

THE UNITED STATES FOOD AND DRUG ADMINISTRATION:
ITS ROLE, AUTHORITY, HISTORY, HARMONIZATION ACTIVITIES,
AND COOPERATION WITH THE EUROPEAN UNION¹

The purpose of this article is to provide background about the United States Food and Drug Administration (FDA). The article will focus particularly upon the agency's authority, its place in the United States system, and its history as a domestic institution and as a participant in international activities. Finally, the article summarizes principal areas of regulatory cooperation with the European Union in the foods area and outlines future areas of cooperation.

The article may be of interest to counterparts in other countries, confronted with such food safety issues - particularly the recent evidence that humans might develop a variant of a fatal neurological disease (Creutzfeld-Jakob disease) as a result of eating beef from cattle afflicted with bovine spongiform encephalopathy (BSE).

I. FDA's Role

FDA is a component of the Department of Health and Human Services but traditionally has functioned with a high degree of independence (but, at the same time, with many checks and balances, or "safeguards," to assure public accountability and prevent official abuse of authority).

FDA's regulatory autonomy rests upon three pillars: strong legal underpinnings, a solid basis in science and public health protection for its decisions, and support of the public.

oConcerning the legal underpinnings, FDA administers and enforces comprehensive laws to assure that food and cosmetics are safe, that pharmaceuticals and medical devices have been shown by the manufacturer to be safe and effective, and that all products are properly labeled. Its institutional semi-autonomy is aided by the statutory provisions that provide for an agency charter, as well as regulations that delegate to the Commissioner (from the Secretary of Health and Human Services) virtually all authority under the statutes FDA administers.

oFDA's science and public health foundation has, as its core, a highly expert and dedicated staff of intensely dedicated investigators, scientists, physicians, attorneys, consumer safety enforcement officers, support staff, and leaders who are drawn to the agency, and often stay, because of its compelling mission. Despite government salaries

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that are not competitive with private sector opportunities, the agency has gone to great lengths to recruit, reward, and retain top-notch people. Also, the agency maximizes outside comments on its decisions by operating in a highly transparent manner, through advisory committees and frequent meetings and other communications with a diverse array of groups including academics, health professionals, consumers, and industry.

o Surveys of the American public consistently show that FDA is one of the most trusted of American institutions. A factor that strengthens this trust is that the agency's only mission is to determine how best to protect the public, given the scientific information before it, and the agency is supposed to do this even if making the right decision means that a company goes out of business or an affected industry loses money. There is not a commingling of public protection and economic protection.

Related factors strengthen the agency's legal/scientific/public support pillars, including an agency moral compass whose "north" is public health protection. The agency has a long history of standing up to economic or political pressures: historians can point to occasions when these pressures resulted in Congressional action to reduce the agency's authority. (Saccharin and dietary supplements are two examples.)

Where these pressures have been applied not through Congress, in an attempt to change legislation, but through executive branch officials, the agency has likewise been stalwart in maintaining its principles. FDA's history includes a number of incidents, some of them from the early years of this century and others from the 1980s, in which the agency initially succumbed to these pressures only to experience corrective action due to lawsuits, embarrassing publicity, Congressional oversight, or several of these in combination. The history suggests the importance to a country, in the prevention of official abuse, of Freedom of Information laws and other transparency, consumer groups, and meaningful oversight. These factors are probably even more important than civil service laws, internal investigations, inspector general offices, ombudsmen, and integrity statutes.

High-level support for science-based decisions also is important.

FDA is at its strongest when, as now, it enjoys solid Presidential and Secretarial support for the integrity of its decision making.

Last, but not least, at crucial points in its history the agency has been blessed by effective and charismatic leaders. Two of the best were the first Commissioner, Harvey Washington Wiley, discussed below, and the most recent one, David Kessler, whose six years at FDA ended on February 28, 1997.

The domestic and international regulatory challenge posed by BSE-bovine spongiform encephalopathy, or mad cow disease--is only one very sobering example of the tough scientific and policy issues confronted by food and veterinary medicine regulators as this century draws to a close. Although every indication is that the United States is BSE-free, our country is confronting the same difficult issues as Europe concerning domestic regulation, importation restrictions, and product composition requirements for animal feeds and medicinal products.

II. FDA's Authority

FDA has broad authority.² It is the sole United States regulatory body for pharmaceuticals for human use and for medical devices. In the food area, FDA is the principal regulatory body, with some authority over all food products. FDA inspects food establishments and ensures compliance through voluntary correction or enforcement action, when warranted. It issues and enforces regulations on good manufacturing practices, Hazard Analysis Critical Control Points (HACCP), and food labeling. It approves food and color additives and veterinary drugs.

For meat, poultry, and egg products, the Food Safety and Inspection Service (FSIS) is the principal United States regulatory body: it is the agency solely responsible for the inspection of meat, poultry, and egg products inside "official establishments" where these products are processed. However, where meat, poultry, and egg products are located somewhere other than the official establishments, such as before these animal products reach the official establishments, and after the products leave these establishments,³ FDA and FSIS share responsibility for them⁴ and cooperate on a broad

² The principal statutes that FDA administers are the Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. §§321-393); certain provisions of the Public Health Service Act, most importantly sections 301, 351, and 361 (42 U.S.C. §§ 241, 262, 264); and the Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451-1461). Other statutes administered by FDA are listed in FDA's delegation of authority regulations (21 CFR § 5.10).

³ FDA and FSIS share authority to detain meat, poultry, and egg products outside official establishments. 21 U.S.C. §§ 679(b), 467f(b), 1031 et seq.

⁴ Section 902(a) of the Federal Food, Drug, and Cosmetic Act provides that, "Meats and meat food products shall be exempt from the provisions of the [Federal Food, Drug, and Cosmetic] Act to the extent of the application...of the Meat Inspection Act," 21 U.S.C. § 392. "Notwithstanding any other provisions of law, including [21 U.S.C. §392(b)], the provisions of [the Federal Meat Inspection] Act shall not derogate from any authority conferred by the Federal

range of enforcement activities. Also, FDA regulates any food additives used in meat or poultry (e.g., nitrites in ham), decides whether to allow radiation of meat and poultry, and approves animal drugs used in food-producing animals. Thus, Congress wrote the laws on food in general, and meat, poultry, and egg products in particular, so as to avoid regulatory gaps: FDA has broad, residual authority that resumes wherever FSIS authority ends. The Animal and Plant Health Inspection Service (APHIS) also administers laws aimed at curbing spread of animal and plant disease. (Other agencies with responsibilities of food are described in **Appendix 1.**)

The 50 States of the United States, as well as the District of Columbia, Puerto Rico, and territories, also have public health protection activities in the food area, particularly concerning retail sales (such as restaurants, supermarkets, hospital and school cafeterias).

FDA's authority over food in interstate and foreign commerce has been interpreted very broadly and could encompass even retail establishments. The agency traditionally has preferred to leave oversight of such establishments to State (or city or county) governments and to confine its own compliance activities over such establishments to issuance of uniform guidance on desirable sanitation practices.

Food Drug, and Cosmetic Act prior to enactment of the Wholesome Meat Act." 21 U.S.C. §679(a). "Poultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act to the extent of the application or extension thereto of the provisions of this act, except that the provisions of [the Wholesome Poultry Products] Act shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act prior to the enactment of the Wholesome Poultry Products Act." 21 U.S.C. §467f(a). The provisions of [the Egg Products Inspection] Act shall not affect the applicability of the Federal Food, Drug, and Cosmetic Act...or other laws...except that the Secretary of Agriculture shall have exclusive jurisdiction to regulate official plants processing egg products and operations thereof as to all matters within the scope of this Act." 21 U.S.C. §1041.

III. FDA's History

A. When Was FDA Created?

The seemingly simple question of when FDA was founded is difficult to answer:⁵

oWas it 1883, when Harvey Wiley, the father of United States national food and drug legislation, was appointed to head the chemistry unit⁶ of the Department of Agriculture?

oWas it 1899, when that unit first obtained enforcement authority, albeit only over imports?

oWas it 1906, when the famous Food and Drugs Act of 1906 was passed, giving the Bureau of Chemistry authority for the first time over food and drugs generally?⁷

oWas it 1927, when the Bureau of Chemistry was renamed the Food, Drug, and Insecticide Administration?

oWas it 1930, when the agency was given its current name, the Food and Drug Administration?⁸

oOr was it 1988, when Congress finally provided the agency with a statutory charter in the Food and Drug Administration Act?

