Organizing Federal Food Safety Regulation

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INTRODUCTION

Protecting the safety of food has been a core function of government officials for more than two millennia.[1] It became a responsibility of the United States government in 1906, when Congress enacted the Meat Inspection Act (MIA)[2] and the Pure Food and Drugs Act (PFDA).[3] That responsibility has grown in both importance and controversy throughout this century.[4]

The importance of safe food is obvious.[5] Every individual is exposed to whatever risks the food supply holds on a daily basis for her entire lifetime. Although estimates of the incidence of foodborne illness are imprecise, there is agreement that it is significant and possibly growing.[6] However, most foodborne illnesses are either transitory,[7] and thus unlikely to be the basis for legal claims that would force suppliers to internalize their costs, or difficult to trace to their source.[8] Consumers can protect themselves against some hazards through careful selection and preparation of food, but others are impossible to control at the site of preparation.[9]

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[1] *See* Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2 (1984) (detailing food safety codes from biblical times).

[2] Act of Mar. 4, 1907, ch. 2907, 34 Stat. 1260, *amended by* Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584 (1967).

[3] Act of June 30, 1906, ch. 3915, 34 Stat. 768, *repealed by* 21 U.S.C. § 392(a), Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[4] *See* PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 4-14 (2d ed. 1991) (summarizing the bureaucratic and statutory development of federal food safety regulation). *See also* U.S. FOOD AND DRUG ADMIN., MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY (1999), *available at* http://www.fda.gov/opacom/backgrounders/miles/html (last visited Nov. 11, 2000) (summarizing the history of the FDA's involvement in federal food safety regulation) [hereinafter FDA MILESTONES].

[5] *See, e.g.*, President William Jefferson Clinton, Remarks Supporting Food Safety Legislation, 34 WEEKLY COMP. PRES. DOC. 374, 375 (Mar. 4, 1998) ("Food safety really is part of the basic contract now between the consumers of our country and their Government."). *See also* Secretary of Agriculture Dan Glickman, Remarks at the Kennedy School of Government, Harvard University (Feb. 11, 1998) (transcript available at United States Department of Agriculture, National News Releases, *at* http://www.usda.gov/news/releases/1998/02/0071) ("Food safety is one area where people want strong government. It's the same with airplane safety, bank solvency and national security; people look to government to protect them in ways they cannot protect themselves, and cannot rely exclusively on the private sector to do it either.").

[6] *See, e.g.*, INSTITUTE OF MED. & NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION 1 (1998) ("Although estimates vary widely, there is agreement that foodborne illness is a serious problem.") [hereinafter ENSURING SAFE FOOD].

[7] *See* discussion *infra* Part I.B.

[8] *See, e.g.*, Sharlene W. Lassiter, *From Hoof to Hamburger: The Fiction of a Safe Meat Supply*, 33 WILLAMETTE L. REV. 411, 417-44 (1997) (arguing that civil remedies do not provide meat processors with proper incentives to minimize the risks of foodborne illness).

[9] *See* discussion *infra* Part I.B.1.

We make no attempt to define the proper scope of government in reducing foodborne risks. We take as given that government has many important roles to play, that federal authorities are important actors in fulfilling those roles, and that significant federal resources will, and should, continue to be devoted to these activities. Our interest is in the management and, in particular, the organization of these governmental activities, a subject to which attention has once again been drawn by a series of food poisoning episodes and the criticisms of thoughtful observers of the regulatory process. The critics' central claim, whose implications we seek to explore, is that the organization of federal food protection functions is seriously flawed. To state it baldly, their claim is that there is no "organization" worthy of the name. Instead, responsibility for what should be a holistic task—assuring that marketed foods do not contain harmful microorganisms or toxic materials—is dispersed among several agencies that lack central direction and administer diverse, sometimes inconsistent, statutes.[10] The "reform" implied by this critique is consolidation of federal food safety functions in a single organization, under the direction of an identifiable leader and advocate.

This, in substance, is the message of a recent report from the National Academy of Sciences (NAS), produced by a committee of which one of us was a member.[11] The report, *Ensuring Safe Food From Production to Consumption*, was released in August 1998.[12] It depicted a large problem—the risk of foodborne illness—that may well be growing as eating habits and food preparation practices change and food sources proliferate. The report described the several federal programs that share responsibility for food safety, and it highlighted the puzzling allocation of federal resources among them.[13] The NAS committee recommended:

> Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources

[10] *See, e.g.*, ENSURING SAFE FOOD, *supra* note 6, at 8-9 (arguing that federal food safety statutes are "inconsistent, uneven, and at times archaic"; finding a "lack of coordination" among federal food safety agencies; and noting the fragmentation of food safety agencies and statutes).

[11] *See id.* at iii.

[12] *See id.* The 1998 NAS report was funded by Congress through the FY 1998 Agriculture Department appropriations bill. *See* 143 Cong. Rec. H7518 – H7519 (daily ed. Sept. 17, 1997) (describing the House and Senate conference agreement calling for the NAS to "examine the current mechanisms in place for assuring a safe food supply and the extent to which they are effective in addressing food safety issues from the farm to the table," and directing the agency "to analyze the extent to which current functions . . . should be assigned or reassigned to existing food safety agencies or an independent food safety agency") [hereinafter NAS Panel Appropriation].

[13] *See* summary *infra* Part IV.A.4.

> for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.[14]

This is not the first time that a respected official body has endorsed reorganization of federal food safety functions. In the last fifty years, more than a dozen expert panels inside and outside government have called for the consolidation of the federal agencies that exercise and share food safety responsibilities.[15] Reiteration of these proposals, however, has so far proved impotent. For example, the current federal food safety structure closely resembles the one described a generation ago by the Senate Government Affairs Committee Study on Federal Regulation.[16] Reactions to the NAS Report inspire little confidence that its renewal of a now-familiar prescription will be any more influential.[17] To be sure, the General Accounting Office (GAO) has supported the principle of consolidation,[18] and a few bills have been introduced to achieve it.[19] *The New York Times*, along with several other papers, has repeatedly endorsed efforts to "streamline" federal food safety regulation.[20] But press accounts have

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[14] *See* ENSURING SAFE FOOD, *supra* note 6, at 12.

[15] "Consolidation" can mean many things in regard to federal agencies. Consolidation may include organizational mergers, combinations of statutory responsibilities, creation of new statutory obligations, and transfer of current responsibilities to new organizations. Thus, part of the difficulty that policy makers address in evaluating the concept of consolidation is to pinpoint precisely what proposals for consolidation actually entail. *See* DONNA U. VOGT, CONGRESSIONAL RESEARCH SERVICE, FOOD SAFETY: RECOMMENDATIONS FOR CHANGES IN THE ORGANIZATION OF FEDERAL FOOD SAFETY RESPONSIBILITIES, 1949-1997 (1998), *reprinted in* ENSURING SAFE FOOD, *supra* note 6, at 115-59 (summarizing twenty-one sets of recommendations for consolidating most federal food safety responsibilities into a single federal agency).

[16] *See* STAFF OF SENATE COMM. ON GOVERNMENTAL AFFAIRS, 95th CONG., 5 STUDY ON FEDERAL REGULATION: REGULATORY ORGANIZATION 113 (Comm. Print 1977) [hereinafter STUDY ON FEDERAL REGULATION].

[17] *See, e.g., infra* notes 414-18 and accompanying text (indicating that President Clinton's Council on Food Safety supports the "goal" of achieving "a fully integrated food safety system," but stops short of endorsing the NAS Panel's call for unified food safety framework headed by a single government official).

[18] *See* LAWRENCE J. DYCKMAN, U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/T-RCED-99-256, FOOD SAFETY: U.S. NEEDS A SINGLE AGENCY TO ADMINISTER A UNIFIED, RISK-BASED INSPECTION SYSTEM 6-9 (1999) ("The most effective solution to the current fragmentation of the federal food safety system is consolidating food safety programs under a single agency with uniform authority.").

[19] *See* Safe Food Act of 1999, S. 1281, 106th Cong. (1999); H.R. 2345 106th Cong. (1999) [hereinafter the Safe Food Act]. An identical bill was introduced in 1997 as S. 1465, 105th Cong. (1997) and H.R. 2801, 105th Cong. (1997).

[20] *See The Food Poisoning Toll*, N.Y. TIMES, Sept. 18, 1999, at A16 ("The current system for protecting the public from unsafe food is a dangerously inefficient jumble administered by a dozen different agencies. A promising measure pending in the Senate would create a streamlined system under the authority of a new independent Federal agency. The latest C.D.C. findings make it seem all the more timely."); *Food Safety Confusion*, N.Y.

described a tepid reaction in Congress, which would have to authorize any major restructuring.[21] Moreover, the Clinton Administration conspicuously refrained from endorsing this NAS recommendation.

These varied reactions to the NAS Reports are the stimulus for our inquiry. Our primary interest is not in the explanations for the past lack of congressional enthusiasm for consolidation, or in whether consolidation would make sense if one were designing a federal food safety system from scratch. Rather, we are interested in understanding the obstacles that consolidation would face if undertaken seriously and discovering what past reorganization efforts suggest could be the effects of combining the existing programs in a single organization.

Although we conclude that the obstacles to consolidation are formidable, we do not reject the NAS proposal. Rather, this Article is an effort to explore questions that the NAS committee did not address, such as: What programs should be consolidated? What would be the institutional consequences of combining the Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) with the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN)? Or of removing the FSIS from the USDA? Does experience with similar reorganization efforts suggest consolidation would be successful? We also explore a more fundamental question: To what extent are the indisputably serious challenges confronted by officials charged with protecting food a function of, or aggravated by, the current dispersal of regulatory responsibilities?

Part I of this article surveys the nature and sources of foodborne risks in the United States. Part II reviews the origins of the current governmental structure through an historical examination of the enactment of federal food safety laws and successive proposals for reorganization. Part III describes in more detail the current set of agencies that are responsible for controlling foodborne risks. Part IV summarizes the major proposals for reorganizing federal food safety regulation and examines the reasons offered to support reform of the current regime. Part V examines a recent experiment in regulatory consolidation, the creation and operation of the Environmental Protection agency. Part VI outlines the practical challenges in constructing a plan for food safety consolidation. Finally, Part VII describes the political obstacles to consolidation of federal food

TIMES, Aug. 10, 1999, at A16 ("The Clinton Administration has done much to improve food safety inspection. But further streamlining is clearly in order.").

[21] *See, e.g.*, Clif Wiens, *Single Food Safety Agency Proposed by Durbin*, FOOD CHEM. NEWS, June 28, 1999 ("Broad support is lacking for the measure, with the Clinton administration thus far calling only for better coordination among the respective food safety agencies. Republican backing is limited to one co-sponsor . . . .").

safety assets.

I. FOODBORNE ILLNESS IN THE UNITED STATES

Americans face real—even if difficult to quantify—hazards in the foods they consume. The 1998 NAS panel reported that food-related hazards cause thousands of deaths and millions of illnesses each year.[22]

A. Incidence of Foodborne Illness

Government officials regularly claim that the U.S. food supply is the safest in the world,[23] a claim we have no basis for disputing. Even so, an estimated 5,000 people,[24] or nearly 0.002% of the nation's populace,[25] die each year due to illness caused by foodborne pathogens. Though food poisoning is notoriously underreported, the Centers for Disease Control (CDC) has estimated that foodborne pathogens cause approximately 76 million illnesses and 325,000 hospitalizations annually.[26] One prominent epidemiologist has estimated that upwards of 300,000,000 cases of foodborne illness occur each year.[27] The broad category of "foodborne illnesses" encompasses a variety of medical conditions that together rank second in

[22] *See* ENSURING SAFE FOOD, *supra* note 6, at 1. The CDC is quick to point out that the oft-quoted figure of 9,000 annual food-related mortalities is merely an estimate due to significant underreporting of foodborne illness. *See Sensible Talk About Food Safety*, FOOD INSIGHT, Jul.-Aug. 1998, at 1, 4. Moreover, the CDC has recently updated its estimates of morbidities and mortalities caused by foodborne illness. *See* Mead et al., *infra* note 24, at 607.

[23] While announcing the largest meat recall in U.S. history during the summer of 1997, Secretary of Agriculture Dan Glickman stated, "Today, America has the safest food in the world." Several countries do have lower reported rates of foodborne illness than the United States, however CDC officials put little faith in international food safety comparisons due to differing dietary consumption patterns and reporting requirements for food-related illnesses. *See* Jake Thompson & Paul Hammel, *Is U.S. Food Safer? Ag Secretary Lacks Evidence to Support His Statement*, OMAHA WORLD-HERALD, Dec. 18, 1997, at 12, *available at* 1997 WL 6324884.

[24] *See* Paul S. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607, 607 (1999). Significantly, these estimates include only morbidities and mortalities caused by foodborne pathogens, not long-term illnesses—such as cancer—that may also be caused by food intake.

