes protected by winged creatures and cinnamon grew in deep glens infested with poisonous snakes. In the 1890s, European countries and the United States passed a plethora of protectionist laws against importation of cattle and other livestock. Today, even with the World Trade Organization attempting to arbitrate, the same countries are locked in disputes about the use of growth hormones and genetically modified organisms.

The disparity among nations in all aspects of food law and policy defies description. No two countries provide for the identical approach to food labeling. No two countries authorize the identical food ingredients. Indeed, the very approach by which the food supply is regulated differs widely throughout the world. In some countries, everything is allowed that is not prohibited. In others, everything is prohibited that is not allowed. Taking only our very friendly neighbor to the north, even after the North American Free Trade Agreement, food products that are permitted in the United States are prohibited in Canada and the reverse is equally true.

Analysis of government food policy is easier in some countries than in others. In the United States, the 1966 Freedom of Information Act permits access to internal government documents that were completely unavailable before the enactment of this landmark statute. For years, European nations declined to follow the same approach. Only now is the European Union moving toward a greater openness that will facilitate better public understanding of governmental action and more complete scholarly evaluation of the development of European food policy.

The placement of a federal regulatory agency, and the scope of its jurisdiction as determined in the organizing statute, is an important element of food law and policy. FDA was incubated in the United States Patent Office in the mid-1800s, became a part of USDA when it was first created in 1862, and was then consecutively made a part of the Federal Security Agency in 1939, the Department of Health, Education, and Welfare in 1953, and now the Department of Health and Human Services since 1979. During all that time, it was only an administrative creation, without a statutory base. Only in 1988 did Congress, at long last, create FDA by statute. When FDA was taken out of USDA in 1939, the regulation of meat was left behind—later joined by the regulation of poultry and eggs. Ever since, there has been intense debate about whether these two regulatory programs should be reunited and, if so, whether that should occur in USDA or in the Department of Health and Human Services.

The very structure of a regulatory statute has enormous influence on the way that the agency implements the statute, and on the economic impact it has on the regulated industry and the economy as a whole. There is a clear hierarchy of regulatory controls. At the top is the requirement of premarket approval. At the bottom is simple policing of the marketplace. Coming down from the top, there is premarket notification, premarket testing, compliance with standards, and perhaps other forms of regulatory control. There has been little or no scholarly investigation of the factors that lead to a choice among these various methods of regulatory control or the differential impact that results from that choice. The success and failure of some of these statutory controls, when implemented by a food regulatory agency, has similarly been the subject of little scrutiny. This is a field that is wide open for serious investigation.

Each statute, each regulation, each guidance, and each statement of policy relating to the regulation of food represents the culmination of a deliberative process both within and without the government; and each one also expresses new policy objectives and methods of implementation. Each of these documents has its own history that, when

uncovered, reveals both the process and the substance involved. Whether one searches the legislative history in congressional hearings, reports, and debates, or delves into the administrative history available under the Freedom of Information Act, the trade press, Federal Register notices, and informal materials, the exploration is certain to lead to greater insight into the development of our food law and policy in the United States.

Without understanding the historical context of a statute, and the perceived problems that the new law was intended to address, neither the provisions of the law nor the policy that they are intended to embody can truly be understood. The 1906 publication of Upton Sinclair's novel, *The Jungle*, in the United States triggered enactment of both the Federal Meat Inspection Act and the Federal Food and Drugs Act later that year. Twenty-seven years of congressional hearings and USDA reports had prepared the country for this type of legislation. In contrast, the 1975 publication of Yuri Olesha's comparable novel, *Envy*, in communist Russia provoked little or no public reaction. Some events have triggered enormous public response, while others have fallen on deaf ears.

For food, as in any other area, politics plays a large role in the consideration of all legislation. A public tragedy can assure the immediate consideration and enactment of protective legislation, as it did with the Infant Formula Act of 1980, and political ideology can spell doom for even the most venerable of statutes, as it did with the repeal of the ninety-nine-year-old Tea Act in 1996. Tracing the statutory and regulatory history of individual food products can be particularly rewarding. The debate between Cato and Pliny the Elder in the 1st century A.D. on "adjusting" wine (by the addition of functional ingredients) parallels the fight of Harvey W. Wiley against adulteration of blended whiskey in the early 1900s.

The Federal Food and Drugs Act of 1906 was a relatively short and simple statute. Its legislative history, which extends back to 1879, has never been published, nor has it been the subject of thorough research and scholarship. The 1906 Act was amended fewer than ten times before its repeal in 1938. It was one of the most important statutes in American history because it transformed our entire food supply. Yet the history of this remarkable piece of legislation between 1906, and the time it was repealed in 1938 and replaced with our current law, is sparse and inadequate.

The FDCA is often erroneously viewed as a comprehensive organic statute. In fact, it began as a relatively short and simple law, and has since been amended more than one hundred times. The interplay between the broad and general provisions of the original FDCA,

and the extraordinarily detailed and complex provisions that have been added more recently, offers endless opportunity for thoughtful analysis. The very complexity of the FDCA, as currently amended, is a tempting invitation for a comprehensive recodification. Yet the only attempt made at recodification was rebuffed, even in the era of the relatively simple provisions in the statute that existed in the 1950s.