⁵ The author favors observance of the agency's birthday as March 1, 1899, when its legal mandate began, a date that offers the opportunity for a centennial celebration soon, and on the eve of the next millennium. FDA could still celebrate the centennial of the Food and Drugs Act in 2006, of the "FDA" name in 2030, of the Federal Food, Drug, and Cosmetic Act in 2038, and so forth.

⁶ The name of the unit was Division of Chemistry from 1883 until 1903, then Bureau of Chemistry from 1903 until 1927. Hutt and Merrill, Food and Drug Law: Cases and Materials, at 4.

⁷ On the same day, the Meat Inspection Act was enacted, a law inspired by insanitary conditions in meat packing plants as publicized in Upton Sinclair's The Jungle-and assigned not to the Bureau of Chemistry but the Bureau of Animal Husbandry. This split between regulatory handling of meat, and regulatory handling of other foods, continues to this day.

⁸ Angry farmers' protests concerning agency restrictions on certain pesticides led Congress to strip the agency of its powers over these products. The authority was moved to another part of the Department of Agriculture, then to the Environmental Protection Agency in 1970. Reorganization Plan No. 2 (1970).

B. Landmarks in Food Regulation History

FDA's early history, with an emphasis on statutes empowering the agency to regulate food, international activities, and parallel events in the early life of the meat and poultry program, is summarized in **Appendix 2**.

Turning to modern history, watershed events that brought FDA's food program to where it is today include the following highlights in its in the agency's organizational, legal, and regulatory history:

o the Federal Food, Drug, and Cosmetic Act of 1938;

o FDA's move from the Department of Agriculture to the Federal Security Administration in 1939;

o the Supreme Court's 1943 Dotterweich decision, holding corporate executives strictly liable for criminal prosecution due to violations of the Act, without need for the government to prove knowledge or intent;

o the upgrading of the Federal Security Administration to the Department of Health, Education, and Welfare in 1953;

o the "enforcement era" of the 1940s, 50s, and 60s, in which FDA emphasized law enforcement and brought many court cases that resulted in judicial decisions upholding a pro-consumer protection interpretation of the law;

o the enactment of new authorities over pesticides, food additives, and color additives in 1954, 1958, and 1960 respectively, heralding a move from after-the-fact enforcement to the "preventive era;"

o the creation of the Codex Alimentarius Commission in 1962, which began an era of international cooperation;⁹

⁹ In 1962 the Codex Alimentarius Commission was founded as a joint activity of the World Health Organization (WHO) and the Food and Agricultural Organization (FAO) of the United Nations (UN) to establish international food standards. Depew, The Joint FAO-WHO Conference on Food Standards, 18 Food Drug Cosmetic Law Journal 34 (1963); J.P. Frawley, Codex Alimentarius--Food Safety--Pesticides, 42 Food Drug Cosmetic Law Journal 168 (1987). FDA's Deputy Commissioner, John Harvey, was instrumental in the founding of Codex and served as its first chair. WHO and FAO had already begun, during the 1950s, to hold international consultations on the safety of chemicals in food. C. Feldman, The Food and Drug Administration's Redbook: Toxicological Principles for the Safety Assessment of

- othe placement of FDA in the Public Health Service in 1968, which brought into FDA several food programs for milk, shellfish, and interstate sanitation previously carried out elsewhere in the Service;
- othe creation in 1970 of the Bureau of Foods (later the Center for Food Safety and Applied Nutrition) and the movement of pesticide tolerance-setting to the new Environmental Protection Agency that same year;
- othe 1972 Bon Vivant vichyssoise botulism poisoning and resultant increase in resources for FDA food programs ("Operation Hire");
- othe "FDA rulemaking era" of the 1970s, with significant initiatives on food labeling, vitamins and minerals, and good manufacturing practices and a significant body of court opinions upholding a liberal interpretation of FDA's authority to fashion the rules it believes necessary to carry out the broad purposes of the Act;
- othe sweetener and color additive controversies of the 1970s and 1980s (in which cyclamate, and Red No. 2 and 4 were forced off the market, saccharin was saved by Congress from an FDA ban, and aspartame and Red No. 40 were approved);
- othe creation of the Department of Health and Human Services in 1979;
- othe Community Nutrition Institute litigation of the 1980s that required rulemaking when the agency gives certain kinds of guidance and established FDA's authority to set regulatory limits for contaminants through ordinary rulemaking (rather than a more burdensome statutory procedure that entails a hearing);

Direct Food Additives and Color Additives Used in Food--International Implications, 38 Food Drug Cosmetic Law Journal (1982) 368, 371. See also FDA Oral History Project, interviews with present or former FDA officials, William Horwitz, July 23, 1983, at 51-52; L.W. Beacham, Aug. 28, 1985, at 62; J.W. Cook, June 18, 1980, at 33; and W.V. Eisenberg, July 25, 1984, at 38.

- o the generic drugs bribery scandal of the late 1980s, the consequent undermining of both the public's confidence in the agency and the pride of the FDA workforce;
- o Commissioner Kessler's arrival in 1990 and the seizure of orange juice mislabeled as "fresh" (signaling an end to the laissez faire regulatory philosophy of the 1980s);
- o the enactment of the Nutrition Labeling and Education Act of 1990 and the Dietary Supplement Act of 1992;
- o the United States food agencies' ban on imports of British beef and many bovine products after the discovery that bovine spongiform encephalopathy (BSE) can develop from cattle ingesting feeds with materials from affected animals, and FDA's directive to manufacturers to derive bovine materials in health products from BSE-free countries;
- o approvals in the mid 1990s of the biotechnology-derived Flavr Savr tomato, bovine somatotropin (BST) to increase milk output, and the fat substitute Olestra;
- o FDA's strengthening of its program to regulate seafood (after prevailing in governmental controversy about which United States agency would regulate seafood, with a decision to leave the responsibility in FDA rather than move it to USDA) and, the development and implementation of a landmark 1995 seafood safety rule;¹⁰
- o the increased emphasis on international harmonization and particularly Codex Alimentarius activities, spurred in part by the ratification in 1993 of the North American Free Trade Agreement and in 1994 of the World Trade Organization Agreements;¹¹
- o the January 1997 proposed ruminant-to-ruminant feed ban; and
- o the new attention to infectious disease problems in many countries, followed by a range of national and international initiatives on food borne illness.

¹⁰ 60 FR 65096 (December 18, 1995).

¹¹ The Uruguay Round Agreements resulted in a new WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) that, along with an updated Agreement on Technical Barriers to Trade (TBT), are intended to prevent member countries from using technical regulations and food safety and environmental protection measures as disguised barriers to trade. "Sanitary" refers to protection of people and animals; "phytosanitary" refers to protection of plants.

During this era, United States food and drug requirements have been highly influential around the world--in international standards organizations, when other countries are establishing their own requirements, and in day-to-day choices by other countries' regulatory officials.

IV. International Harmonization for Food: the Challenge

FDA regards international harmonization as important but difficult.

When food crosses international borders, it is expected to meet the requirements of the receiving country, which may be different from those of the country in which it was produced. In these circumstances, the benefits of uniform food laws for firms in international trade are obvious: it is easier to identify what the requirements are, and to comply with one set of requirements rather than many, some conflicting.

The benefits of uniform food laws to consumers are less obvious, but are just as real. If food laws are not only sufficiently protective but uniform--and if uniformity helps producers to understand and comply with the law--the food sold to consumers is more apt to be safe and properly labeled, and the food may also be more economical due to the avoidance of the costs of compliance with duplicative regulation or destruction of noncompliant products.

International approaches to assuring food safety are essential because imports of food into the United States--and into the European Union--have increased tremendously. And regulatory agency resources to monitor imports have not kept pace with this deluge of shipments.

The growth in imports in relation to our very limited resources to inspect them has led FDA to become increasingly interested in knowing more about the conditions and regulations in the countries sending us these products. FDA wants to familiarize itself with regulatory systems in place in other countries that assure that their exports meet our standards.