[25] *See* U.S. Bureau of the Census, *POPClocks*, *at* http://www.census.gov/main/www/popclock.html (last visited Aug. 1, 1999) (listing current population as 273,138,186). Foodborne illness thus accounts for nearly 0.2% of all deaths in the United States. *See* Donna L. Hoyert et al., *Deaths: Final Data for 1997*, 47 NAT'L VITAL STAT. REP. 1, 1 (1999) (reporting 2,314,245 total deaths in 1997).

[26] *See* Mead et al., *supra* note 24, at 607.

[27] *See* Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 694 (1998) (citing an estimate by Dr. Michael Osterholm of the Minnesota State Department of Health).

prevalence only to respiratory disease.[28]

While popular reporting on foodborne illness outbreaks has increased in recent years, the actual trend in incidence is unknown.[29] The Clinton Administration has recently taken steps to improve the government's ability to monitor foodborne illness, but it is difficult to determine whether higher reported rates of food-related morbidity and mortality reflect increased risk or more sensitive monitoring.

B. Nature of Foodborne Risks

Consumers face several types of foodborne hazards. They include microbiological pathogens, intentional and unintentional food additives, naturally occurring toxins, allergens, modified food components, agricultural chemicals, environmental contaminants, animal drug residues, and inordinate consumption of certain dietary supplements.[30] Foodborne pathogens mainly cause gastrointestinal symptoms such as diarrhea, vomiting, and sometimes dysentery.[31] In as many as 3% of cases, however, foodborne illnesses—including those induced by such common pathogens as *Salmonella* and *E. coli* bacteria—may cause more severe symptoms, such as autoimmune thyroid disease, inflammatory bowel disease, neuromuscular disorders, and heart damage.[32] The CDC estimates that 5% of *E. coli* 0157:H7 infections result in renal failure, which can lead to stroke and death.[33]

1. Sources of Foodborne Hazards

Though the magnitudes of different foodborne risks are difficult to measure, their general sources are better understood. They include: (1) contaminated, diseased, or otherwise harmful materials that are not detected and excluded or cleansed; (2) inadequate storage, handling, or processing, which fails to detect and exclude harmful food materials or contaminants of food materials; and (3) purposeful introduction into the

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[28] *See* James A. Lindsay, *Chronic Sequelae of Foodborne Disease*, 3 EMERGING INFECTIOUS DISEASES 443, 443 (1997).

[29] *See* ENSURING SAFE FOOD, *supra* note 6, at 51.

[30] *See id.* at 21.

[31] *See* Lindsay, *supra* note 28, at 443.

[32] *See id.* at 443-50. *See also* David Barstow, *A Deadly Germ Taints a Tradition; E. Coli Devastates Families and Leaves a Fair in Doubt*, N.Y. TIMES, Sept. 20, 1999, at B1 (detailing the symptoms associated with a child's death due to a recent outbreak of *E. coli* 0157:H7).

[33] *See Food Safety: Oversight of the Centers for Disease Control Monitoring of Foodborne Pathogens—Hearing Before the Subcomm. On Human Resources and Intergovernmental Relations of the House Comm. on Government Reform and Oversight*, 104th Cong. 27 (1996) (statement of David Satcher, Director of the Centers for Disease Control and Prevention) [hereinafter David Satcher Congressional Testimony].

food supply of potentially harmful materials (including pesticides, fertilizers, animal drugs, packaging materials, and food ingredients).

Many risks stem from bacteria and parasites that live on or near animals or contact crops during food production, processing, or storage.[34] Because there is a tendency for bacteria to contaminate entire flocks or herds, one contaminant can incubate in a farm or processing plant and eventually contaminate food across wide areas. The effective methods of reducing bacterial risk include basic sanitation (both on the farm and in processing), use of antibacterial agents, application of radiation (for meat and poultry), and pasteurization.[35]

The sources of non-bacterial risk are similarly diverse. Pesticides can contaminate food through agricultural run-off into the water supply and by forming residues on raw agricultural commodities and in prepared foods.[36] Drugs administered to livestock can leave residues in human food. Insect and rodent pests can infect foods in processing and storage plants. Natural contaminants, such as aflatoxin, occur naturally in some foods and may pose risks greater than any chemicals that require regulatory safety approval.[37] Food allergens are ubiquitous and some pose serious risks to sensitive consumers.[38] More recently, federal agencies have become concerned about possible bioterrorist attacks on the food supply.[39]

The dietary choices that consumers make can also affect their risk of disease. Certain foods, such as red meat, are correlated with higher incidence of certain cancers, while others, such as fruits and vegetables, are believed to be linked to lower cancer risks.[40] As Americans have come to rely more heavily on restaurants and processed foods, they have relinquished control over risks inherent in food preparation and storage.[41] And, because consumer

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[34] *See* Natalie Pargas, *Food Safety Initiative to Move Beyond Microbiological Issues, FDA Official Says*, FOOD CHEM. NEWS, Jul. 5, 1999, at 10 (noting ability of *E. coli* 0157:H7 from manure to survive in soil and cross-contaminate food products).

[35] *See id.*

[36] *See generally* Shelia Hoar Zahm & Mary H. Ward, *Pesticides and Childhood Cancer*, 106 ENVTL. HEALTH PERSP. 893 (1998) (discussing pesticide health risks).

[37] *See* Bruce N. Ames et al., *Ranking Possible Carcinogenic Hazards*, 236 SCIENCE 271, 276-77 (Apr. 17, 1987).

[38] *See* Marion Nestle, *Allergies to Transgenic Foods—Questions of Policy*, 334 NEW ENG. J. MED. 726, 726 (1996).

[39] *See* Judith Miller, *Long Island Lab May Do Studies of Bioterrorism*, N.Y. TIMES, Sept. 22, 1999, at A1.

[40] *See* Fabio Levi et al., *Food Groups and Risk of Oral and Pharyngeal Cancer*, 77 INT'L. J. CANCER 705-09 (1998) (finding positive and negative correlations of dietary choices and cancer incidence based on a case-control study of 156 cancer patients and 284 control subjects).

[41] *See* ENSURING SAFE FOOD, *supra* note 6, at 53; Biing-Hwan Lin et al., *Nutrient Contribution of Food Away From Home, in* AMERICA'S EATING HABITS: CHANGES AND CONSEQUENCES 213, 213 (Elizabeth Frazao ed., 1999) (finding that consumer spending on

demand for fresh agricultural commodities has surpassed domestic supply,[42] supermarkets are now stocked with imported fresh foods on a year-round basis. Imported foods may present greater risks than domestically-produced foods because of less rigorous food safety controls or production factors, such as spoilage through shipping.

2. Foodborne Pathogens

According to the CDC, bacterial pathogens such as *Campylobacter*, *Salmonella*, and *E. coli* 0157:H7 are the most common causes of foodborne morbidity and mortality in the United States.[43] The CDC considers *Campylobacter* the most common bacterial cause of diarrhea in the United States, affecting approximately 1% of the population annually.[44] These three bacteria are most commonly found in red meat (especially *Salmonella* and *E. coli* 0157:H7) and poultry (especially *Campylobacter* and *Salmonella*).[45] However, they and other bacteria can also grow on many other types of food, including fruits, vegetables, fish, and juices.[46] The risk of cross-contamination among products regulated by separate federal agencies presents regulators with growing challenges.[47]

Many of the largest outbreaks of bacterial foodborne disease have been caused by consumption of undercooked animal-based foods or foods prepared under unsanitary conditions.[48] Meat and poultry are believed to be the most common sources of these pathogens.[49] Because food preparation conditions

food away from home has increased from about 25% of the food budget in 1970 to about 40% in 1995).

[42] *See* discussion *infra* Part III.G.

[43] *See Incidence of Foodborne Illnesses: Preliminary Data from the Foodborne Diseases Active Surveillance Network (FoodNet)—United States, 1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 189, 191 (1999) [hereinafter *1999 FoodNet Report*]. For a comprehensive discussion of the major foodborne pathogens and several recent outbreaks, see Deliganis, *supra* note 27, at 681-701.

[44] *See* Mead et al., *supra* note 24, at 610 tbl. 2.

[45] *See* ENSURING SAFE FOOD, *supra* note 6, at 53.

[46] *See* FOOD SAFETY AND INSPECTION SERV., U.S. DEPT. OF AGRIC., SALMONELLA QUESTIONS AND ANSWERS (1998), *available at* http://www.fsis.usda.gov/OA/background/bksalmon.htm (last visited Nov. 10, 2000).

[47] Pathogens such as *E. coli* do not obey the product-based boundaries established by the federal government. *See, e.g.*, Amy Waldman, *A Summer Fair, a Deadly Germ, and a Family Mourns the Loss of a Young Child*, N.Y. TIMES, Sept. 7, 1999, at B5 (describing an *E. coli* outbreak at a New York county fair believed to be caused by water contaminated by farm runoff).

[48] For example, a 1995 outbreak of *Salmonella* which led to more than 850 illnesses was caused by the presence of raw meat on a cutting board with vegetables. *See* Janet E. Collins, *Impact of Changing Consumer Lifestyles on the Emergence/Reemergence of Foodborne Pathogens*, 3 EMERGING INFECTIOUS DISEASES 471, 473 tbl. 1 (1997).

[49] *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-96-96, FOOD SAFETY—INFORMATION ON FOODBORNE ILLNESSES 29 (1996).

play so significant a role in the spread of bacterial foodborne pathogens, increasing consumer reliance on commercially prepared foods is likely to take on special importance in the battle against foodborne illness.[50]

The Department of Agriculture's Economic Research Service (ERS) has estimated that illnesses caused by the seven most common foodborne pathogens result in $6.5 billion to $13.3 billion of lost wages and health costs annually (1995 dollars).[51] The ERS has also estimated that the total cost of illness plus the implied value of lives lost due to these pathogens is between $19.7 billion to $34.9 billion per year.[52] Table 1.1 below provides the ERS estimates of incidence as well as illness and death costs caused by six common infectious foodborne agents.

Table 1.1[53]
Selected Foodborne Pathogens: Estimated Incidence and Illness / Death Costs

Pathogen	Morbidities			Mortalities			Cost ($ billion)		
Campylobacter	1,375,000	-	1,750,000	110	-	511	$0.6	-	$1.0
Clostridium			10,000			100			$0.1
E. coli 0157:H7	8,000	-	16,000	160	-	400	$0.2	-	$0.6
Listeria	1,526	-	1,767	378	-	485	$0.2	-	$0.3
Salmonella	696,000	-	3,840,000	696	-	3,840	$0.6	-	$3.5
Staph. Aureus			1,513,000			1,210			$1.2
TOTAL RANGE	**2,080,526**	**-**	**7,130,767**	**1,344**	**-**	**6,546**	**$1.6**	**-**	**$6.7**

In a 1996 study, the CDC analyzed 77,373 cases of foodborne disease reported between 1988 and 1992—a small fraction of the estimated outbreaks.[54] Of these cases, bacterial pathogens caused 90% of cases and 79% of outbreaks. *Salmonella* caused the largest number of illnesses and

[50] Restaurants now take in 43% of consumer spending on food, and the average American over age eight consumed more than four restaurant meals per week in 1996. *See* Collins, *supra* note 48, at 473.

[51] *See* Jean C. Buzby & Tanya Roberts, *ERS Updates U.S. Foodborne Disease Costs for Seven Pathogens*, FOODREVIEW, Sept.-Dec. 1996, at 20, 24.

[52] *See id.* ERS used a value of $5 million per life, which has been adopted by OMB as a midpoint of several hedonic wage valuations. *See* W. Kip Viscusi, *The Value of Risks to Life and Health*, 31 J. ECON. LIT. 1912 (1993)

[53] *See* JEAN C. BUZBY ET AL., BACTERIAL FOODBORNE DISEASE: MEDICAL COSTS & PRODUCTIVITY LOSSES 70 (1996).

[54] *See* Nancy H. Bean et. al., *Surveillance for Foodborne-Disease Outbreaks—United States, 1988-1992*, MORBIDITY & MORTALITY WKLY. REP., Oct. 25, 1996, at 1.

deaths (most due to eating undercooked, infected eggs).[55] The most common practices that led to disease outbreaks were food storage at improper holding temperatures and poor personal hygiene of food handlers.[56]

While researchers are developing more accurate models of the various causes of foodborne illness, public health officials are still struggling to produce good estimates of disease incidence. Table 1.2 summarizes laboratory-confirmed cases of the CDC's seven targeted foodborne pathogens for a sample population of 20.5 million.

Table 1.2
1997 FoodNet Pathogen Detection[57]

Pathogen	Rate per 100,000	Total Cases	Deaths
Campylobacter	27.9	3,974	1
Salmonella	14.2	2,207	12
Shigella	8.3	1,263	1
E. coli 0157	2.1	340	4
Yersinia	0.8	139	0
Listeria	0.5	77	15
Vibrio	0.4	51	0
Total		**8,051**	**33**

As Table 1.2 illustrates, even the most common foodborne pathogens do not seem to present large individual risks. For example, based on the 1997 data above, which may or may not be representative, the risk of dying from *Salmonella* (12 deaths / 15.9 million) was less than one in a million. The occurrence of morbidity from microbial contamination, however, is far more common and can be prolonged and costly for both victims and care-givers. Thus, the population burden of microbial infection seems significant, given the numbers of individuals exposed and the ability to reduce the risk through

[55] *See id.*

[56] *See id.* at 4.