The annual ritual of the appropriations process offers scholars a vast source of historical material about the policy that underpins implementation of our food laws. Each year in the United States a government agency must submit voluminous materials to Congress describing the past year's achievements and projecting plans for the coming year. All of these materials are fully available to the public. Members of the appropriations committees hold tremendous power over regulatory agencies. In the early 1950s, for example, Representative John Taber from western New York became incensed at the regulatory action taken by FDA's Buffalo District Office against a constituent's dried raspberries, and using his position on the House Appropriations Committee, he engineered a drastic cut in FDA budget. It took nearly a decade before the agency recovered. In contrast, beginning in 1992 Congress has now enacted user fee statutes to help fund FDA premarket approval process for new drugs, new animal drugs, and medical devices, but not for food additives. The ability of any governmental agency to implement its statutory mandate to protect and promote the food supply can only be appreciated in the context of the resources available to carry out its mission.

The process by which government food policy is adopted is often as important as the substantive policy itself, because process can directly influence that substance. Prior to the 1930s, FDA simply announced its regulations and other policies without the need for any form of public process. With the enactment of the Federal Register Act in 1935 and the Administrative Procedure Act in 1946, however, this changed dramatically. The Federal Register Act required publication of all significant proposed and final regulations, notices, policy statements, and other regulatory documents. The Administrative Procedure Act required public participation in the development of regulations. Not content simply to implement these statutes, FDA in turn published its own comprehensive procedural regulations in the 1970s to govern all aspects of the agency's work and added the self-imposed requirement of lengthy preambles to proposed and final regulations in order to explain their intended meaning and rationale. No other United States agency has followed suit. A thorough evaluation of the impact of these experiments, as an administrative technique for im-

plementing food law and policy, would be a welcome addition to the published literature.

The evolution and application of enforcement powers and penalties, and the way that they are used, often reveals a great deal about social mores as well as effective compliance action. The Medieval English custom of leading a guilty butcher through the streets with a piece of putrid meat around the neck may not have been a serious deprivation of liberty, but it was undoubtedly a more effective deterrent than the warning letters or civil fines that prevail today. The effectiveness of the unique imposition of strict criminal liability (without knowledge or intent) for violation of the food provisions of the FDCA deserves comparison with the penalties under other regulatory statutes both here and abroad.

Under most food laws, there are both formal enforcement powers (specified in the statute) and informal compliance mechanisms (not granted under the statute) that emerge from the administrative agency responsible for implementing the law. The criteria used by administrative agencies in determining what enforcement powers to use, and what penalties to impose, vary over time and among different countries. In the United States, FDA relied almost exclusively upon formal enforcement powers during the first half of the twentieth century and relied on informal compliance mechanisms during the second half of the century. European food law, in contrast, was poorly enforced before the development of the European Union, and only now is becoming the subject of the same type of tough enforcement for which FDA has been known.

More than one United States constitutional scholar has pointed out that most important principles of United States constitutional law have been developed in the context of food regulation in general, and milk regulation in particular. The power of both state and federal governments to regulate private business in order to protect not only the public health and safety, but also the economic stability of the industry, and the power of the federal government over intrastate as well as interstate commerce, have all been adjudicated by the Supreme Court in the context of food legislation. In Europe, the authority of the new European Union to override national law in order to achieve a common marketplace was decided by the European High Court of Justice in the context of a sixteenth century German statute regulating beer.

THE EVER-CHANGING FOCUS OF FOOD LAW AND POLICY

A close study of the historical development of food law and policy reveals that virtually all new developments are based upon advances in

science, not upon new legal insight. The Assize of Bread and Ale of 1266 in England prohibited the addition to bread and ale of any substance “not wholesome for Man’s body.” That statute remained in force, without amendment, until it was repealed in 1844. Today, our FDCA prohibits the addition to food of any “poisonous or deleterious substance that may render it injurious to health.” Thus, a full 738 years after Parliament enacted the 1266 statute, we are unable to come up with any more articulate or specific statutory requirement to assure the safety of the food supply.

There is a world of difference, however, between what was available to the English in enforcing the 1266 statute and the exquisite analytical methodology and toxicological knowledge available to FDA to enforce the FDCA today. In short, the history of the development of food regulation is the history of science, not the history of laws and regulations.