The difficult phase of aligning FDA standards to those international norms that achieve the requisite level of protection--or, as every country would prefer, promoting international adoption of one's already existing norms--is just beginning. FDA's standards and harmonization policy laid the groundwork (see **Appendix 3**).

The 1996 Administration Report, Reinventing Food Regulations,¹² included several international initiatives:

¹² National Performance Review, Reinventing Food Regulations, January 1996, at 8, 20-21.

- oHarmonizing requirements with international partners to facilitate trade in food commodities without compromising high United States standards of safety;
- oAdopting a preventative system for quality control, Hazard Analysis and Critical Control Points (HACCP), which has been widely adopted as an international standard and by other countries;¹³
- oReforming FDA's standards of identity for food, with adoption of international standards as a promising possibility;¹⁴
- oDeveloping pilot programs to enhance use of private and state or local laboratories for analyzing food imports;¹⁵
- oRelaxing restrictions on exports of animal drugs to countries that have approved such drugs for marketing;¹⁶ and
- oGranting import tolerances for veterinary drug residues in food, whether or not the drug is licensed in the United States.¹⁷

The President's recently announced food safety initiative, and the budget increase request he submitted to the Congress, will further strengthen our program.

The difficulty of the task of harmonizing food regulations should not be underestimated. In the words of one expert, supporters of harmonization will "have to win it drop by drop": and high priority choices with some probability of success fall into two areas: (1) hygiene, contaminants, and inspections, and (2) additives, flavors, and colors.¹⁸ Impediments to United States-European Union harmonization are economic factors (particularly the perception of local sellers that harmonization may be less helpful to them than

¹³ Id. at 7-13. This initiative also involves the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) with respect to meat and poultry.

¹⁴ Id. at 8, 18-19.

¹⁵ Id. at 8, 22-23.

¹⁶ Id. at 8, 23.

¹⁷ Id. at 8, 24.

¹⁸ C. Lister, A World Out of Tune: The Prospects for Harmonizing International Food Law, in Bureau of National Affairs, World Food Regulation Review (June 1996), 19, 21.

to multi-national corporations), fear that harmonization will lead to homogenization (or Americanization), and honest differences of opinion on every food regulatory subject from "lite" to biotechnology.¹⁹

An example of the difficulty of food harmonization is the long-standing controversy between the United States and the European Union concerning the use of hormones for growth promotion in beef cattle. In early 1997, the World Trade Organization (WTO) announced that a draft WTO panel report had concluded that the EU Law on Imports of such beef violated the WTO Agreement on Sanitary and Phytosanitary Measures.

Working in an international forum, such as Codex, can be helpful.

As stated above, procedures for acceptance of Codex standards, announced as a Reinventing Government priority in 1996, have long been a challenge for FDA, due to the need to compare United States standards with Codex standards and consider making harmonizing changes in the United States standards. Shortage of FDA resources to do this work was a problem in the early 1970s and continues today.

With respect to foods and veterinary medicine, FDA foresees the following as its principal activities in the area of international harmonization:

- oContinuing to participate actively in Codex Alimentarius in the development of international standards, to improve procedures for United States evaluation and, where appropriate, acceptance of Codex standards, and to facilitate public participation in that process;
- oPromoting international adoption of United States standards whenever appropriate, e.g., FDA's approach to nutrition labeling;²⁰
- oImproving procedures for consideration of international standards in FDA rulemaking, including procedures for the review of Codex and other international standards, guidelines, and recommendations with a view toward accepting those that provide adequate health protection;

¹⁹ Id. at 20.

²⁰ See, L. Horton, International Harmonization and Compliance, in Nutrition Labeling and Education, R. Schapiro, Ed. (1995). The Nutrition Labeling and Education Act of 1990, Public Law 101-535, 104 Stat. 2353 (1990) gave Americans a wonderfully informative food label that promotes healthy eating habits. However, it has increased the complexity of international harmonization for food labeling.

- oParticipating in the Veterinary International Conference on Harmonization and other activities for harmonizing registration requirements for animal drugs;
- oIntensifying harmonization activities with the European Union and with Canada and Mexico, our North American Free Trade Agreement (NAFTA) partners;²¹
- oEvaluating the food inspection systems of other countries, with the purpose of entering into agreements with those countries having food safety systems that offer equivalent levels of public health protection to those of the United States or that can provide assurance that their products will be in compliance with United States requirements;
- oIssuing guidance on the agency's Memoranda of Understanding (MOUs), particularly those finding equivalence with other countries' systems;
- oGrappling with thorny issues in several areas where there is controversy or disagreement as to policy, law, or both, such as novel foods that are the product of recombinant DNA biotechnology²² and dietary supplement regulation.

We at FDA see the 1990s as the beginning of an era of greater cooperation among food and drug health authorities around the world, including those of the European Union, with corresponding impacts on health and trade.

V. FDA Cooperation with the European Union on Food Regulation²³

For many reasons, FDA views regulatory cooperation with the European Union and others to be vitally important at this time. Regulatory cooperation with other countries and with the European Union is a means of achieving our own regulatory objectives and promoting world public health.

FDA's world has changed a lot in the last two decades, and we now

²¹ These activities include annual Trilateral meetings and efforts of existing technical working groups formed under the Canada/U.S. Free Trade Agreement concerning food additives, pesticides, food labeling and standards, fish products, and veterinary medicine.

²² See FDA, Food Labeling: Foods Derived From New Plant Varieties, 58 FR 25837 (April 28, 1993).

²³ The author is grateful to Naomi Kawin of her staff for drafting section V of this paper.

need to be much more internationally-involved than ever before. As discussed above, new international trade agreements demand our attention, and international standards have taken on new importance.

Thus, we see international regulatory cooperation as a means of helping us achieve our core mission--domestic public health.

What are the means we can use to cooperate with other countries? Three means of cooperation that are very important to us relative to the European Union are bilateral information exchange meetings, harmonization, and equivalence.

A. Bilateral Meetings

FDA has been conducting bilateral meetings with the European Union's Directorate-General III, or DG-III, since the late 1980s. Directorate General III is the part of the European Commission that deals with industrial products, including drugs, medical devices, and processed foods. Representatives of other Directorates General also participate in these meetings. The meetings are generally held annually, most recently in Brussels in January 1997.

At these meetings, FDA and the European Commission share information on a very wide range of common subjects of interest. We find that there is great benefit in getting first-hand knowledge about what is happening in Europe and in developing the professional relationships and contacts with our European partners. We compare notes on policy directions that we are taking and always find that we bring home new ideas.

B. Harmonization

The second form of cooperation with the European Union that FDA is engaged in is harmonization. Harmonization is said to exist when two (or more) countries have a common set of requirements in place.

Sometimes a country must revise an existing standard to achieve harmonization, and sometimes harmonization can be achieved prospectively. Our most successful harmonization effort to date has been in the pharmaceuticals area, that is, the International Conference on Harmonization (ICH) initiative with the European Union and Japan.

The agency believes strongly that harmonization can and should lead to better consumer protection. There is a tendency to focus on the trade reasons for regulatory cooperation, but in matters affecting health and safety, FDA believes that the public health impetus for regulatory cooperation needs to be the principal focus.

C. Equivalence

A third form of cooperation is the United States food agencies' work with the European Union towards regulatory equivalence. Equivalence can be said to exist when two (or more) regulatory systems are different, but achieve the same level of health protection. In other words, the two countries may use different means to achieve the same level of protection against a health risk. The WTO agreements that became effective last year encourage countries to work towards equivalence on food safety issues.

FDA recently finished negotiation of three equivalence-type agreements with the European Union. One agreement covers products that the European Union calls "veterinary products," that is, products--mainly foods--derived from animals such as meat, poultry, seafood, dairy products, and pet food. We are also actively working towards equivalence in certain areas related to drugs and devices, as part of overall mutual recognition agreement (MRA) negotiations.

DG-I leads these negotiations for the EU, with technical representatives from DG-III. At a summit held on May 28, 1997, President Clinton, for the United States, and President Santer, for the EU, announced that the parties had reached agreement in principle on these MRAs.