[57] *See* FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, REPORT TO CONGRESS—FOODNET: AN ACTIVE SURVEILLANCE SYSTEM FOR BACTERIAL FOODBORNE DISEASES IN THE UNITED STATES (1998). Cases reported to FoodNet represent only a fraction of the number of total illnesses, since FoodNet monitors only those patients who seek medical attention and submit stool cultures. The actual rates and number of cases are likely to be much higher due to patient underreporting, medical misdiagnosis, and failure to send bacterial samples to a lab that would report the pathogen to CDC. *See generally* FOOD SAFETY AND INSPECTION SERV., U.S. DEP'T OF AGRIC., REPORT TO CONGRESS—FOODNET: AN ACTIVE SURVEILLANCE SYSTEM FOR BACTERIAL FOODBORNE DISEASES IN THE UNITED STATES (1998).

low-cost activities such as proper food refrigeration, washing, and cooking.[58]

3. Food-Use Chemicals

While pathogenic bacteria present the most common food-related risks, other substances, such as pesticides, food additives, and naturally occurring toxins in food, are also potential causes of disease. In the CDC's 1996 study, non-bacterial sources were responsible for nearly 10 percent of foodborne illnesses in the following proportions: chemical agents (2%), parasites (1%), and viruses (6%).[59] Because these hazards are likely to produce illness, if at all, principally through long-term exposure the risks they present are more difficult to measure.

Man-made chemicals—pesticides, additives, animal drug residues—have frequently been characterized as major hazards in food, and they receive close regulatory scrutiny. But the evidence that any of them contribute significantly to morbidity or death is at best ambiguous. In a famous study conducted at the request of Congress, British epidemiologists Sir Richard Doll and Richard Peto estimated that 35% of all fatal cancers among Americans might be attributable to diet.[60] But they emphasized that the dietary constituents of concern were "natural" nutrients, such as fat, which is consumed in excessive amounts, and fiber, which has become less plentiful in American diets. Doll and Peto concluded that food additives could not be responsible for more than 1% of cancer deaths and that pesticides, though probably more toxic as a class, were responsible for an "unimportant fraction."[61] Although some authorities have questioned the Doll and Peto estimates,[62] later reports have failed to demonstrate that man-made additives to food contribute significantly to human morbidity or death.

These substances are, nonetheless, subject to close regulatory oversight, and among them pesticides engender the greatest controversy and attract the greatest attention. Herbicides and insecticides are widely used to increase crop yields and enhance quality and appearance, but they commonly leave residues—albeit at low levels—on the treated raw crops and even in

[58] *See* FOOD SAFETY AND INSPECTION SERV., U.S. DEP'T OF AGRIC., FOOD SAFETY EDUCATION: MAKING A DIFFERENCE IN IMPROVING PUBLIC HEALTH (1998), *available at* http://www.fsis.usda.gov/OA/background/fsed.htm visited Nov. 10, 2000).

[59] *See* Bean et al., *supra* note 54.

[60] *See* RICHARD DOLL & RICHARD PETO, THE CAUSES OF CANCER 1256 (1981).

[61] *See id.* at 1250 (finding that there has been "no general increase in the incidence of liver tumors in developed countries since the long-lasting pesticides were introduced, despite the fact that hepatomas are the principal type of cancer to have been reported in laboratory animals under experimental conditions").

[62] *See, e.g.*, D. Schmahl et al., *Causes of Cancer—An Alternative View to Doll and Peto (1981)*, 67 KLINISCHE WOCHENSCHRIFT 1169, 1172-73 (1989) (concluding that the causes of less than half of all cancers are known and avoidable).

processed foods. Because they are designed to be toxic in order to target pests, pesticides may pose special risks for humans. Consequently, major regulatory efforts are made to minimize pesticide residues in food. Monitored residues are generally within government-prescribed limits, but debate continues over whether these limits are sufficiently protective, particularly of children and other vulnerable segments of the population.[63]

While episodes of acute poisoning from pesticide residues occasionally occur, the more serious risks associated with pesticide use are likely to be the result of long-term exposure. Unfortunately, there are no reliable estimates of these risks. In its 1987 report, *Unfinished Business: A Comparative Assessment of Environmental Problems*, the EPA concluded that pesticide residue exposure posed a high risk to human health.[64] The agency estimated that the one-third of the pesticides now in use cause 6,000 cases of cancer annually.[65] Other groups (including the FDA) have questioned the EPA's estimate, and many argue that in any case the cancer prevention benefits of a diet rich in fruits and vegetables far outweigh the cancer risks associated with pesticides.[66]

We have found no good estimates of the incidence of disease attributable to other potential toxins in food, such as purposeful ingredients (*i.e.*, so-called "direct food additives"), incidental additives (such as carryover residues of veterinary drugs and migrating packaging materials), and inherent or "natural" contaminants of agricultural commodities (such as aflatoxin on peanuts and certain grains). Yet each of these categories of foodborne chemicals is assumed by Congress and the regulatory apparatus to present potential health risks significant enough to justify special prophylactic controls.[67]

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[63] *See* Zahm & Ward, *supra* note 36. Residues on food are not the only source of human exposure to pesticides. They can also contaminate drinking water and areas of the home and yard where they are applied. *See id.*

[64] *See* U.S. ENVTL. PROT. AGENCY, UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS (1987), *available at* http://www.epa.gov/opperspd/history7/unfinish/toc/htm (last visited Nov. 10, 2000).

[65] *See id. See also* U.S. ENVTL. PROT. AGENCY, COMPARING RISKS AND SETTING ENVIRONMENTAL PRIORITIES (1989), *available at* http://www.epa.gov/opperspd/history7/bluebook/toc.htm (last visited Nov. 10, 2000).

[66] *See Review the Implementation of the Food Quality Protection Act: Hearing Before the Subcomm. on Dep't Operations, Oversight, Nutrition, and Forestry of the House Comm. on Agric.*, 106th Cong. 88-89 (1999) (statement of Frances B. Smith, Executive Director of Consumer Alert) (citing an American Cancer Society panel that "did not believe that any increased intake of pesticide residues associated with increased intake of fruits and vegetables poses any risk of cancer") [hereinafter *1999 FQPA Oversight Hearing*].

[67] *See, e.g.*, *Aldicarb as a Cause of Food Poisoning—Louisiana 1998*, 48 MORBIDITY & MORTALITY WLY. REP. 269 (1999); Allison Wright, *CDC Supports FDA's Draft Guidance for Evaluating Human Health Effects of Food Animal Drug Use*, FOOD CHEM. NEWS, Jul. 5, 1999, at 4 (summarizing FDA's efforts to limit antimicrobial resistance in humans through

4. Innovative Food Technologies

U.S. regulators also concern themselves with the potential risks associated with new food production technologies. Though rarely used until very recently, irradiation has been declared a safe and effective method for killing foodborne pathogens by the NAS, the American Medical Association, and the World Health Organization, as well as the FDA.[68] Ironically, the food industry has been slow to adopt this technology because of consumer worries about its safety. Few other technologies have any risk-reducing pedigree, and indeed some are claimed to be the source of new hazards. The controversy between the European Union (EU) and the United States and Canada over hormone-treated beef is but one example.[69]

The reliance of American agriculture on genetically engineered crops has attracted even greater notoriety.[70] The use of genetic techniques to increase crop yields, enhance pest-resistance, and improve the nutritional content of agricultural commodities has raised fears over "Frankenstein foods" in Europe, and similar popular uneasiness seems to be mounting in the United States.[71] Despite controversy, especially in Europe, U.S. regulators have generally affirmed the safety of genetically modified foods.[72] Likewise, the United Kingdom's Chief Medical Officer and Chief

regulation of therapeutic animal drugs); Kevin Adler, *FDA Studies Creating Fumonisin Advisory Levels, But Scientists Believe Far More Research Needs to be Done*, FOOD CHEM. NEWS, Jul. 5, 1999, at 4 (noting the agency's efforts to mitigate the risk of a naturally occurring corn toxin).

[68] *See* Charles W. Schmidt, *Safe Food: An All-Consuming Issue*, 107 ENVTL. HEALTH PERSP. A144, A147 (1999).

[69] *See, e.g.*, Helene Cooper, *U.S. Imposes 100% Tariffs on Slew of Gourmet Imports in War over Beef*, WALL ST. J., Jul. 20, 1999, at A6.

[70] *See generally* Jeffrey Kluger et al., *Food Fight: The Battle Heats Up Between the U.S. and Europe Over Genetically Engineered Crops*, TIME, Sept. 13, 1999, at 42 (noting that in 1998, 26% of the U.S. corn crop and 35% of the soybean crop was grown from genetically modified seeds).

[71] *See* Schmidt, *supra* note 68, at A148; *Seeds of Discontent*, ECONOMIST, Feb. 20, 1999, at 75.

[72] *See* Declan Butler et al., *Long-term Effect of GM Crops Serves Up Food for Thought*, 398 NATURE 651, 651 (1999) (quoting Robert McKinney, director of the National Institutes of Health safety division: "I don't see any problems at all for genetically modified plants in terms of human health."). *But see* Jeffrey K. Francer, *Frankenstein Food or Flavor Savers? Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 258 n.10 (2000) (citing Sheldon Krimsky, *Simple and Complex Models of Genomics and Their Impact on Risk Assessment and Regulation of Bioengineered Food Products* 2 (Oct. 1999) (forthcoming manuscript, presented at the Colloquium on the Risks and Regulation of GMO Food Products, New York University School of Law) ("Rarely, if ever, in the modern history of technological risk, has there been a global debate of such intensity and polarization on a subject for which there is so little definitive knowledge, so much conjecture, and so little mutual understanding"))).

Scientific Advisor recently concluded: "There is no current evidence to suggest that . . . [genetic modification] technologies used to produce food are inherently harmful."[73] Yet there remains a concern that genetic techniques can transfer the allergenic traits of one crop to another and put at risk a subset of consumers who may unwittingly be exposed to allergens.[74] The uncertainty surrounding the risks of genetically modified foods has caused the EU to mandate special labeling of foods derived from genetic modification.[75] U.S. regulators, on the other hand, have thus far deemed such labeling to be unnecessary unless specific foods present safety risks or exhibit properties that are not substantially equivalent to current foods.[76]

The controversy over foods derived from genetically modified organisms provides a window on the fragmented nature of food safety regulation in the United States. Under the government's "Coordinated Framework for Regulation of Biotechnology," foods, drugs, medical devices, biologics, and pesticides developed through modern biotechnology are regulated within the same statutory framework as comparable products made using traditional techniques.[77] Thus, the FDA has primary jurisdiction under the Federal Food, Drug, and Cosmetic Act (FDCA) over the regulation of foods developed by biotechnology.[78] The EPA retains jurisdiction over the creation and environmental release of foods with pesticide qualities that are manufactured using biotechnology through the Toxic Substances Control Act[79] and the Federal Insecticide, Fungicide, and Rodenticide Act.[80] Meanwhile, the USDA regulates the release of new plants into the environment, including those produced by modern biotechnology.[81]

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[73] LIAM DONALDSON & SIR ROBERT MAY, HEALTH IMPLICATIONS OF GENETICALLY MODIFIED FOODS 2 (1999), *available at* http://www.doh.gov.uk/gmfood.htm (last visited Nov. 10, 2000).

[74] *See, e.g.*, Nestle, *supra* note 38.

[75] *See* Council Regulation 258/97, 1997 O.J. (L 43) 1 (providing for mandatory labeling of genetically modified products in the European Union).

[76] *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (1992) (declaring that FDA would not require specialized labeling of genetically modified foods as a class).

[77] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,304 (1986).

[78] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1994)).

[79] Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601-2692 (1994)).

[80] Act of Oct. 30, 1947, ch. 125, 61 Stat. 163 (codified as amended at 7 U.S.C. §§ 136-136y (1994)).

[81] *See, e.g.*, Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms, 60 Fed. Reg. 43,567

II. HISTORICAL ORIGINS OF THE FEDERAL FOOD SAFETY BUREAUCRACY

Though nearly a century old and now widely dispersed, today's federal food safety bureaucracy originated in a single cabinet department, the USDA. The job of assuring that food is safe, however, has sometimes seemed an uncomfortable fit with the Department's primary mission of assisting and promoting U.S. agriculture. As a result of this perception, the formal dispersal of food safety functions began in 1940, when the FDA was removed from the Department of Agriculture. Long before this formal restructuring, however, administrative separation was encouraged by statute. In 1906, Congress created separate legal regimes for regulating meat products and non-meat foods, and responsibility for administering these two laws fell to separate departmental units.