Perhaps there is no better example of the importance of the development of scientific knowledge to the implementation of food law and policy than the extraordinary impact of analytical methodology. Although food adulteration was commonplace in ancient Greece and Rome, it was difficult to detect because of the primitive nature of analytical methodology. Pliny the Elder contended that food adulteration could be detected “by smell, color, weight, taste, and the action of fire.” Nonetheless, most subtle adulterations went undetected and unpunished. Merchants set up a system of “garbeling” in order to separate the genuine pepper from the garbel (the adulterating materials) in the Dark Ages and Middle Ages, when pepper was used for currency, medicine, and as a spice. When chemistry emerged out of alchemy, one of the greatest seventeenth century scientists, Robert Boyle, wrote the first modern tract on the use of analytical chemistry to detect the adulteration of food through specific gravity. Frederick Accum’s 1820 treatise offered detailed chemical methods for the detection of adulterated food, Arthur Hassall pioneered the use of the microscope to determine food adulteration in the mid-1800s, and thereafter public analysts were established in England to assure the purity of the food supply. Yet FDA Commissioner C.A. Browne, writing in 1909, complained that the ability of the agency to detect food adulteration at that time was little better than it was in the time of Pliny the Elder. Just fifty years later, however, the sensitivity of analytical methodology had improved to two parts per billion or less, and today it can reach below a part per quintillion. The problem today is not finding adulteration, but understanding what regulatory action is or is not appropriate once an adulterant is detected.

The discovery and development of the field of toxicology had been as important to the evolution of food law and policy as the improvement in analytical methodology. From earliest times, the safety of the food supply could only be determined by human trial and error or by watching the dietary habits of wild animals. In the sixteenth century, Paracelsus enunciated the founding principle of toxicology—that everything is a poison and nothing is a poison, because the difference between a poison and a remedy is the dose—but no one was able to elucidate how to determine the boundary between a safe and unsafe dose for another four hundred years.

In the early 1900s, Harvey W. Wiley sought to publicize the need for a national food and drug law by testing the safety of the five most widely-used food preservatives: boric acid and borax, salicylic acid and salicylates, sulfurous acid and sulfites, benzoic acid and benzoate, and formaldehyde. He chose the only means by which food safety could be determined at that time—he fed them to a “poison squad” of twelve USDA employees during 1902 through 1904. The reports were long on clinical chemistry but very short on pharmacologic analysis, because the field of toxicology had not yet been discovered. When industry complained directly to President Theodore Roosevelt about Wiley’s conclusion that one of the ingredients was unsafe, the President convened a panel of five eminent scientists to resolve the dispute. Those scientists then resorted to the only means available to address the issue in 1911: they fed the ingredient to their students. This was less than a hundred years ago.

Within a decade, however, researchers began to develop colonies of inbred laboratory animals to replace human testing. Even then, there was substantial scientific debate and uncertainty about how to interpret the animal test results and apply those results to ascertain safe consumption levels for humans. Regulatory necessity ultimately led to the solution. Following the Elixir Sulfanilamide tragedy in the fall of 1937 (when more than 100 people died because the product contained diethylene glycol, a highly toxic compound), FDA toxicologists obtained all of the data from the humans who took that ill-fated medicine and compared that data with animal feeding studies on the same product. They discovered that there was a ten-fold variation in the lethal dose of diethylene glycol both among humans and among test animals. Multiplying ten by ten, the FDA scientists concluded that a safety factor of 100 to one was appropriate. From then to this day, the safety of a food ingredient has been determined in part by dividing the highest no observed effect level (NOEL) in test animals by a factor of 100. In this and many other ways, government regulatory officials charged with protecting the safety of the food supply have

made substantial advances not just in regulatory science but in a more fundamental appreciation of basic science itself.

Some of the old food laws have become obsolete, and new laws have been substituted, because of the changed circumstances. In Medieval England, it was essential to enact laws that closely regulated the amount of livestock to be kept on each farm, in order to assure an adequate food supply. It was the very tyranny of these laws that led one-third of the population of England to leave their homeland and settle in the American Colonies. Today, we have quite a different problem. Even with a smaller acreage and a larger population, we have a surplus of food. Thus, our laws today are designed to reduce production in order to bring it more closely in line with consumer demand both here and abroad.

Some old regulatory programs have acquired new uses over many centuries. The food standards of ancient Rome constituted an elaborate price-fixing program, designed to assure that there would be no price gouging on a staple food product. A fixed price (set by the government) was all that could be charged for a particular quantity and type of bread. England continued this tradition through the Assize of Bread and Ale, and reinforced it by prohibiting the forestalling, regrating, and engrossing of any food. Today the role of food standards is quite different. When first authorized under the FDCA in 1938, food standards were intended to assure the safety of the permitted ingredients and to preserve the defining characteristics and nutritional quality of the food involved. With the advent of the Food Additives Amendment of 1958 the need for food standards to assure food ingredient safety disappeared. And with the explosion of modern food technology, FDA itself has questioned whether there is any remaining justification for food standards.

CONCLUSION

There is an inexhaustible amount of material to be uncovered and analyzed, and an enormous body of literature to be developed, on the history and current status of food law and policy both in the United States and abroad. In 2006 we will be celebrating the 100th anniversary of the original Federal Food and Drugs Act of 1906 and also the 740th anniversary of the Assize of Bread and Ale of 1266. The *Journal of Food Law & Policy* has been established just in time to participate in this celebration and lead the way into the future. Because of the central importance of food in all of our lives, food law and policy is a subject that will never become obsolete.