Part of FDA's mission is to ensure the healthfulness of products imported into the United States, but FDA does not have the resources to inspect many food firms abroad. Consequently, we want to be able to rely on the results of foreign regulatory agencies' inspections of their firms for our own decisionmaking purposes. If we know that another country's regulations are as good as ours, and if we know that their inspection and enforcement system is as good as ours, we can be assured that the products they ship to the United States generally attain our level of health protection. Furthermore, if

we know which of the foreign country's firms are "not in good standing" with the foreign regulatory agency, we could look at those firms' imports more closely when they come to our borders, to be sure that they meet our standards.

With respect to the veterinary equivalence discussions with the European Union, USDA and USTR are participating in these discussions, as well as FDA. USDA is involved because the agreements would cover meat and poultry, which are principally regulated by USDA. USTR and the trade components of USDA are involved, because there is a trade angle to these discussions as well as a public health angle. In 1992 the EU and the U.S. "settled" a trade dispute by agreeing to negotiate on 40 areas of difference. (This mixing of public health and trade aspects has greatly complicated the negotiations and made it much more difficult to reach an agreement than has been the case in the 50 other agreements that FDA already has in place with more than 20 other countries.)

The proposed veterinary agreement would establish what we are calling a "framework" for working towards equivalence on the various products covered by the agreement. The agreement would lay out a consultation process that the United States and the European Union would follow in working towards equivalence, and it sets up various information exchange mechanisms, as well. The consultation process is very important, since equivalence is such a new concept that there could be many different ways of defining it and many ways of determining whether two systems are indeed equivalent.

Each FDA determination of equivalence will address both the equivalence of the foreign country's standards and the equivalence of the country's inspection system (including its compliance activities). In addition, FDA will reach determinations of equivalence for only those product areas where the foreign standards and enforcement system assure the same (or a higher) level of health protection as does the United States regulatory system. FDA will not revise its own standards downward in order to achieve equivalence.

Furthermore, we intend to go through notice and comment rulemaking on each equivalence determination that we reach. In other words, before declaring the seafood regulatory system of the European Union countries to be equivalent to that of the United States, we will seek public comment on the basis for our equivalence determination. (This is actually required in the United States legislation implementing the WTO agreements.)

There had been hopes of having a veterinary equivalence agreement signed by the end of 1996. Unfortunately, that did not happen, as the parties could not reach agreement on a wide range of issues. An agreement in principle was reached on April 30, 1997, but many details were still being worked out in the months that followed.

VI. Opportunities for Increased Cooperation

In sum, we at FDA have seen how cooperation with the European Union can help achieve public health objectives, and it might be productive to outline areas for increased cooperation.

A. Strengthening Codex

In large part because of its recognition in the WTO Agreement on Sanitary and Phytosanitary Measures, Codex is attempting to streamline its standards and its procedures for developing standards.

Similarly, FDA is attempting to update its own procedures regarding acceptance of Codex standards, so that the agency can more easily accept Codex standards when they meet the agency's food safety requirements.

FDA also is interested in improving the procedures by which Codex standards are developed and the transparency (openness) of the development process. Regarding FAO/WHO expert committees, FDA wants to ensure that potential conflicts of interest among expert committee members are revealed, and that the different Codex committees and expert committees that report to Codex follow consistent scientific procedures both in evaluating data and in requirements for the quality and quantity of data--so that the agency and the public can have greater confidence in the scientific quality of Codex standards. The better the quality of the science and the procedures that Codex uses in developing standards, the better the standards, and the easier it will be for FDA to accept them.

The European Commission has already independently expressed concerns similar to some of the ones described, suggesting opportunities for collaboration.

B. The Role of the International Organizations Other Than Codex in Food Harmonization

FDA and the European Commission--and the member states--could work together to help define what the appropriate role should be for ISO, OECD, and environmental programmes in food harmonization activities, particularly considering the tightening of agency resources to staff international activities (and the costs to industry of monitoring duplicative activities).

ISO, the International Organization for Standardization, has a

Technical Committee on Agricultural Food Products ("TC-34"). The United States is neither a participant nor an observer to this group, and our government and industry participates in only a few working groups. We do not have the resources to staff participation in this Committee's work.

OECD is an international organization of advanced industrial economies that has as its aim the promotion of sustainable growth and employment in its members and in the world generally.²⁴ Together, FDA, the European Union, and countries at various stages of accession to the European Union make up a majority of the members of OECD.

Although OECD has many useful activities, including programs on toxicology testing, biotechnology, and good laboratory practices for non-clinical studies, it is important that these programs not duplicate other activities already underway in other fora, e.g., Codex. Also, testing guidelines need to be scientifically sound and realistic.

A similar concern can be expressed about other international activities, that are attempting to cover food and drugs with blanket chemical hazard classification and labeling requirements unsuited for these products. The Intergovernmental Forum on Chemical Safety (IFCS) was created to support sound management of chemicals, improved coordination of related international activities, and establishment of a new intergovernmental mechanism on chemical risk assessment and management.²⁵ The IFCS was a product of the 1992 Rio Summit, the UN Conference on Environment and Development (UNCED).

UNCED recommended the creation of the IFCS to pull together under one umbrella an earlier group--the International Programme on Chemical Safety (IPCS)²⁶ that has had a traditional role, tied to

²⁴ As of 1997, members are Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, South Korea, Spain, Sweden, Switzerland, Turkey, the U.K., and the U.S., OECD News Release, Paris, May 26, 1997.

²⁵ Coordinating Group for the Harmonization of Chemical Classification Systems, Translation of the Technical Work of Harmonization of Chemical Classification and Labeling Systems into an International Instrument or Recommendation Applicable at the National Level, IOMC/HCS7/95.4Draft9.10.95.

²⁶ The IPCS is a consortium of three international organizations--WHO, the UN Environmental Programme (UNEP), and the International Labor Organization (ILO)--that is coordinated by WHO.

Codex, on food safety together with other organizations (OECD, FAO, and the UN Industrial Development Organization, or UNIDO).

The six tasks set by UNCED are to expand chemical risk assessment, to harmonize chemical classification and labeling, to promote information exchange, to enhance risk reduction, to improve national capabilities, to prevent illegal international traffic.²⁷ Because of the role of the IPCS in supporting the scientific assessment needs of Codex, FDA and its European counterparts have an interest in assuring that the food safety activities of the IPCS that support Codex continue to receive support without loss of priority to environmental chemical issues. It is important to guard against the application to foods and drugs of hazard classification and labeling schemes that are scientifically defective, that impose unnecessary costs, or both.

C. Biotechnology

The difficulties in the past two or three years due to perceptions about biotechnology among consumers, particularly in Europe, have led to interest in increasing United States-European Union activities on this topic. There is generally agreement between FDA and the European Commission as to the science and many policy matters. In particular, Commission officials agree that biotechnology is not in need of a special regulatory scheme but can be handled in accordance with established processes for approval of new foods and food additives, pesticides, drugs, and other products. Within some European Union member states, however, the issue of biotechnology is extremely controversial. These views are reflected in consumer organizations active in the Europe and the United States, the green (environmental) parties in the European Parliament,²⁸ and even in the European Council, the principal European Union legislative body.

Even putting aside international organizations such as OECD and Codex that have activities on biotechnology, we now have a plethora of bilateral fora for discussing this topic, and how to reduce public concern about biotechnology products that have been shown to be safe.

Biotechnology is discussed regularly during FDA's bilaterals with the European Commission, in broader United States-European Union consultations such as a periodic meeting known as the United States-European Union Biotechnology Task Force.²⁹ A conference under

²⁷ International Organization Guidebook (1995), at 374.

²⁸ OTA Biotechnology Report, at 187.

²⁹ The New Transatlantic Agenda for the U.S. EU Summit announced the renewal of the mandate for this task force, which "ensures a continued transatlantic exchange of ideas and information in this rapidly changing sector." Senior Level Report, June 12, 1996, at 4.

the auspices of the Transatlantic Business Dialogue was held in April 1997. Additional activities are planned.

The Commission's new novel foods directive is patterned in many ways on FDA's thinking on the subject of what requirements are appropriate for such foods to be placed on the market for the first time. (Novel foods may not be marketed until three months after notification to the Commission if they meet general criteria in an annex, they are supported by scientific data demonstrating safety, and the Commission raises no objection.) The recent difficulty has concerned the question of whether labeling should be required for food biotech generally or only in cases of possible allergens or "ethical concerns."