A. Foundations of Federal Food Safety Regulation

Established in 1862, the Department of Agriculture's primary mission has always been to aid and promote American agriculture. In creating the Department, Congress specified that its "general design and duties" were "to acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture . . . and to procure, propagate, and distribute among the people new and valuable seeds and plants."[82] The Department's original legislation did not mention food safety, but the USDA was the logical place to lodge responsibility when Congress decided that the federal government had a role in assuring the purity of food.

The earliest federal food law, enacted in 1883, sought to prevent importation of adulterated tea.[83] In 1886, Congress passed the first statute aimed at the adulteration of domestic food.[84] This statute taxed margarine and sought to regulate butter and cheese imitations. The legislation was, of course, designed to protect dairy farmers from the growing threat of competition from margarine as much as to protect consumers.[85] Three years later, Congress appropriated funds for a "Chemical Division," whose purpose was to enable the Secretary of Agriculture to extend and continue the investigation of "the adulteration of foods, drugs, and liquors.[86] Thus, the

(1995) (amending USDA regulations requiring notification and permitting of field testing of genetically engineered organisms under authority of the Federal Plant Pest Act and the Federal Noxious Weed Act).

[82] 7 U.S.C. § 2201 (1994).

[83] *See* STEPHEN WILSON, FOOD & DRUG REGULATION 10 (1942).

[84] *See id.* at 13-14.

[85] *See id.* Significantly, this first federal regulation of dairy safety, which was justified on food purity grounds, was also a form of economic protectionism. The use of food safety and wholesomeness standards to mask economic exclusion remains one of the significant barriers in contemporary international trade.

[86] *See id.* at 12.

Bureau of Chemistry, the precursor of today's FDA, was based in a department whose primary mission at the time was to assist American food producers.

1. Passage of the Pure Food and Drug Act and the Meat Inspection Act

Congress prohibited food adulteration in the District of Columbia in 1879, but it took nearly thirty more years and the defeat of 190 bills before legislation was passed to prohibit the marketing of adulterated food in interstate commerce.[87] A coalition that included the American Medical Association, the American Public Health Association, labor unions, and consumer groups formed to support the legislation, and to overcome the opposition of food producers.[88] The publication of Upton Sinclair's *The Jungle* helped persuade President Theodore Roosevelt to support, and Congress to pass, the PFDA and the MIA on the same day in 1906.[89] The PFDA made it a misdemeanor to introduce adulterated food into interstate commerce. It granted the Secretary of Agriculture the authority to examine food specimens for possible adulteration and directed the Secretary to report potential violations to the Department of Justice.[90] The MIA established the program of continuous examination by resident federal inspectors in meat processing facilities that persists to this day.[91] Implementation of the PFDA was assigned to the new Bureau of Chemistry, and the Department's Bureau of Animal Industry assumed responsibility for administering the MIA.[92]

2. Friction Within the USDA

During the period between the passage of the PFDA in 1906 and the transfer of what was to become the FDA to the Federal Security Agency in 1940, relations within the USDA were often turbulent. Dr. Harvey Wiley, Chief of the Bureau of Chemistry from 1883 until 1912, had long been an advocate for the federal government's responsibility for food safety, and had actively advised the congressional committees that drafted the PFDA.[93]

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[87] *See id. See also* HUTT & MERRILL, *supra* note 4, at 6-9 (summarizing early state and federal food and drug laws).

[88] *See* HARVEY WILEY, THE HISTORY OF A CRIME AGAINST THE FOOD LAW 52 (1929).

[89] *See* WILSON, *supra* note 83, at 36 (describing Roosevelt's active role in the passage of the Meat Inspection Act after reading *The Jungle*); *see also id.* at 401.

[90] *See* 21 U.S.C. § 11 (1906), *repealed by* 21 U.S.C. § 392(a), Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[91] *See infra* note 247.

[92] *See* ARTHUR D. HERRICK, FOOD REGULATION AND COMPLIANCE 35 (1944).

[93] *See* WILEY, *supra* note 88, at 51 (revealing that Dr. Wiley accompanied the House Interstate and Foreign Commerce Committee in executive session as the PFDA was finalized).

According to several accounts, Agriculture Secretaries under whom Wiley served often attempted to dampen his vigorous approach to regulation. Between 1907 and 1911, the Department declined to publish at least a dozen of the Bureau's scientific reports on such topics as the use of sulfur dioxide in fruits, corn syrup as a synonym for glucose, the use of glycerin in meat preparation, and the bacterial content of shell eggs.[94] Only a year after the PFDA was signed, the Secretary created a new Board of Food and Drug Inspection, whose official role was to advise the Secretary on issues of food and drug enforcement but whose objective, Wiley believed, was to counterbalance the influence of the Bureau of Chemistry.[95]

The Bureau of Chemistry suffered an important defeat in 1908. President Roosevelt, who took saccharin every day on the advice of his doctor, became enraged when he learned that the Bureau was considering banning the sweetener as an adulterant.[96] Roosevelt had previously appointed Dr. Ira Remsen, the discoverer of saccharin, to chair a new Board of Consulting Scientific Experts to help resolve issues of food and drug safety.[97] After the Board advised that saccharin was safe, and the industry engaged in heavy lobbying, Secretary of Agriculture James Wilson kept the product on the market.[98] A critical House committee later charged: "Thus the administration of the [PFDA] began with a policy of compromise between the Secretary and the purveyors of our national food supplies."[99]

Because of the perceived conflict between the Bureau of Chemistry's production research duties and its enforcement responsibilities, pressure grew to separate the Bureau's two functions.[100] Even Secretary of

[94] *See id.* at 63-64.

[95] *See id.* at 158. The effect of this Board was to dilute the power of Dr. Wiley. Prior to the establishment of the Board of Food and Drug Inspection, the Bureau of Chemistry alone advised the Secretary on enforcement matters, as the Bureau was the only USDA agency mentioned in the PFDA. When the Secretary of Agriculture placed two of his allies in positions on the new three-person Board with Dr. Wiley, the chief of the Bureau of Chemistry called the situation "a complete paralysis of the law." *See id.*

[96] *See generally* Richard A. Merrill & Michael R. Taylor, *Saccharin: A Case Study of Government Regulation of Environmental Carcinogens*, 5 VA. NAT. RESOURCES L.J, 25-26 (1985).

[97] *See id.* at 163. According to another account, Roosevelt had appointed the Remsen Board to help the Bureau address the controversial issue of the safety of food preservatives, such as benzoate of soda. *See* CLAYTON A. COPPIN & JACK HIGH, THE POLITICS OF PURITY 125-27 (1999).

[98] *See* Merrill & Taylor, *supra* note 96, at 26-27. Seventy years later, the Bureau of Chemistry's successor agency, the FDA, would once again be rebuffed—this time by Congress—in an attempt to ban saccharin as a carcinogenic food additive. *See id.* at 49-57.

[99] Report of the House Committee on Expenditures in the Department of Agriculture, as quoted in WILEY, *supra* note 88, at 180.

[100] *See* VOGT, *supra* note 15, at 3 (quoting Michael Brannon, *Organizing and*

Agriculture Wilson acknowledged what Wiley had characterized as "the antagonism between research and practical chemistry."[101] Dr. Walter Campbell, who succeeded Wiley as Chief of the Bureau, proposed separating the Bureau's research and enforcement responsibilities, suggesting that the latter be assigned to a new Food, Drug, and Insecticide Administration (FDIA) still within the USDA.[102] In 1927, Congress adopted Campbell's proposal and created the FDIA, assigning it responsibility for enforcement of the PFDA.[103] Three years later the USDA deleted the "I" from the agency's name, leaving the title that we use today.[104]

3. The 1938 Federal Food, Drug, and Cosmetic Act

The next major overhaul of federal food safety law occurred in 1938 with the passage of the FDCA,[105] which, with the Fair Labor Standards Act[106] passed the same year, was one of the last two domestic legislative achievements of the New Deal.[107] In a pattern later repeated many times, Congress acted in response to public outrage over the government's apparent inability to assure product safety. The immediate catalyst was the death of 107 people who ingested an untested drug, elixir of sulfanilamide.[108] The FDCA's most significant innovation was the requirement that new drugs be shown to be safe before marketing,[109] but it also enlarged the FDA's food safety authority.[110] The Act authorized the

Reorganizing FDA, *in* SEVENTY-FIFTH ANNIVERSARY COMMEMORATIVE VOLUME OF FOOD AND DRUG LAW 142 (1984)).

[101] The Secretary of Agriculture testified at hearings before the split of food safety research and regulatory responsibilities within USDA that "[r]esearch work and regulatory work do not mix any more than water and oil." WILEY, *supra* note 88, at 369. Dr. Wiley, whose early "poison squad" had conducted some of the earliest applied food safety research in the U.S. government called this split "a regrettable mistake." *See id.* at 370. Wiley's position has been substantially vindicated, as the FDA currently spends approximately $25 million per year on food safety research apart from its more traditional regulatory activities. *See* ENSURING SAFE FOOD, *supra* note 6, at 183.

[102] *See id.*

[103] *See* VOGT, *supra* note 15, at 3-4.

[104] *See id.*

[105] Act of June 25, 1938, ch. 675, 52 Stat. 1040 (codified at 21 U.S.C.A. §§ 301-397 (West Supp. 1999)).

[106] Act of June 25, 1938, ch. 676, 52 Stat. 1060 (codified at 29 U.S.C.A. §§ 201-219 (West Supp. 1999)).

[107] *See* CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL vii (1970).

[108] *See* FDA MILESTONES, *supra* note 4.

[109] *See* 21 U.S.C. § 355 (1994) (providing for pre-market approval of new drugs).

[110] *See* WILSON, *supra* note 83, at 137-48. For a brief comparison of the 1906 PFDA to the 1938 FDCA see also JACKSON, *supra* note 107, at 195-96.

agency to inspect factories,[111] establish safety tolerances for unavoidable poisons,[112] and create identity and quality standards.[113] It also required manufacturers to label food ingredients.[114]

Passage of the 1938 Act was protracted.[115] When new food and drug legislation was first proposed in 1933, public attention was focused elsewhere. In addition, the bill faced strong opposition from food and drug trade groups.[116] President Franklin Roosevelt wrote in 1933, "I hope we can get . . . [the FDCA] through in spite of the lobbies."[117]

One of the battles in the struggle to enact the FDCA revolved around which agency should have authority to regulate the advertising of foods, drugs, and cosmetics. While many in the food and advertising industries favored FDA regulation—based on the agency's presumed scientific expertise—the Proprietary Association and the Institute of Medicine Manufacturers argued that jurisdiction should rest with the Federal Trade Commission (FTC).[118] Some manufacturers saw FTC regulation as less threatening.[119] In particular, they appreciated that the FTC could only issue orders to cease advertising that it found false in formal proceedings, whereas the FDA had, or would be given, power to seek criminal penalties for past violations.[120] In the end, the FTC was given exclusive jurisdiction to regulate the advertising of food, drugs, medical devices and cosmetics by the Wheeler-Lea Act of 1938.[121] Only much later was the FDA given limited authority over the advertising of prescription drugs and, later still, of restricted medical devices.

B. The FDA's Removal from the USDA

President Roosevelt moved the FDA out of the USDA in 1940. While the agency had never represented a significant financial responsibility for the

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111 *See* 21 U.S.C. § 374 (1994) (providing FDA with inspection authority of food, drug, medical device, and cosmetic production facilities).

112 *See* 21 U.S.C. § 346 (1994) (allowing FDA to promulgate tolerances for substances that "cannot be avoided" in food production).

113 *See* 21 U.S.C. § 341 (1994) (authorizing FDA to promulgate food identity and quality standards to promote "honesty and fair dealing").

114 *See* 21 U.S.C. § 343(q) (1994) (establishing nutritional labeling standards).

115 *See* HUTT & MERRILL, *supra* note 4, at 4.

116 *See* JACKSON, *supra* note 107, at 26-27.

117 *Id.* at 27 (quoting personal letter from President Roosevelt to Harvey Cushing (Apr. 21, 1933)).

118 *See id.* at 90-92.

119 *See id.* at 90 (citing *Beware of the Medicine Man*, NEW REPUBLIC, Mar. 6, 1935, at 90).

120 *See* JACKSON, *supra* note 107, at 90.

121 Act of Mar. 21, 1938, ch. 49, 52 Stat. 111. *See also* JACKSON, *supra* note 107, at 171-74.

Department, claiming substantially less than 1% of its total budget in 1933, many saw a conflict between the agency's food safety mission and the Department's primary goals.[122] By the 1930's, groups such as Consumer's Research, the predecessor of Consumer's Union, were calling for the FDA's removal from the USDA.[123] They envisioned a new agency that "would be staffed with men disposed to take as prompt and effective steps in a food and drug and health emergency as the Department of Agriculture now does on the Mexican bean beetle, the corn-borer, a grasshopper plague, or an epidemic of hog cholera."[124]

The USDA fought to retain the FDA. Surprisingly, it offered instead to trade away its meat inspection responsibilities. In 1939, Henry Wallace wrote to Roosevelt: "[Meat inspection] might be associated with other health or public-welfare work. Meat inspection is of course a technical job and it seems logical to have the technical inspectors attached to the bureau most competent in this field."[125] Arguing that the FDA would fit better in the new Federal Security Agency (FSA), however, a Bureau of the Budget staff member advised the President:

> It is true that most food traces back to the soil, and hence to agriculture, but it is not to be believed that the activities of the Department of Agriculture in tomato culture, for example, vests it with any legitimate interest in canned tomatoes where the problem becomes one of toxicity, under measure, adulteration, or deceptive labeling.[126]

The latter argument apparently carried the day. On April 11, 1940, Roosevelt proposed to transfer the FDA into the FSA, explaining in his message to Congress:

> The work of the Food and Drug Administration is unrelated to the basic functions of the Department of Agriculture. There was, however, no other agency to which these functions more appropriately belonged until the Federal Security Agency was created last year. I now believe that the opportunity for the Food and Drug Administration to develop along increasingly constructive lines lies in this new Agency.[127]

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[122] *See* ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS—DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS 254 (1933) (stating that the food and drug budget of the USDA was $1 million out of the $300 million total Department budget in 1933).

[123] *See id* at 276. Kallet and Schlink were writers for Consumer's Research.

[124] *Id.* at 277.

[125] Memo from Henry Wallace to Franklin D. Roosevelt (April 20, 1939), *quoted in* STUDY ON FEDERAL REGULATION, *supra* note 16, at 140.

[126] Memorandum from the Bureau of the Budget to Franklin D. Roosevelt (undated), *quoted in* STUDY ON FEDERAL REGULATION, *supra* note 16, at 140.

[127] Franklin D. Roosevelt, Message to Congress (April 11,1940), *quoted in* WILSON, *supra* note 83, at 150.

A new unit in the executive branch, the FSA had only been in existence since 1939.[128] At the time of the FDA's transfer, the Federal Security Administrator oversaw the Public Health Service, the Civilian Conservation Corps, the Office of Education, and the Social Security Administration.[129] A decade after World War II, these and additional functions were aggregated in a new cabinet Department of Health, Education, and Welfare (HEW).[130]

The FDA's transfer from the USDA was effected by Roosevelt's "Reorganization Plan Number Four,"[131] issued pursuant to the Reorganization Act of 1939,[132] which had called on the President to recommend consolidation within the rapidly growing New Deal executive branch.[133] Roosevelt's Plan stated in part: "The Food and Drug Administration in the Department of Agriculture and its functions, except those functions relating to the administration of the Insecticide Act of 1910 and the Naval Stores Act, are transferred to the Federal Security Agency . . . ."[134]

Thus, by the end of 1940, the Roosevelt Administration had attempted to resolve the apparent conflict in federal food regulation that had frustrated Dr. Wiley while in the service of the President's older cousin. But the separation of regulation from promotion was not complete. Meat and poultry inspection remained the responsibilities of the USDA's Bureau of Animal Husbandry, later renamed the FSIS. Regulation and market surveillance of non-meat products were performed by the FDA, part of the FSA and much later the Department of Health and Human Services (HHS).[135]

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[128] *See* VOGT, *supra* note14, at 4.

[129] *See id.*

[130] *See* HUTT & MERRILL, *supra* note 4, at 5.

[131] *See* Reorganization Plan No. IV § 12, *reprinted in* 54 Stat. 1237 (1940).

[132] Act of Apr. 3, 1939, ch. 36, 53 Stat. 561, *amended by* Reorganization Act of 1966, Pub. L. 89-554, 80 Stat. 394 (codified at 5 U.S.C.A. § 901 (West Supp. 1999)).

[133] The Reorganization Act directed the President to investigate the organization of federal agencies to determine changes that would (1) decrease expenditure; (2) enhance efficiency; (3) consolidate agencies by their major goals; (4) decrease the number of federal agencies by consolidating ones with similar functions, and; (5) eliminate overlapping and duplicative efforts. *See id.*

[134] *See* Reorganization Plan No. IV § 12, *reprinted in* 54 Stat. 1237 (1940).

[135] The FSA became the HEW in 1953. HEW became HHS in 1979, after the creation of the separate Department of Education. For a chronology of the relationship between FDA and its parent agencies, see HUTT & MERRILL, *supra* note 4, at 4-5.

C. Origins of Administrative Fragmentation

The jurisdictional boundaries that divide federal food safety functions are anchored in the bifurcated statutory framework that Congress created in 1906. In addition to enacting separate laws for meat and non-meat foods, Congress divided authority to make rules implementing the PFDA among three entities. The 1906 Act provided that "the Secretary of the Treasury, the Secretary of Agriculture and the Secretary of Commerce . . . shall make uniform rules and regulations" for implementing the statute.[136] This led Wiley to complain that the Bureau of Chemistry actually served three masters based in three separate cabinet departments.[137]

The original dispersal of regulatory authority over food established the pattern that is evident today. By 1949, as the Hoover Commission noted, the FDA regulated food labeling while the FTC oversaw food advertising; the FDA set limits for and monitored pesticide residues on food while the USDA was responsible for approving the marketing of pest control agents used by farmers; the FSA regulated human drugs while the USDA monitored drugs used in livestock; and the Department of the Treasury administered the tax on margarine and imitation cheeses and regulated the labeling of alcoholic beverages.[138]

Two generations later, the federal food safety "organization chart" had become even more complex. In 1970, President Nixon reassigned responsibility for pesticide regulation from the USDA to the new EPA.[139] The EPA was also assigned the FDA's responsibility (and personnel) for setting and enforcing pesticide tolerances on food.[140] Research on food, nutrition, and health became divided among several units within the USDA and shared with the CDC and the National Institutes of Health.[141] The Commerce Department was for many years responsible for regulating the harvesting, processing, and shipment of seafood—a function that the USDA and the FDA both believed they could perform better.[142] In

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[136] 21 U.S.C. § 3 (1906), *repealed by* 21 U.S.C. § 392(a), Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[137] *See* WILEY, *supra* note 88, at 89 (describing a regulation signed by the Secretaries of Agriculture, Treasury, and Commerce that overruled the Bureau of Chemistry's labeling requirements for corn syrup).

[138] *See* U.S. COMM'N ON ORGANIZATION OF THE EXECUTIVE BRANCH OF THE GOVERNMENT, THE HOOVER COMMISSION REPORT (McGraw-Hill ed., 1949) 250-51 [hereinafter THE HOOVER COMMISSION REPORT].

[139] *See* discussion *infra* Part VI.A.

[140] *See id.*

[141] *See* ENSURING SAFE FOOD, *supra* note 6, at 182-83.

[142] *See* Daniel P. Puzo, *Seafood Faces Inspections; Consumers: Congress Is Considering Mandatory Regulation to Replace Current Voluntary Efforts*, L.A. TIMES, Jul. 26, 1990, at H42.

addition, during the decades following the EPA's creation, Congress enacted several new laws or amendments to existing laws that enlarged the duties of the several agencies that exercised food safety responsibilities.[143] One result of this proliferation, ironically, was to embed the oldest programs even more firmly in the organizations where they were first rooted.

D. Pesticide Regulation and the Birth of the EPA

Since World War II the federal government has administered companion legal regimes for regulating the marketing of agricultural pesticides and protecting consumers from unsafe residues on food. These programs are governed by two separate statutes, which are currently administered by another governmental entity—the EPA. Unlike the FDA and the USDA, which hold more generalized food safety responsibilities, the EPA's involvement in food safety is focused on one class of products: pesticides.[144]

Congress passed the first federal pesticide law, the Insecticide Act,[145] in 1910 to regulate the labeling of pesticides. The Bureau of Chemistry, later the FDA, performed the testing necessary to set allowable levels for pesticide residues on food. During the early part of the century, one third of the Bureau's staff was involved in pesticide regulation.[146] This role sharpened the tension implicit in the Bureau's location within the USDA, and it was not long before critics of the agency were warning the public about the conflict between its public health responsibilities and the Department's responsibility to assist producers of food. The authors of the famous *100,000,000 Guinea Pigs* wrote in 1933:

> [W]ith numerous fruit growers completely unequipped for removing the spray residue, with the staff of Government inspectors available for fruit inspection far too small to exercise more than a fraction of the necessary supervision, and with the Food and Drug Administration, in its usual fashion far more concerned about the economic interests of the

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[143] *See, e.g.*, Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1513 (1996); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997); Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

[144] This is not completely accurate. The EPA is responsible for administering the Safe Drinking Water Act ("SDWA"), pursuant to which it regulates systems that supply potable water to homes and businesses, including food processors. Water is a "food" when intended for ingestion. By memorandum of understanding, The FDA and the EPA have divided responsibility for assuring the safety of water. Under the SDWA, the EPA regulates public drinking water supplies—and the agents they use to purify or filter them—while the FDA confines itself to bottled water.

[145] Act of Apr. 26, 1910, ch. 191, 36 Stat. 331.

[146] *See* WILSON, *supra* note 83, at 63; KALLET & SCHLINK, *supra* note 122, at 48-49.

> growers than about the health of the public, one must be blind to suppose that a large part of the supply of apples and pears and many other fruits and vegetables is not contaminated with far more arsenic than is legally permitted.[147]

Indeed, while the Bureau reduced the allowable level of arsenic on apples for export in order to avoid a British boycott, the Secretary of Agriculture, under pressure from U.S. growers, set the level for domestic apples two and one-half times higher.[148] Despite claims that industry had captured the pesticide program, however, when the FDA was removed from the USDA, responsibility for administering the Insecticide Act was left with the Department.

In 1947, Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[149] replacing the outdated Insecticide Act. The FIFRA required pesticide manufacturers to obtain federal (then USDA) approval before shipping any pesticide for use on food crops.[150] Responsibility for setting permissible residue levels on food, however, remained with the FDA, operating under the FDCA.[151] Congress amended the FDCA in 1954[152] and again in 1958[153] to confirm the FDA's authority to set safe "tolerances" for pesticides on food and place on industry the responsibility of conducting the tests necessary to set limits that would protect consumers.[154] Thus, until 1970, the FDA and the USDA divided responsibility for pesticide regulation.[155]

In 1970, President Nixon transferred the responsibility for administering the FIFRA to the newly created EPA.[156] At the same time, Nixon also assigned to the EPA the tolerance-setting function that the FDA had been performing.[157] With these changes, the administration could be said at last to have addressed the charges of agricultural industry "capture" of pesticide regulation expressed in *100,000,000 Guinea Pigs*. The EPA now registers pesticides under the FIFRA and establishes safe tolerances

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147 KALLET & SCHLINK, *supra* note 122, at 48 (footnote omitted).

148 *See* WILSON, *supra* note 83, at 64.

149 Act of Oct. 30, 1947, ch. 125, 61 Stat. 163.

150 *See* 7 U.S.C. § 136a (1994).

151 *See* 21 U.S.C. § 346a (1994).

152 *See* Act of July 22, 1954, ch. 559, 68 Stat. 511.

153 *See* Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958).

154 *See* 21 U.S.C.A. § 346a (West Supp. 1999) (providing EPA Administrator with authority to promulgate tolerances).

155 *See* HUTT & MERRILL, *supra* note 4, at 306-07.

156 *See* Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15,623 (1970), *reprinted in* 42 U.S.C.A. § 4321 (West 1999), *and in* 84 Stat. 2086 (1970) [hereinafter Reorganization Plan No. 3] (establishing the EPA).

157 *See id.*

for food-use pesticides under the FDCA.[158] It also recommends "action levels" for the FDA to apply to pesticide residues that accidentally appear on foods for which they are not approved.[159] The FDA and the USDA enforce the limits on pesticide residues prescribed for their respective product categories.[160]

E. Geographic Dispersal

The fragmentation of federal food safety programs is not only statutory and administrative, it is physical as well. The major participants—the USDA, the FDA, and the EPA—are based in several different locations in and around the nation's capitol. The FDA occupies forty buildings in more than eighteen locations around Washington, D.C.[161] The Center for Food Safety and Applied Nutrition has field personnel in five regional offices, twenty-one district offices, sixteen laboratories, and 120 resident posts that serve as bases for its investigators.[162] The USDA's several programs with food safety-related functions are equally widely distributed.[163] In contrast, the EPA's pesticide program is large, but physically centralized.[164]

This snapshot of the bureaucratic landscape does not reflect the even more obvious dispersal of personnel and facilities that is the inevitable result of a system that depends, critically, on physical examination of facilities and of products. The USDA's meat and poultry inspectors are based in approximately 6,000 establishments.[165] The FDA's field inspection force is officed in fewer locations but is responsible for monitoring nearly ten times as many business establishments.[166] Nor does this account address the administrative structure or operating locations of

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158 *See* 21 U.S.C.A. § 346a (West Supp. 1999).