D. Learning From European Union Harmonization Successes

FDA is aware of recent efforts to modernize old European directives on food composition that are now regarded as unduly detailed and prescriptive. We have a similar problem in the United States. We sense that the Community's work in this area is more advanced in many respects than our own, and we are interested in learning more about it, and looking for useful models upon which to pattern our own regulatory changes. An FDA Deputy Commissioner participated in a Commission meeting to develop a revised approach to food regulation, in May 1997.

We are also interested in ascertaining the current status of two DG-III directives. First, a 1989 General Directive on the Official Control of Foodstuffs describes the general standards for member state inspections but provided no information on the nature and frequency of inspections or the follow-up needed in case of violation, so that foods are removed from the market or barred entry.³⁰ Second, we understand that a 1993 amendment creates a European Union food inspectorate, creates a program of cooperation, sets rules for a mutual assistance system among member states, promotes information exchange on food safety problems (with confidentiality safeguards for commercially sensitive information), requires members' food laboratories to comply with European³¹ and OECD standards. More information about the status of these initiatives would be of interest to United States food regulators.

E. Nutrition Labeling

The American public has found the FDA Nutrition Label to be useful

³⁰ Council Directive 89/397, amended in 93/99 (October 1993). IO Guidebook (1995) at 244.

³¹ Council Directive 85/591 prescribes methods of analysis and sampling.

and informative in making everyday decisions about what foods to buy and eat. An unexpected consequence of the popularity of the label is the establishment of a "bond of appreciation" between the agency and the ordinary consumer.

Because FDA believes in the nutrition label as a valuable public health tool, the agency would like to promote the international acceptance of this approach. The Codex guideline on the subject is quite old (it was modeled on the 1973 FDA regulation that our more recent regulation rejects), and the Codex Alimentarius Commission has listed nutrition labeling as a medium-term priority for updating.³²

The EU law on nutrition labeling is based upon the Codex guideline, and thus upon a now-obsolete FDA regulation. Although the European Commission have in the past been critical of the FDA nutrition label requirements, FDA is hopeful that the EU will be willing to reconsider this label as a useful international model, considering the data collected on how consumers actually use the label in making healthy choices, how minimal the enforcement problems have been with it, and how grateful the consuming public is to FDA for requiring the label.

F. Agreements: Seafood and Good Laboratory Practices (GLPs)

FDA and the European Commission could probably conclude an agreement on seafood and on many aspects of dairy products, even if the overall veterinary equivalence discussions involving DG-VI (discussed above) cannot be solved. Focus on public health issues, rather than trade, would assist in a successful conclusion to the discussions.

³² L.R. Horton, International Harmonization and Compliance, in R. Shapiro, Ed., Nutrition Labeling Handbook, Marcel Dekker, Inc., New York, 85 (1995); C.J. Lewis, A. Randell, and F.E. Scarbrough, Nutrition Labeling of Foods, Comparisons Between U.S. Regulations and Codex Guidelines, Food Control (March 1996).

With respect to GLPs, both FDA and the Commission (DG-III) have requirements that closely resemble OECD guidelines,³³ so that rapid progress was expected in negotiations undertaken in 1993-94 between the FDA and the United States Environmental Protection Agency and the European Commission about a possible agreement. At first, substantial progress was made, before the project was set aside due to FDA and EPA concerns about disparities in European Union member states' systems and a disagreement about the extent of FDA inspections after an agreement is signed. These negotiations could be resumed, after the successful completion of the ongoing pharmaceutical good manufacturing practices negotiations in which similar issues have arisen. Alternatively, current multilateral arrangements in OECD on GLPs may make a bilateral U.S.-EU GLP agreement unnecessary.

Participation by public health-oriented officials from the Commission or member states in the GLP discussions would have facilitated a successful conclusion of this negotiation.

Meanwhile, bilateral MOU's have been entered between FDA and five European Union member states (France, Germany, Italy, the Netherlands, and the United Kingdom). At present only the European Commission has authority to negotiate new MOUs.

G. New Emerging Concerns

As the 1990s draws to a close, it may be advisable for FDA and the European Union to strengthen their capacity to deal with new food safety concerns of all types, as they arise. Examples are coordination of research and regulatory activities concerning BSE, endocrine disruptors (evidence that certain synthetic and naturally occurring organic chemicals might affect female and male sex hormones and thus human cancers³⁴), and spread of food borne illness due to microbial contamination and hygiene problems in the country of origin.

On the issue of new emerging and reemerging diseases, in June 1996, as part of the New Transatlantic Agenda, the United States and the European Union announced the establishment of a United States-European Union Task Force on Communicable Diseases to build a global early warning and response network for such diseases to

³³ OECD Council Recommendation on Compliance with Principles of Good Laboratory Practice C(89)87(Final); OECD Council Decision C(81)30(final). The GLP approach is more stringent and specific than those of ISO Guide 25 on laboratory accreditation.

³⁴ P. Fenner-Crisp, EPA, "Incorporating New Science into Environmental Health Risk Decisions," at the Chemical Industry Institute of Toxicology meeting, April 30, 1996; Food Chemical News, vol. 38, no. 12 (May 13, 1996), at 31-32.

facilitate decisive joint activities to curtail the health threats of the future.³⁵

H. Technical Assistance Coordination

A pressing priority, recognized in one international meeting after another, is for developing countries to improve the safety of water and foods produced for their own consumption, as well as food exports.

Also, the European Union and the United States should help promote implementation of HACCP in other countries, and particularly developing countries.

We should regularly exchange information about technical assistance efforts, either to collaborate or to avoid duplication. For example, FDA has recently embarked on a cooperative activity with India to improve the safety and quality of its shrimp, much of which is rejected by FDA due to failure to meet agency requirements. Earlier, we helped Brazil to reduce salmonella contamination of pepper.

VII. Conclusion

As the 20th century draws to a close, we can see that, at the very time when resources are shrinking, international harmonization activity needs to intensify and food regulators in developed countries such as the United States and the European Union must also confront new challenges (such as products derived from recombinant DNA biotechnology, unique food additives such as Olestra, and the ever-present issue of dietary supplements.) Even older technologies increase the difficulty of harmonization. The sheer numbers of individual substances for use in food or processes for food (pesticides, veterinary drugs, aids in processing, direct food additives, irradiation technologies, and food packaging materials) -- and the tendency of FDA and other advanced regulatory agencies to make decisions on these substances on an individual, one-by-one basis -- magnify the number of decisions lacking international uniformity.

Despite the challenge, much progress has been made. FDA believes that the groundwork is being laid for more progress, in bilateral discussions between the United States and the European Union and in international settings such as Codex Alimentarius.

³⁵ President William Clinton, Press Conference by President Clinton, President Santer of the European Commission, and Prime Minister Prodi of Italy, June 12, 1996, at 2; New Transatlantic Agenda, Senior Level Group Report to the U.S.-EU Summit, June 12, 1996, at 2.

Appendix 1. Other United States Food Agencies (Besides FDA and USDA)

A. EPA

EPA registers pesticides and establishes pesticide tolerances that are enforced by FDA and FSIS. EPA has extensive international activities in the pesticides area, particularly under the auspices of the International Programme on Chemical Safety under the United Nations Environmental Programme, FAO, WHO, Codex Alimentarius, and OECD.

B. BATF

Regulation of alcoholic beverage standards and labeling generally, and product names particularly, are generally handled by the Bureau of Alcohol, Tobacco, and Firearms (BATF) of the Department of the Treasury. FDA approves additives used in these beverages and enforces EPA tolerances for pesticide residues in them.

C. Fee-for-Service Agencies

Commercial needs have led to the creation of fee-paid voluntary grading and inspection services for exports, even for those food products (other than meat, poultry and egg products) that are regulated principally by FDA. Such programs are administered by USDA's Agricultural Marketing Service (AMS) under the Agricultural Marketing Act of 1946,³⁶ the Federal Grain Inspection Service (FGIS), and the Department of Commerce's National Marine Fisheries Service (NMFS).

Appendix 2. Early United States Food and Drug Laws

A. Colonial Era

English common law applied in the American colonies, and early colonial legislatures, starting with Massachusetts in 1784, practiced a form of international harmonization in that they passed food protection laws imitating those of the mother country.³⁷ British enactments had begun as early as the 1203 Assize of Bread, which prohibited adulteration of bread with cheap ingredients,³⁸ leading

³⁶ 60 Stat. 1082 (1946), 7 U.S.C. § 1622.

³⁷ The General Laws and Liberties of the Massachusetts Colony 17 (1672 ed.), Wallace F. Janssen, "America's First Food and Drug Law," 30 Food, Drug, Cosmetic Law Journal 665 (1975).

³⁸ FDA Backgrounder, Milestones in U.S. Food and Drug Law History; Peter Barton Hutt, Government Regulation of the Integrity of the

eventually to parliamentary passage in 1860 of the first nationwide general food law of modern times.³⁹

B. State Laws

After United States independence, state governments carried over such laws,⁴⁰ but 130 years passed before the first comprehensive national law--the Food and Drugs Act of 1906⁴¹--was enacted.

C. Early National Laws

When Congress begun to pass laws that recognized the need for Federal food safety controls, it initially focused upon laws directed toward potentially hazardous imports or exports, or both, due to the existence of some controls at the State level over domestic food. Early national laws included:

- oThe Drug Importation Act, of 1848;⁴²
- oThe Food and Drug Importation and Exportation Act of 1890;⁴³
- oThe Food Importation Act of 1899⁴⁴
 - o The Tea Importation Acts of 1893 and 1897 (repealed in 1996).

Early legislators believed that exporters in other countries, particularly European countries, were dumping substandard and, in some cases, dangerous food and drug products upon the growing American market.⁴⁵ Of course, State governments were ill-equipped to screen

Food Supply, 4 Annual Review of Nutrition 1 (1984), in Hutt and Merrill, Food and Drug Law: Cases and Materials, at 2-3.

³⁹ Wallace F. Janssen, "The U.S. Food and Drug Law: How it Came, How it Works, a reprint from FDA Consumer magazine.

⁴⁰ 23 and 24 Vict., c. 84 (1860).

⁴¹ 34 Stat. 768, June 30, 1906.

⁴² 9 U.S. Stat. 237, June 26, 1848.

⁴³ 26 Stat. 414, August 30, 1890.

⁴⁴ 30 Stat. 951, March 1, 1899.

⁴⁵ James Harvey Young, Pure Food: Securing the Federal Food and Drugs Act of 1906, Princeton University Press, Princeton, N.J., 1989, at 1-17. See the international harmonization chapter on drugs

imports, both legally and practically: the United States Constitution assigned to the Congress, not the states, the task of regulating interstate and foreign commerce, and the concentration of product entries in a few ports, particularly New York, overwhelmed local authorities.⁴⁶

The focus of these early national laws upon imports or exports, or both--rather than food generally--was based, not on a discriminatory rationale, but rather on views that the Constitution assigned to states the task of maintaining adequate control of domestic production or that, even if Federal action was constitutional, state action was adequate. As the country became more urban and industrialized, and less agrarian, views began to change. By the beginning of the 20th century, there had developed a widespread conviction that nationwide, Federal action to assure that food and drugs are neither adulterated nor misbranded was both constitutional and necessary.⁴⁷ Federal laws were seen as girding the strength of State measures that had also, a few years earlier, been upheld as a constitutional exercise of State police power.⁴⁸

D. International Influence Upon Harvey Wiley

An international aspect of FDA's early history was that Harvey Washington Wiley may never have come to Washington in 1883 to become Director of FDA's predecessor, the Bureau of Chemistry, had he not been influenced by food safety research underway in Europe.

In 1878, when Dr. Wiley had moved from practicing medicine to serving as a chemistry professor at Purdue University in Indiana, he asked for a one-year leave of absence in order to study how laboratory research was being conducted on sugar in Vienna, Berlin, Bonn,

and biologics, of the companion volume of this treatise on Food and Drug Law, for a discussion of the problems that led to the Drug Importation Act of 1848.

⁴⁶ Id.

⁴⁷ Mitchell Okun, *Fair Play in the Marketplace: The First Battle for Pure Food and Drugs*, Illinois: Northern Illinois University Press (1986). Hipolite Egg Co. v. United States, 22 U.S. 45 (1911); McDermott v. Wisconsin, 228 U.S. 115, 128 (1913).

⁴⁸ Id. 13, 164. In Plumley v. Massachusetts, 155 U.S. 461 (1894), the Supreme Court upheld the constitutionality of a state oleomargarine law under "the acknowledged power of the States to protect the morals, the health, and safety of their people" including "the protection of the people against fraud and deception in the sale of food products." Id. at 479. See also Crossman v. Lurman, 192 U.S. 189 (1904).

Heidelberg, and Leipzig.⁴⁹ Dr. Wiley returned to the United States with a new passion for examining food products and a firm decision to abandon medicine altogether in order to concentrate upon the study of food adulteration.⁵⁰

Drawing upon what he learned in Europe, Dr. Wiley applied himself to research on the adulteration of honey with glucose and to related work on sugar, earning such national recognition as an expert that he attracted the attention of political leaders in Washington.

Not long after, Dr. Wiley was appointed in 1883 as Chief Chemist in the Bureau of Chemistry in the United States Department of Agriculture.⁵¹ And his interest in international collaboration did not cease: agency records show that Dr. Wiley traveled to a conference in Geneva in 1908 on the subject of food regulation.⁵²

Considering the critical role of Dr. Wiley in laying the scientific and administrative framework for what later became FDA, and in securing the passage of the 1906 Act, that 1878 trip to Europe in search of international answers to United States problems had an undeniable impact upon the birth of modern United States food and drug law and the agency itself!

The Bureau of Chemistry under Dr. Wiley's leadership dedicated itself to research on food adulteration (including tests done on human volunteers known as the Poison Squad) and building support for a comprehensive food and drugs law.

⁴⁹ Suzanne Rebecca White, *Chemistry and Controversy: Regulating the Use of Chemicals in Foods, 1883-1959*, in partial fulfillment of the requirements for a Ph.D., Emory University, Georgia (1994), at 4.

⁵⁰ Id. This early international influence thus shaped FDA: were it not for his European studies, would Dr. Wiley have remained an Indiana physician?

⁵¹ Id. at 25.

⁵² Dr. Wiley Goes to Geneva, FDA Scrapbook [on file in FDA History Office, Rockville, MD].

E. An English Model for What Became the Food and Drugs Act

As discussed above, during the last quarter of the 19th century, public support grew for enactment of a national food and drug law.

And those who think that international harmonization was only a recent priority of FDA may be surprised to learn that the landmark Food and Drugs Act of 1906 was the product of an international harmonization endeavor!

In 1881, amid growing publicity about the use of dangerous substances in food and other products, the United States National Board of Trade sponsored a contest for drafting a proposed food and drug law.⁵³ The winner of the first prize, Dr. G.W. Wigner, was a public policy analyst in England who was knowledgeable about the English laws⁵⁴ and who had reviewed existing law from around the world. A bill based upon his draft was the first to use the term "adulteration" and the first to cover both food and drugs.⁵⁵ In 1888 bills began to prohibit "misbranding," a term that was embraced to capture the notion of "false trade description" in the English antecedent, the British Merchandising Marks Act of 1887.⁵⁶ The purpose of these provisions was to prevent the passing off of food or drugs falsely labeled or branded or otherwise represented to be of standard quality, strength, or purity when they were not.

Thus, the key statutory concepts of "adulteration" and "misbranding" found their way from the mother country to ours, more than a century after independence.

⁵³ Litman, R.C., and Litman, D.S., "Protection of the American Consumer: The Congressional Battle for the Enactment of the First Federal Food and Drug Law in the United States," 37 Food Drug Cosmetic Law Journal, 310, 313 (1982).

⁵⁴ Id.

⁵⁵ Combination of food and drug law in the same basic legislation is more often seen in countries that once were British colonies than in other countries. J.G. Zimmerman, "Food Law--International," 31 Food Drug Cosmetic Law Journal 218, 222 (April 1976). For example, a 1976 German law covered foods, tobacco, cosmetics, and other objects that come in non-casual contact with the human body but not pharmaceuticals. Id.

⁵⁶ Litman and Litman, supra note 53 at 315.