159 *See* HUTT & MERRILL, *supra* note 4, at 307.

160 *See* 21 U.S.C. § 346 (1994).

161 *See* U.S. FOOD AND DRUG ADMIN., BUILDINGS AND FACILITIES, *at* http://www.fda.gov/oc/oms/budget/faclegres.htm (last visited Nov. 9, 2000).

162 *See* U.S. FOOD AND DRUG ADMIN., DESCRIPTION OF FIELD ACTIVITIES, *in* FY 2000 BUDGET REQUEST (1999), *available at* http://fda.gov/pc/oms/ofm/budget/fieldfoods.htm [hereinafter FDA FIELD ACTIVITIES].

163 FSIS alone has eighteen district offices and a technical center. *See* 9 C.F.R. § 300.3(c) (1999).

164 *See* Interview with Jon Cannon, Professor of Law, University of Virginia School of Law (October 23, 2000). Until 1998, Professor Cannon served as General Counsel to the Environmental Protection Agency.

165 *See* U.S. DEP'T OF AGRIC., FOOD SAFETY, *in* USDA BUDGET SUMMARY (1999), *available at* http://www.usda.gov/agency/obpa/Budget Summary/2000/text.html#fs (last visited Nov. 10, 2000).

166 In 1998, FDA performed 5,013 direct inspections on food establishments and contracted to the states for an additional 4,279 inspections. *See* FDA FIELD ACTIVITIES, *supra* note 162.

other governmental entities, most notably fifty state and many more local bodies that have important roles in assuring safe food or in investigating outbreaks of foodborne disease.

Table 2.1[167]
Selected Food Safety and Quality Statutes and Relevant Implementing Federal Agencies

Legislation	**Relevant Implementing Food Safety Agencies**
Agricultural Marketing Act of 1946	AMS, FSIS
Agricultural Marketing Agreement Act of 1937	AMS
Egg Products Inspection Act	FDA, AMS
Federal Anti-Tampering Act	FDA, AMS, FSIS
Federal Food Drug, and Cosmetic Act	FDA, EPA
Federal Insecticide, Fungicide, and Rodenticide Act	EPA
Federal Meat Inspection Act	FSIS
Federal Import Milk Act	FDA
Infant Formula Act of 1980	FDA
Lacey Act	NMFS
Magnuson Fishery Conservation and Management Act	NMFS
National Ocean Pollution Research and Development and Monitoring Planning Act	NMFS
Pesticide Monitoring Improvements Act	FDA
Poultry Products Inspection Act	FSIS
Public Health Service Act	FDA
Safe Drinking Water Act	FDA, EPA
Toxic Substances Control Act	EPA
U.S. Grain Standards Act	GIPSA

[167] *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-91-19A, FOOD SAFETY AND QUALITY—WHO DOES WHAT IN THE FEDERAL GOVERNMENT 16 (1990).

III. THE CONTEMPORARY STRUCTURE OF FOOD SAFETY REGULATION

The current federal food safety bureaucracy is multi-layered and separated by statutory boundaries defined either by product category or regulatory function.

A. Overview

Four federal agencies share primary responsibility for federal food safety. The largest of these, the USDA's Food Safety and Inspection Service (FSIS), regulates meat[168] and poultry[169] through the continuous inspection of processing operations and review and approval of product labels.[170] The FDA, through its Center for Food Safety and Applied Nutrition (CFSAN), monitors the safety and labeling of most non-meat and processed foods, and licenses food-use chemicals other than pesticides.[171] The EPA Office of Pesticide Programs (OPP) registers pesticides and sets pesticide tolerances that are enforced by the FDA or the FSIS.[172] Finally, the CDC is the federal government's primary clearinghouse for disease morbidity and mortality surveillance data, and its chief resource for epidemiological investigations.[173]

In addition to the four major organizations, at least a dozen other federal agencies play ancillary or supporting roles in the government's regulatory efforts. They include the USDA's Agricultural Marketing Service; the USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA); the USDA's Office of Risk Assessment and Cost-Benefit Analysis; the Commerce Department's National Marine Fisheries Service (NMFS); the USDA's Agricultural Research Service (ARS); the USDA's Animal and Plant Inspection Service (APHIS); the USDA's Cooperative State Research, Education, and Extension Service (CSREES); the USDA's Economic Research Service (ERS); the Treasury Department's Bureau of Alcohol, Tobacco and Firearms (ATF); the Federal Trade Commission (FTC); and the U.S. Customs Service.[174]

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168 *See* 21 U.S.C. §§ 601-695 (1994).

169 *See* 21 U.S.C. §§ 451-471 (1994).

170 The FSIS also regulates the safety and labeling of egg products and enforces EPA pesticide tolerances in meat, poultry, and egg products. *See* 7 U.S.C.A. § 138a (West 1999) (establishing a laboratory accreditation program for monitoring pesticide residues in agricultural products); 9 C.F.R. § 590 (1999) (providing egg product standards).

171 *See* 21 U.S.C. §§ 301-397 (1994).

172 *See* 7 U.S.C. §§ 136-136y (1994); 21 U.S.C § 342(a)(2)(B) (1994).

173 *See* U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, NCID SURVEILLANCE ACTIVITIES, *at* http:/www.cdc.gov/ncidod/ncidsurv.htm (last visited Nov. 9, 2000) [hereinafter NCID SURVEILLANCE ACTIVITIES].

174 *See generally* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-91-19A, FOOD SAFETY AND QUALITY—WHO DOES WHAT IN THE FEDERAL GOVERNMENT (1990). For a

Table 3.1
Federal Safety Responsibilities for Selected Food Products

Food	Regulator(s)	Comments
Alcoholic Beverages	ATF, FDA	ATF licenses and inspects breweries/distilleries. FDA oversees wine coolers.
Eggs	FDA, AMS, FSIS, APHIS	FDA has lead jurisdiction over shell eggs. FSIS continuously inspects egg products. AMS operates a voluntary grading program. APHIS monitors animal health.
Fruits and Vegetables (includes genetically enhanced varieties)	FDA, EPA, USDA	EPA and USDA share pesticide regulation responsibilities. FDA enforces standards for pesticide residues on processed food.
Grain	FDA, GIPSA, EPA	GIPSA establishes and enforces identity standards through inspection. FDA enforces standards for pesticide residues on processed food.
Meat and Poultry	FSIS, FDA	FSIS inspects meat during processing. FDA holds regulatory authority once meat leaves the slaughtering or manufacturing plant.
Processed Foods	FDA	FDA is responsible for most non-meat products.
Seafood	FDA, NMFS	FDA oversees seafood safety generally. NMFS runs a voluntary inspection service.
Water	FDA, EPA	EPA regulates tap water, FDA bottled water.

more recent, but less detailed, overview of the respective agencies with federal food safety responsibilities, see also U.S. FOOD AND DRUG ADMIN., FOOD SAFETY: A TEAM APPROACH, *available at* http://www.fda.gov/opacom/backgrounders/foodteam.html (last visited Nov. 9, 2000) [hereinafter FOOD SAFETY: A TEAM APPROACH].

As Table 3.1 indicates, several classes of food are subject to regulation by more than one agency. For example, grain, the paradigmatic American commodity, has many overseers. Identity standards for grain are established and enforced by the GIPSA,[175] pesticide residues on grains are regulated by the EPA[176] and enforced by the FDA,[177] and grains that become ingredients in processed food are potentially subject to FDA regulation as food additives.[178] Seafood and eggs are both subject to regulation by two agencies, the FDA and the USDA for eggs, and the NMFS and the FDA for seafood.[179] And while the USDA traditionally inspects meat processors, the FDA shares with the USDA authority to carry out surveillance and enforcement of meat adulteration standards once products have left USDA-regulated processing plants.[180] Further overlap is occasioned by the FDA's responsibility for approving additives to meat and poultry products.[181] Such fragmentation can be confusing to consumers who often address complaints to the wrong agency.[182]

B. The Food and Drug Administration

1. The FDA's Food Safety Responsibilities

The FDA may have the most diverse set of food safety duties. The agency bears some responsibility for the safety and wholesomeness of most food sold in interstate commerce other than meat or poultry.[183] Yet, both its food safety budget and workforce are much smaller than those available to the FSIS. Food safety is not the FDA's only, and certainly no longer its major, responsibility. The agency is also supposed to assure the safety and

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[175] *See* 7 C.F.R. § 2.81 (1998) (delegating grain standard-setting and inspection responsibilities to the Administrator of GIPSA).

[176] *See* 7 U.S.C. § 136a(a) (1994) (establishing that no pesticide may be distributed that is not registered by the EPA).

[177] *See id.* § 342(a)(2).

[178] *See id.* § 321(s) (defining regulated food additives).

[179] *See, e.g.*, 21 C.F.R. § 102.54 (1998) (establishing FDA standard for seafood cocktails). *But see* 50 C.F.R. § 261.101 (1994) (defining standards for NMFS voluntary seafood inspection service). *See also* 7 C.F.R. § 2.79 (1998) (delegating egg grading authority to the Administrator of AMS). *But see* 7 C.F.R. § 59.411 (1998) (authorizing FDA review of egg product nutritional labels).

[180] *See* 21 U.S.C. § 679(b) (1994) (providing the FDA with statutory authority—in the Meat Inspection Act—to regulate meat products that have left the manufacturing plant).

[181] *See* 9 C.F.R. § 318.7 (1999) (describing FSIS authority to approve substances used in the preparation of meat and poultry products).

[182] Interview with FSIS field personnel (Feb. 17, 1998).

[183] *See* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION, FDA ALMANAC (1998), *available at* http://www.cfsan.fda.gov/~lrd/almcfsan.html (last visited Nov. 9, 2000) [hereinafter FDA ALMANAC].

clinical effectiveness of all drugs and medical devices.[184] In addition, it regulates cosmetics, blood products, radiation-emitting products, veterinary drugs, and a host of exotic medical technologies, such as gene therapy, tissue transplants, and human cloning.[185]

The FDA uses a variety of means to protect the safety of food. The agency performs pre-market safety reviews of food and color additives and animal drugs.[186] It periodically inspects food processing and storage operations.[187] It establishes and enforces regulations governing food labels.[188] Though federal law does not demand their pre-market approval, the FDA monitors the safety of dietary supplements,[189] infant formulas,[190] and medical foods.[191] It also has formal authority to police sanitation in supermarkets and restaurants, but it relies on state and local officials to inspect and oversee such establishments.[192] Finally, the FDA conducts research—although on a much smaller scale than the USDA—to improve its understanding of the health risks posed by foodborne chemicals and microbiological contaminants.[193] The FDA's authority stems chiefly from the frequently amended FDCA, but it is also authorized to implement parts of some thirty other statutes, including the Public Health Service Act[194] and the Egg Products Inspection Act.[195]

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[184] *See* 21 U.S.C.A. § 393(b)(2) (West 1998) The FDA's broad mission requires the agency to:

> protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; and public health and safety are protected from electronic product radiation.

Id.

[185] *See id.*

[186] *See id.* § 348.

[187] *See id.* § 374 (providing inspection authority).

[188] *See* 21 U.S.C. § 331(b) (1994) (prohibiting the misbranding of any food in interstate commerce).

[189] *See id.* § 321(ff) (deeming dietary supplements to be foods and therefore exempt from FDA premarket approval requirements for drugs).

[190] *See id.* § 350a.

[191] *See* HUTT & MERRILL, *supra* note 4, at 39.

[192] *See* 21 U.S.C. § 342(a)(4) (categorizing foods that have been "prepared, packed, or held under insanitary conditions" and may have become contaminated or injurious to health as adulterated).

[193] *See, e.g.*, Statement of Organization, Functions, and Delegations of Authority, 62 Fed. Reg. 2,674 (1997) (referring to certain FDA databases on toxicology and carcinogenicity).

[194] Act of July 1, 1944, ch. 373, 58 Stat. 682 (codified at 42 U.S.C. §§ 201-300qq-91(1994)).