F. The Food and Drug Importation Act of 1899⁵⁷

The first legal mandate for the Bureau of Chemistry arrived as an obscure provision in its appropriations for the year 1900 that authorized the investigation, through inspection and analysis, of the adulteration of foods, drugs, and liquors and to bar entry of imports "which are dangerous to the health of the people of the United States."⁵⁸

A 1903 Act added two new categories of forbidden imports, those bearing false labels and those forbidden or restricted from sale within the nation from which they had been shipped.⁵⁹ Similar provisions are found today in the Federal Food, Drug, and Cosmetic Act.

United States Customs worked out a cooperative arrangement with the Bureau of Chemistry to conduct the necessary analytical work to ascertain whether to admit the products into the United States. After the enactment of the 1899 Act, the Bureau established six import laboratories in major ports (Boston, Chicago, New Orleans, New York, Philadelphia, and San Francisco) and began to enforce the 1899 law.⁶⁰

Thus, the Bureau had experience and infrastructure that later was helpful after Congress passed the Food and Drugs Act of 1906.

G. The Food and Drugs Act of 1906

At last the Congress enacted the landmark Food and Drugs Act of 1906, which outlawed the adulteration or misbranding of food and drugs.

H. Early Meat Inspection Laws

The popular view that Upton Sinclair's The Jungle led to the first United States meat inspection laws is an oversimplification, as United States export interests were the first incentive for Federal action.

The 1890 Food and Drug Importation and Exportation Act,⁶¹ and its

⁵⁷ Id. at 164. 30 Stat. 951, March 1, 1899.

⁵⁸ Id. at 164. 30 Stat. 951, March 1, 1899.

⁵⁹ Id.

⁶⁰ "The United States ceased to be a dumping ground for shoddy foods and liquors sent from abroad," and "[n]o importers took one of the bureau's restrictive decisions to court." James Harvey Young, Pure Food, at 164.

⁶¹ 26 Stat. 414, August 30, 1890.

later refinements,⁶² contained regulatory provisions used by FDA's predecessor, the Bureau of Chemistry in the then Department of Agriculture to bar entry of adulterated food and drugs, and it also gave that Department's Bureau of Animal Industry--predecessor to both FSIS and APHIS--authority to inspect meat exports and imports.

Of interest is that the principal motivating factor in Congressional enactment of this law was response to European demands concerning animal quarantine and meat hygiene requirements.⁶³ European requirements were based, to some degree, upon a genuine concern about the safety of United States meat as well as upon a protectionist response to cheap United States meat shipments from the power packing houses of Armour and Swift. Scare stories about trichinae from American hogs and pneumonia in cattle led to a wave of embargoes against United States meat.⁶⁴

Congress did not accept European doubts about the safety of United States exports but, seeing an opportunity to expand annual exports by \$50 million, decided pragmatically to pass an inspection law to increase confidence in the products.⁶⁵

⁶² 26 Stat. 1089 (1891).

⁶³ James Harvey Young, *Pure Food*, at 130-35. U.S. Trade Representative, USDA, and FDA participants who, as of 1996, are growing weary of discussions with the European Commission's Directorate General VI about its directives' hygiene requirements--or about the E.U.'s continued ban on meat from hormone-treated animals--will draw scant comfort in knowing that the U.S. has been trying for more than a century to satisfy European demands concerning U.S. meat!

⁶⁴ James Harvey Young, *Pure Food*, at 131. Germany, Italy, Portugal, Greece, Spain, France, Austria-Hungary, Turkey, Romania, and Denmark excluded U.S. pork products wholly or in part. While Great Britain did not embargo U.S. meat, its imports fell sharply. See John L. Gignilliat, "Pigs, Politics, and Protection: The European Boycott of American Pork," *Agricultural History* 35 (1961), 3-12; Louis L. Snyder, "The American-German Pork Dispute, 1879-1891," *Journal of Modern History* 17 (1945), 16-28.

⁶⁵ Id. at 132.

The 1890 law forbade export or import of infected cattle and the export of unwholesome meat, authorizing the "careful inspection" (meaning microscopic examination for trichinae) of pork for export.⁶⁶

When other countries protested that the inspection did not include the condition of the hog at the time of slaughter, Congress in 1891 expanded the law to require mandatory antemortem inspection for all live cattle, hogs, and sheep.⁶⁷ Carcasses and products intended for export also were required to be inspected. The law authorized inspection of meat in interstate commerce, but as no funds were appropriated for this provision, it was not implemented, and domestic coverage awaited the Federal Meat Inspection Act of 1906. European reaction to the American measures was mixed:

Representatives from European states came to observe American procedures, and shortly restraints on the acceptance of pork abroad were abandoned or relaxed. Sales soared, by 1895 reaching their preembargo high. . . . [However,] in an effort to assure themselves of avoiding trichinosis while continuing to eat raw pork, Germans, through their local governments, set up an extensive network of microscopists, an inspectional army, in fact, larger in number than the entire enlisted ranks of the United States Army at the outbreak of the Spanish-American War.

The German states insisted on reinspecting imported American pork, charging such high fees as virtually to price it out of the market.⁶⁸

By sending to Berlin in 1898 a highly competent zoologist, armed with a microscope, as United States agricultural attache, the United States countered German concerns and in the process identified weak spots in both the United States export control system and the German states' import control systems.⁶⁹ Germany nevertheless eventually called off its pork embargo. By then, however, the "embalmed beef" scandals of the 1898 Spanish-American War had generated United States' concern about its own meat, another stimulus to the 1906 meat law that predated The Jungle.⁷⁰ This book also was an important factor in the enactment of the 1906 Meat Inspection Act, which provided uniform coverage for United States meat intended for

⁶⁶ James Harvey Young, *Pure Food*, at 133.

⁶⁷ 26 Stat. 1089, March 3, 1891. In 1895, the law was further strengthened. 28 Stat. 727, March 2, 1895.

⁶⁸ Young at 133-34.

⁶⁹ Id. Charles Wardell Stiles, the American attache, had trained in Germany.

⁷⁰ Id. at 130, 135.

domestic markets and provided for enforcement.⁷¹

I. The 1938 Act and World War II

The Federal Food, Drug, and Cosmetic Act of 1938⁷² modernized the Food and Drugs Act of 1906. The agency obtained explicit authority to conduct inspections, establish food standards and issue other regulations, and set tolerances for poisonous or deleterious substances.

When President Franklin Roosevelt moved FDA from the Department of Agriculture to the new Federal Security Agency in 1939, international considerations influenced his decision to let the meat inspection program under Agriculture. With clouds of war on the European horizon, the fear was expressed that reorganizing United States meat inspection into an unknown agency might dampen European confidence in the safety of United States beef at the very time that demand for United States meat shipments was expected to rise due to diminished capacity in war-torn Europe to meet Allied needs.

Appendix 3. Organization of Food Regulation in Other Countries

Despite widely shared beliefs in the importance of food safety regulation, differences in regulatory approaches abound, even in highly developed countries in Europe and North America. In developed countries and even many middle-income and developing countries, food regulatory functions are commonly dispersed among separate agencies.

Few countries have managed to place food authority in one agency.

FDA believes strongly that its placement in the United States Department of Health and Human Services, rather than in the Agriculture Department, has helped it to maintain its vigilant public health orientation over the years. The President's and Vice President's first report on Reinventing Government, issued in 1993, recommended that United States food regulatory programs be brought together under FDA. (Congressional proponents of retaining the meat, poultry and egg products programs in USDA promptly responded by enacting legislation to create a new position of Undersecretary for

⁷¹ Sinclair had said there was never any inspection of meat after slaughter, "except the meat intended for export to Germany, France, and England, where the laws were enforced;" the charge led President Theodore Roosevelt to establish an investigative commission whose report also supported new legislation. Litman, R.C., and Litman, D.S., Protection of the American Consumer: The Congressional Battle for the Enactment of the First Federal Food and Drug Law in the United States, 37 FDCL Journal, 310, 325 (1982).

⁷² 52 Stat. 1040 (1938).

Food Safety that would be kept separate from the production- and trade-oriented parts of the Department.)

Although thwarted in its reorganization proposal, the Clinton Administration has achieved many of its desired regulatory and philosophical reforms at USDA, by rulemaking that is moving meat and poultry inspection to a more modern, risk-based inspection system founded on the principles of Hazard Analysis Critical Control Points (HACCP), and by sending seasoned FDA officials to serve as Administrator, FSIS, and as Acting Undersecretary for Food Safety.

Most importantly, FDA and FSIS are working together as never before on a wide range of activities in the area of food safety, food labeling, and international harmonization.

Questions have arisen as to whether the U.S. government has ever considered creating a separate food agency, independent of any existing Department (along the lines of EPA). The answer is that very little consideration has been given to this idea.

The other question asked is whether consideration has been given to removing FDA, in its entirety, from DHHS. The answer is, yes, in 1972 the Senate passed a bill that would have created an independent Food, Drug, and Consumer Product Agency. The House preferred to leave FDA in DHEW and to create an independent Consumer Product Safety Commission. The House view prevailed. Later in the 1970s, Senator Kennedy espoused a "Drug and Device Agency" and a separate "Food Agency" that would have included veterinary medicine functions. These ideas did not get very far.

The placement of meat and poultry in an agriculture-oriented agency is not unusual.⁷³ The concern is that such a placement may tend to create conflict of interest situations (such as the current BSE situation in Europe). In France, the UK, and Ireland, most or all of the food regulatory responsibilities are under the agriculture ministry. Recently questions have been raised about whether the assignment of food regulatory responsibility in this way creates a potential for conflict of interest when there arises a food borne hazard such as BSE. The issue is whether a ministry that is responsible for both agribusiness and consumer protection can do justice to that latter when there is a threat to the former. Serious questions are being asked about whether adequate steps were taken to contain the spread of the disease and to inform the public and high governmental officials, of the possible risks at hand.

Prior to a recent decision to move certain of its food safety programs

⁷³ One reason for such placement is that control of animal diseases, a function aimed at protecting agricultural production resources, tends to be placed in ministries of agriculture and also involves meat issues.

to DG-XXIV, Consumer Protection, the European Commission had placed most food regulatory responsibility in DG-III, Industry, but assigned to DG-VI, Agriculture, the handling of veterinary products (including seafood), the traditional foods program (to give special protection to traditional appellations like "Parma ham," "feta cheese," and the like), and economic regulatory issues related to the Common Agricultural Program.⁷⁴ Placement of the meat and poultry inspection programs in agriculture ministries also tends to attract more resources-- particularly when there are requirements for antemortem inspection and continuous inspection of processing--and might be a factor in the availability of much fewer resources for the regulation of the foods that make up most of the diet in most countries.

Granted, meat and poultry are inherently more risky than many other foods, but objective risk-based decisions would certainly result in a reallocation of some resources to high-risk foods other than meat and poultry (e.g., seafood, eggs, dairy products, reduction of problems of lead or aflatoxin contamination, microbial risks in already-prepared foods, fruits and vegetables that might contain disease-causing organisms, and improperly canned food). Furthermore, increased resources are needed in the United States and many countries to increase inspectional frequency for firms processing foods generally.

To discuss a few other variations in the organization of food regulation, some countries place seafood inspection under the agriculture agency responsible for meat inspection (Australia, New Zealand, France, UK), while the United States placed it under FDA as the health agency responsible for food generally. Still other countries have a separate fisheries ministry, often with conservation and trade responsibilities as well (Chile, Uruguay, and Thailand).

Another factor in organizing food agencies is conserving resources, aimed at allowing personnel cuts, minimizing overlap, and strengthening coordination. Canada has created a new Food Inspection Agency that will combine forces from its ministries of health, fisheries, and particularly agriculture. The health ministry will write many of the standards for foods generally that will be enforced by the new agency. (The description is that Health Canada will serve as the brains of food regulation while the new inspection agency--comprised largely of inspectors from the ministries for agriculture and fisheries--will serve as the limbs.)

⁷⁴ The European Commission's DG-VI and the Australian Quarantine and Inspection Service (APHIS) combine the animal health aspects, and the human health aspects, of meat regulation into one agency.

Appendix 4. FDA Standards Policy.

On October 11, 1995, World Standards Day,⁷⁵ the Food and Drug Administration published a policy entitled, "International Harmonization; Policy on Standards."⁷⁶ In this document, FDA described the agency's policy on the development and use of standards with respect to international harmonization of regulatory requirements and guidelines:

It is the intent of this policy to enable FDA to:

- (1) Continue to participate in international standards activities that assist it in implementing statutory provisions for safeguarding the public health,
- (2) increase its efforts to harmonize its regulatory requirements with those of other governments, including setting new standards that better serve public health, and
- (3) respond to laws and policies such as the Trade Agreements Act [19 USC 2531-82] and OMB Circular No. A-119 that encourage agencies to use international standards that provide the desired degree of protection.

Accordingly, it is the policy of FDA, concerning the development and use of standards, that:

A. FDA participation in standards development will be based on the extent to which the development activity and expected standard conform to certain factors, with consideration also being given to the resources available in FDA to devote to the effort and expected efficiencies to be gained as a result of the effort; the factors are as follows:

1. The standard stresses product safety and effectiveness and therefore contributes to safe, effective, and high quality products; when necessary, the standard also covers all factors required to ensure safety and effectiveness, including product

⁷⁵ World Standards Day commemorates the founding of the International Organization for Standardization (ISO) on October 14, 1946. In the U.S. its 49th anniversary was October 11, 1995.

⁷⁶ Federal Register of October 11, 1995 (60 FR 53078). This policy document does not create or confer any rights, privileges, or benefits, for or on any person, nor does it operate to bind FDA in any way. In the Federal Register of November 28, 1994 (59 FR 60870), FDA published a draft policy and invited public comment, and in the October 11, 1995 document, FDA responded to comments received.

and process design, and process performance;

2. The standard is based on sound scientific and technical information and permits revision on the basis of new information;

3. The development process for the standard is transparent (i.e., open to public scrutiny), complies with applicable statutes, regulations, and policies, specifically including [21 CFR] § 10.95 and OMB Circular A-119, and is consistent with the codes of ethics that must be followed by FDA employees;

4. The development of an international standard that achieves the agency's public health objectives is generally, but not always, given a higher priority than the development of a domestic standard; and

5. The development of a horizontal standard which applies to multiple types of products is generally, but not always, given higher priority than the development of a vertical standard which applies to a limited range of types of products.

B. FDA is not bound to use standards developed with FDA participation. For example, the agency will not use a standard when, in the judgment of FDA, doing so will compromise the public health.

C. The uses of final (and selected draft or proposed) standards, or selected relevant parts, will include, where appropriate:

- (1) Incorporating such standards into guidance documents for nonclinical testing, applications for conducting clinical trials with investigational products, and applications for permitting products to be marketed;
- (2) conducting reviews of such applications;
- (3) incorporating such standards into compliance policy guides;
- (4) conducting reviews of test protocols used by firms as part of good manufacturing practices;
- (5) conducting reviews of study protocols submitted by firms as required for postmarket surveillance studies or programs;
- (6) serving as the basis for mandatory standards or other regulations promulgated by FDA; and (7) serving as the basis for reference (e.g., evaluation criteria) in a memorandum of understanding with other government agencies.

D. The use of a standard in the regulatory programs of FDA is dependent upon the following factors:

1. The standard stresses product safety and effectiveness and therefore, if adhered to, would help ensure the safety, effectiveness, or quality of products; when necessary, the standard also covers all factors required to ensure safety and effectiveness, including product and process design, and process performance;

2. The standard is based on sound scientific and technical information and is current;

3. The development process for the standard was transparent (i.e., open to public scrutiny), was consistent with the codes of ethics that must be followed by FDA employees, and the standard is not in conflict with any statute, regulation, or policy under which FDA operates;

4. Where a relevant international standard exists or completion is imminent, it will generally be used in preference to a domestic standard, except when the international standard would be, in FDA's judgment, insufficiently protective, ineffective, or otherwise inappropriate; and

5. Where a relevant horizontal standard which applies to multiple types of products exists or its completion is imminent, it will generally be used in preference to a vertical standard, which applies to a limited range of types of products, except when such horizontal standard would be insufficiently protective, ineffective or otherwise inappropriate.

E. FDA employees will comply with agency regulations ([21 CFR] § 10.95) covering participation in standard setting activities outside the agency.