[195] Pub. L. No. 91-597, 84 Stat. 1620 (1970) (codified at 21 U.S.C. § 1031-1056 (1994)). FDA also implements portions of the Controlled Substances Act, the Lead Based Paint Poisoning Prevention Act, the Sanitary Food Transportation Act, the Filled Milk Act, the

The FDA's main food safety functions are divided between its headquarters Center for Food Safety and Applied Nutrition (CFSAN) and sizable force of field inspectors and laboratories. Roughly speaking, the Center establishes the standards, and the agency's field personnel are largely responsible for assuring that they are met. Together these units oversee a vast industry that includes more than 30,000 domestic food manufacturers and some 20,000 food warehouses.[196]

Another facet of the FDA's food safety responsibility is its regulation of animal drugs and feeds. Some animal drugs can reduce or prevent foodborne illness in humans by controlling animal pathogens, but others may leave harmful residues that could enter the human food supply.[197] Approximately 80% of U.S. livestock and poultry are given drugs during their lifetime.[198] The FDA's Center for Veterinary Medicine (CVM) is the unit responsible for pre-market approval of new animal drugs and, in cooperation with the agency's field inspectors (and the USDA), for surveillance of animal drug use to minimize any risk posed by drug residues.[199]

2. The FDA's Approach to Food Safety

The FDA's food safety functions fall under two broad headings. The agency is concerned with threats of acute poisoning caused by the presence of harmful microorganisms that may contaminate or grow in food. It is also responsible, in cooperation with the EPA, for controlling potentially toxic materials that get into food through human activity. In confronting the first challenge, the FDA's primary instruments are the establishment and enforcement of standards for the selection, preparation, storage, and

Federal Import Milk Act, the Trademark Act of 1946, the Federal Anti-Tampering Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Controlled Substances Import and Export Act, the 1997 Modernization Act, the Federal Trade Commission Act, and the Generic Animal Drug and Patent Term Restoration Act of 1988. Moreover, FDA operates under several general procedural statutes such as the Administrative Procedures Act, the Federal Advisory Committee Act, the Government in the Sunshine Act, the Congressional Reports Elimination Act of 1982, federal fines and sentencing guidelines, and the GATT Uruguay Round Patent Provisions. *See* U.S. FOOD AND DRUG ADMIN., COMPILATION OF LAWS ENFORCED BY THE U.S. FOOD AND DRUG ADMIN. AND RELATED STATUTES, *available at* http://www.fda.gov/opacom/laws/lawtoc.htm (last visited Nov. 11, 2000).

196 *See* FDA ALMANAC, *supra* note 183.

197 *See Food Safety: Oversight of the FDA Center for Veterinary Medicine: Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Reform and Oversight*, 104th Cong. 19 (1996) (statement of Dr. Michael Friedman, Deputy Commissioner for Operations, U.S. Food and Drug Administration) [hereinafter CVM Hearing Testimony].

198 *See id.* at 20.

199 *See id.* at 19.

handling of ingredients and finished foods. The agency has promulgated regulations prescribing general "good manufacturing practices" covering all food processors as well as categorical standards for specific classes of products, such as low-acid canned foods.[200]

Two categories of food within the FDA's jurisdiction present significant risks of microbial contamination. One is seafood, for which the FDA shares responsibility with the Department of Commerce through the NMFS.[201] In 1995, the FDA promulgated regulations that mandate Hazard Analysis and Critical Control Point (HACCP) regulation of seafood products.[202] HACCP is a quality assurance strategy that requires producers and transporters to: (1) identify significant food risks (*e.g.*, bacterial contamination) that can occur at every stage of production, transport, and storage; (2) specify validated processes to control such risks (*e.g.*, refrigeration); and (3) establish record-keeping and monitoring procedures to verify effectiveness and detect errors.[203] Some observers have criticized the FDA's largely voluntary seafood HACCP plan for failure to assure adequate oversight of seafood producers.[204]

The FDA also shares with the USDA jurisdiction over shelled eggs, one of the greatest *Salmonella* risks, with the USDA.[205] In a May 1998 advance notice of proposed rulemaking, the FDA and the FSIS announced that they intended to propose regulations to improve the safety of eggs. The regulations would require eggs packed for consumer use to be refrigerated during distribution and mandate a label on packages that refrigeration is needed.[206] Debate continues over the future of the FDA's continued oversight of eggs.[207]

Monitoring compliance with food processing standards is a labor-intensive activity, but the FDA lacks the resources to inspect more than a

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200 *See* HUTT & MERRILL, *supra* note 4, at 269-83.

201 *See* 50 C.F.R. § 260 (1999) (describing the Commerce Department's voluntary seafood inspection program); Michael Friedman, M.D., FDA Deputy Commissioner for Operations, Statement before the Subcommittee on Livestock, Dairy, and Poultry, Committee on Agriculture, U.S. House of Representatives (May 22, 1996), *available at* http://www.fda.gov/ola/1996/cfood.html (last visited Nov. 11, 2000) (summarizing responsibilities of the FDA and other agencies in seafood inspection).

202 *See* Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule, 60 Fed. Reg. 65,095 (1995) [hereinafter Seafood Rule].

203 *See id.* at 65,097; *see also* Lee-Ann Jaykus, *The Application of Quantitative Risk Assessment to Microbial Food Safety Risks*, 22 CRITICAL REVS. IN MICROBIOLOGY 279 (1996) (describing the methodology and implementation challenges of quantitative risk assessment protocols for foodborne hazards).

204 *See, e.g.*, Daniel P. Puzo, *Unsafe at Any Meal?*, L.A. TIMES, Jan. 6, 1994, at H1.

205 *See* notes 443-447 *infra* and accompanying text.

206 *See Salmonella Enteritidis* in Eggs, 63 Fed. Reg. 27,502, 27,509 (1998).

207 *See* note 447 *infra* and accompanying text.

small percentage of food processors.[208] The FDA's regulatory approach thus differs significantly from that employed by the FSIS for meat and poultry. FDA inspectors typically visit any of the approximately 50,000 regulated food processors or warehouses only once every few years.[209] Rather than attempting to inspect all of the producers under its purview, the FDA relies heavily on prescribed performance standards and the good faith of food manufacturers to implement them.[210] This does not mean that the FDA's standards are ignored, for firms have significant incentives to self-monitor for quality and cleanliness. The fact remains, however, that the FDA's inspection resources are stretched thin and indeed have declined in relation to the number of domestic and foreign firms subject to inspection. The growing share of the U.S. food supply made up of imported foods is a source of concern among some members of Congress and public health groups. A recent General Accounting Office (GAO) report asserted that "The FDA's inspections have not kept pace with the growing volume of imported foods."[211] The 1998 NAS Report came to a similar conclusion.[212]

3. Pre-market Licensure of Food Use Chemicals

The second major focus of the FDA's food safety responsibilities is reflected in its regulation of chemicals that are added to, or likely to appear in, food. The agency is responsible for evaluating—and, often, for approving—the safety of ingredients added to processed foods, including foods subject to USDA inspection.[213] This responsibility is imposed by the 1958 Food Additives Amendment[214] to the FDCA, which requires that any "food additive" be found by the FDA to be safe.[215] The 1960 Color Additive Amendments[216] establish a similar requirement for colors added to food (or drugs or cosmetics).[217] The FDA devotes significant resources to these licensing programs because the FDCA not only mandates that it

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208 *See, e.g.*, ENSURING SAFE FOOD, *supra* note 6, at 87 ("FDA's shrunken inspection force is seriously over-extended, and FDA appears to have insufficient resources to meet its statutory obligations.").

209 *See* Michael R. Taylor, *Preparing America's Food Safety System for the Twenty-First Century—Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD & DRUG L.J. 13, 16 (1997).

210 *See id.*

211 U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED 94-192, FOOD SAFETY: CHANGES NEEDED TO MINIMIZE UNSAFE CHEMICALS IN FOOD 51 (1994).

212 *See* ENSURING SAFE FOOD, *supra* note 6, at 89-90.

213 *See* HUTT & MERRILL, *supra* note 4, at 284-86.

214 Pub. L. No. 85-929, 72 Stat. 1784.

215 *See* 21 U.S.C. § 348 (1994).

216 Pub. L. No. 86-618, 74 Stat. 397.

217 *See* 21 U.S.C. § 379e (1994).

review new ingredients, but obligates it to act within a prescribed time limit, an obligation the agency often fails to meet, despite its best efforts.[218]

The CFSAN's Office of Premarket Approval has responsibility for monitoring the safety of two classes of ingredients that do not meet the technical definition of a "food additive": Substances sanctioned by the FDA or the USDA before 1958 and substances that are claimed or have been found to be "generally recognized as safe."[219] In addition, the statutory definition includes food-contact materials that might contaminate food.[220] The FDA's responsibility for reviewing petitions for the latter class of chemicals has caused a major drain on the Center's resources. The Office of Premarket Approval currently employs over fifty reviewers and in 1999, claimed $11.4 million, representing about 12% of the Center's 1999 budget and 5% of the agency's total spending on food safety.[221]

The agency scientists who review petitions for food and color additives are also responsible for another facet of the FDA's food safety program targeted at environmental contaminants of food. Substances like mercury, PCBs, and aflatoxin contaminate several foods, and can pose serious potential health risks. Industrial accidents and other surprise discoveries may suddenly add to the program's workload, demanding analysis by headquarters scientists and enforcement efforts by field personnel.

4. The FDA's Food Safety Budget

With a fiscal 1998 budget exceeding $1 billion and nearly 9,000 full-time-equivalent employees (FTEs), the FDA has grown dramatically since its removal from the USDA in 1940, but so have its responsibilities.[222] Furthermore, in recent years the budget for food regulation has shrunk to less than one quarter of the agency total,[223] or less than one-third of the

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[218] *See id.* § 348(c)(2) (providing a 180-day limit on the FDA's review of new food additive petitions); § 379e(d)(1) (providing similar time restrictions on FDA review of color additive petitions).

[219] *See id.* § 321(s) (defining food additives requiring pre-market approval and exceptions).

[220] *See id.*

[221] *See* U.S. FOOD AND DRUG ADMINISTRATION, EXECUTIVE SUMMARY OF FY 2000 BUDGET REQUEST, *available at* http://www.fda.gov/oc/oms/ofm/budget/finalcj.html (last visited Nov. 11, 2000) (detailing staffing and spending on pre-market review activities) [hereinafter FDA FY 2000 BUDGET SUMMARY]; U.S. FOOD AND DRUG ADMINISTRATION, ALL PURPOSE TABLE, *available at* http://www.fda.gov/oc/oms/ofm/budget/netapt25.htm (last visited Nov. 11, 2000) (detailing FDA total budget by spending category) [hereinafter FDA FY 2000 BUDGET TABLE].

[222] *See* FDA FY 2000 BUDGET SUMMARY, *supra* note 221. *See also* FDA MILESTONES, *supra* note 4.

[223] In 1999, FDA's appropriated food budget was $231.6 million (23%) of the FDA's

USDA's food safety budget.[224] Before it received increased appropriations through the President's Food Safety Initiative for fiscal 1999, the FDA employed approximately 250 food inspectors to monitor the nation's more than 50,000 food production, processing, and storage establishments—only enough to inspect approximately 5,000 facilities per year.[225]

The NAS panel and the GAO have both concluded that the FDA's food safety budget has not kept pace with its responsibilities.[226] The agency's 1998 food inspection budget of $161.4 million was actually $1.8 million *lower* than it was in 1995.[227] These constraints are more troubling in light of evidence that a majority of recent disease outbreaks have been caused by foods subject to regulation by the FDA.[228]

C. The Department of Agriculture

The USDA plays a central role in the government's regulation of food safety chiefly through its continuous inspection of meat and poultry products. The USDA's food safety budget is large—over $746 million in 1998[229]—but of course the Department has many other tasks as well. Its original mission of discovering new seeds and plants for farmers has grown to include helping fund land-grant colleges, rural development projects, the nationwide Extension Service, support for and regulation of agricultural marketing arrangements, and provision of farm loans, to list just a few.[230]

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total budget of $1.0 billion. This was split between CFSAN ($98.5 million) and field activities ($133.0 million). Congress appropriated the animal drugs and feeds programs $42.0 million that was split between the Center for Veterinary Medicine ($29.4 million) and field activities ($12.6 million). Combined, food programs and veterinary programs were budgeted $273.6 million or 27% of the total FDA budget. This was an increase of almost $26 million compared to 1998. *See* FDA FY 2000 BUDGET TABLE, *supra* note 221.

[224] Based on staff communications with six major food safety agencies—FDA, USDA, EPA, CDC, NIH, and NMFS—the National Academy of Sciences compiled perhaps the most precise summary of federal food safety spending from fiscal years 1995 through 1998. The FY 1998 food safety budgets of these agencies were: FDA—$222.6 million; USDA (combined agencies)—$746.4 million; EPA (total pesticide spending)—$181.9 million; CDC—$14.5 million; NIH—$52.9 million; and NMFS—$18.5 million. *See* ENSURING SAFE FOOD, *supra* note 6, at 182-83.

[225] *See* Taylor, *supra* note 209, at 16.

[226] *See supra* notes 208-211.

[227] *See* ENSURING SAFE FOOD, *supra* note 6, at 182.

[228] *See* Caroline Smith DeWaal, et al., Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net (2000) (finding that 682 of 865 publicized foodborne outbreaks between 1990 and 1998 were caused by FDA-regulated foods), *available at* http://www.cspinet.org/reports/outbreak alert/index.htm (last visited Nov. 10, 2000).

[229] *See id.*

[230] *See* OFFICE OF MANAGEMENT AND BUDGET, FISCAL YEAR 1999 BUDGET OF THE UNITED STATES APPENDIX 59-184 (1998) (detailing the USDA's complete appropriations for 1998 and the President's requests for 1998) [hereinafter FY1999 FEDERAL BUDGET APPENDIX].

Thus, the $746 million devoted to food safety represents less than 2% of the USDA's total 1998 budget of over $55 billion.[231]

1. The USDA's Food Safety Activities

Over a half dozen different USDA units have food safety responsibilities. Many of these activities are overseen by the Under Secretary for Food Safety,[232] a new position created in 1994 specifically to address claims that the USDA's agricultural promotion activities would always dominate food safety efforts.[233] The most important of these units, the FSIS, is responsible for inspecting on a continuous basis each plant that processes meat or poultry, and food containing meat or poultry intended for interstate distribution.[234] Another unit, the Agricultural Marketing Service (AMS), operates a large voluntary inspection system for the grading of eggs,[235] and the Animal and Plant Health Inspection Service (APHIS) oversees programs to prevent animal and plant disease,[236] a function the Department has performed for well over a century.[237] The APHIS is also responsible for the USDA's regulation of agricultural biotechnology products.[238] The Grain Inspection, Packers and Stockyards Administration (GIPSA) inspects grains for safety as well as quality.[239] And the Agricultural Research Service (ARS),[240] Cooperative State Research,

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[231] *See* OFFICE OF MANAGEMENT AND BUDGET, FISCAL YEAR 1999 BUDGET OF THE UNITED STATES 69 (1998) (comparing the complete outlays of the federal government by department).

[232] *See* 7 C.F.R. § 2.18 (1998) (detailing the delegated authorities of the Under Secretary for Food Safety).

[233] In 1994, then-Congressman Robert Torricelli had proposed moving the USDA's meat and poultry inspection responsibilities to FDA. While the democratic leadership of the House Agriculture Committee opposed this move, Congress created the USDA's Under Secretary for Food Safety as a means of "elevating and keeping completely separate all food safety activities within the Department." 140 CONG. REC. H9967 (daily ed. Sept. 28, 1994) (colloquy of Reps. Torricelli and Stenholm).

[234] *See* 7 C.F.R. § 2.53 (1998) (describing various FSIS responsibilities).

[235] *See id.* § 2.79 (1998) (describing the delegated authorities of the AMS). This service is provided for grading purposes; the inspection of shell eggs for safety purposes is undertaken primarily by FDA.

[236] *See id.* § 2.80 (1998) (describing the delegated authorities of APHIS).

[237] HERRICK, *supra* note 92, at 35.

[238] Under its authority to protect crops and animals from disease, APHIS issues permits that govern the release of genetically modified pesticides. Both EPA and FDA also regulate genetically modified organisms under their traditional statutes. *See* ANIMAL AND PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., UNITED STATES REGULATORY OVERSIGHT IN BIOTECHNOLOGY, *available at* http://www.aphis.usda.gov/biotech/OECD/usregs.htm (last visited Nov. 11, 2000).

[239] *See* 7 C.F.R. § 2.81 (1998) (describing the delegated authorities of GIPSA).

[240] *See id.* § 2.65 (describing the delegated authorities of the ARS).

Education, and Extension Service (CSREES),[241] and Economic Research Service (ERS),[242] each undertakes or funds agricultural research, including some food safety-related research. The ARS, for example, is spearheading research relating to the federal government's response to potential bioterrorist attacks on the food supply.[243] Together, the several USDA units expended over $60 million in 1998 on food safety research—far more than any other federal agency.[244]

2. The Food Safety and Inspection Service

In its oversight of meat and poultry processing, the FSIS plays a critical role in federal food safety regulation.[245] In contrast to the FDA's unstructured authority to police commerce for adulterated food,[246] Congress imposed on the Secretary of Agriculture statutory obligations to examine every meat and poultry carcass intended for food sold in interstate commerce.[247] Any meat or poultry product that has not undergone inspection is considered adulterated.[248]

This continuous inspection activity claims a larger share of federal food safety resources than any other activity. The FSIS devotes approximately

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[241] *See id.* § 2.66 (describing the delegated authorities of CSREES).

[242] *See id.* § 2.67 (describing the delegated authorities of the ERS).

[243] *See* Miller, *supra* note 39, at 1.

[244] *See* ENSURING SAFE FOOD, *supra* note 6, at 182 (showing the USDA food safety research budget to be over $60 million).

[245] *See* 21 U.S.C. § 603-05 (1994) (mandating that the Secretary of Agriculture perform ante- and post-mortem inspection of meat); *id.* § 455 (mandating that the Secretary of Agriculture perform ante- and post-mortem inspection of poultry); *id.* § 606 (West 1998) (mandating continuous inspection of meat processing facilities).

[246] *See, e.g.*, 21 U.S.C. § 331(a) (1994) (prohibiting the introduction into interstate commerce of any adulterated food).

[247] *See* 21 U.S.C. § 604 (1994). The statute requires that:

> [T]he Secretary [of Agriculture] shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the *carcasses and parts thereof of all* cattle, sheep, swine, goats, horses, mules, and other equines to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food . . . .

Id. (emphasis added). In addition:

> The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors *post mortem inspection of the carcass of each bird processed*, and at any time such quarantine, segregation, and reinspection as he deems necessary of poultry and poultry products capable of use as human food in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection under this chapter [21 U.S.C. §§ 451-470].

Id. at § 455(b) (emphasis added).

[248] *See* 21 U.S.C. § 604 (1994).

88% of its personnel budget[249]—$327 million in 1998[250]—to in-plant inspection. Of this total, $271 million was spent on post-slaughter, carcass-by-carcass inspection of meat and poultry.[251] The MIA's and the PPIA's continuous inspection mandates have thus become "resource anchors" for the FSIS and for the USDA. While the FDA relies on approximately 250 field inspectors to oversee some 53,000 food establishments, the FSIS employs more than 7,300 full-time, residential inspectors in roughly 6,200 meat and poultry plants.[252] Over 90% of the FSIS' full-time employees reside in the field.[253]

The FSIS also administers the labeling requirements of the MIA and the PPIA. The agency is responsible for pre-market approval of the formulas and labeling of most meat and poultry products.[254] It is also responsible for monitoring meat and poultry for chemical residues, including directly added chemicals, animal drugs, and pesticide residues.[255] The FDA, or the EPA in the case of pesticides, is responsible for establishing safe limits on such residues.[256]

The FSIS has by far the largest budget of any federal food safety agency—$590 million in 1998.[257] Of this total, the FSIS spent $494 million regulating domestic meat and poultry. It spent $35 million on in-house laboratory services alone.[258] In contrast, only $12 million was budgeted for inspection of imports and exports.[259]

A controversial feature of the FSIS' continuous inspection program has been its traditional reliance on organoleptic (sight, touch, and smell)

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249 *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/T-RCED-94-110, Food Safety—RISK-BASED INSPECTIONS AND MICROBIAL MONITORING NEEDED FOR MEAT AND POULTRY 41 (1994) [hereinafter 1994 GAO MEAT AND POULTRY REPORT].

250 *See* FY1999 FEDERAL BUDGET APPENDIX, *supra* note 230, at 82 (detailing 1998 total personnel compensation of $372 million).

251 *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-98-224, FOOD SAFETY: OPPORTUNITIES TO REDIRECT FEDERAL RESOURCES AND FUNDS CAN ENHANCE EFFECTIVENESS 6 (1998).

252 *See* Taylor, *supra* note 209, at 16-17.

253 *See* FOOD SAFETY AND INSPECTION SERV., U.S. DEP'T OF AGRIC., FSIS PERMANENT FULL-TIME EMPLOYEES AS OF 10/5/99, *at* http://www.fsis.usda.gov/OM/hrd/stats/stats.htm (last visited Nov. 9, 2000).

254 *See* Richard L. Frank & Dennis R. Johnson, *The USDA's Compliance and Enforcement Programs*, 44 FOOD DRUG COSM. L.J. 205, 209 (1989); 21 C.F.R. § 317.4 (1999).

255 *See* 9 C.F.R. § 309.16 (1999).

256 *See* 21 U.S.C.A. §§ 346, 346a (West Supp. 1999).

257 *See* U.S. DEP'T OF AGRIC., USDA 2000 BUDGET SUMMARY (2000), *available at* http://www.usda.gov/agency/obpa/Budget-Summary/2000/text.html (last visited Nov. 11, 2000).

258 *See id.*

259 *See id.*

examination of each carcass or bird.[260] The MIA and the PPIA mandates appear strict, for example:

> [T]he Secretary shall cause to be made by inspectors appointed for that purpose a *post mortem examination and inspection of the carcasses and parts thereof of all* cattle, sheep, swine, goats, horses, mules, and other equines to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food . . . .[261]

The PPIA imposes a similar obligation to conduct a "post mortem inspection of the carcass of each bird processed."[262] This is important but also resource-intensive work, and as other methods have been devised to monitor product safety, the FSIS has come under pressure to modernize its inspection methods. For example, in a 1987 report, the NAS concluded that "the present system of inspection does very little to protect the public against microbial hazards in young chickens."[263] As microbial pathogens appear to present increasing risks, the FSIS' traditional inspection methods have also come under criticism from the GAO and consumer groups such as the Center for Science in the Public Interest (CSPI).[264]

The FSIS has responded to this criticism in several ways. Not only has it continued sight and smell inspection of each carcass and bird, but it has also adopted requirements for bacterial testing of products. Further, it has taken the first steps toward mandating HACCP protocols in meat and poultry processing plants.[265] New USDA regulations will eventually require all meat and poultry plants to implement a HACCP program that specifically addresses

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[260] *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-92-152, FOOD SAFETY—UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY 11 (1992) (summarizing history of meat and poultry inspection statutes).

[261] 21 U.S.C. § 604 (1994) (emphasis added).

[262] *Id*. § 455(b).

[263] NATIONAL ACADEMY OF SCIENCES, POULTRY INSPECTION: THE BASIS FOR A RISK ASSESSMENT APPROACH (1987). USDA has agreed with the NAS assessment. In a recent Federal Register notice describing inspection changes, FSIS admitted that "[i]nspection methods have . . . not been modified sufficiently to address the microbial causes of foodborne illness." 62 Fed. Reg. 31,553, 31,556 (June 10, 1997).

[264] *See* NATIONAL ACADEMY OF SCIENCES, MEAT AND POULTRY INSPECTION: THE SCIENTIFIC BASIS OF THE NATION'S PROGRAM (1985) (calling for adoption of preventative, risk-based methods of regulation); OPPORTUNITIES TO REDIRECT FEDERAL RESOURCES, *supra* note 251, at 6; CAROLINE SMITH DEWAAL, PLAYING CHICKEN: THE HUMAN COST OF INADEQUATE REGULATION OF THE POULTRY INDUSTRY (1996), *available at* http://www.cspinet.org/reports/polt.html (last visited Nov. 11, 2000).

[265] *See* Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806-38,989 (July 25, 1996) (describing FSIS' HACCP plan for meat and poultry inspection).

all major hazards and includes testing for microbial pathogens.[266]

The FSIS' endorsement of HACCP has likewise been controversial in some quarters. The agency's unionized inspectors have opposed any USDA move away from carcass-by-carcass inspection and have resisted the implementation of HACCP regulations.[267] One union official stated that "organoleptic inspection methods are the only proven methods to remove [tainted] products from the food supply."[268] With strong support from the Clinton administration, however, the USDA has embraced implementation of HACCP as a major priority in the national food safety agenda.[269] The FSIS has responded to public criticism by publishing preliminary data indicating significant decreases in *Salmonella* contamination in 300 large meat and poultry plants that implemented HACCP protocols.[270]

The USDA has disputed the claim that it is legally bound to continue its traditional organoleptic inspections.[271] Both its inspectors and some external critics, like the GAO, have argued that carcass-by-carcass inspections are statutorily mandated.[272] The Department's official position is more nuanced. In response to a recent GAO report on the allocation of food safety resources,

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[266] *See id.*; 21 C.F.R. § 417.2 (1997). *See also* Allison Beers, *FSIS Officials Debate Enforcement of* Salmonella *Performance Standard*, FOOD CHEM. NEWS, Jan. 25, 1999, at 17-18 (discussing the implementation of *Salmonella* testing in FSIS-regulated meat and poultry processing plants).

[267] *See* Allison Beers, *Inspectors Lobby Lawmakers to Support Continuous Inspection*, FOOD CHEM. NEWS, Jan. 25, 1999, at 14-16.

[268] *Id.* at 14.

[269] *See* EXECUTIVE OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2000 241 (1999) (stating the Clinton Administration's goal to have 99% compliance in federally-inspected meat and poultry plants by 2000) [hereinafter FY 2000 FEDERAL BUDGET].

[270] *See* FOOD SAFETY AND INSPECTION SERV., U.S. DEP'T OF AGRIC., NEW MEAT AND POULTRY INSPECTION SYSTEM GREATLY REDUCES THREAT OF SALMONELLA, *available at* http://www.fsis.usda.gov/OA/news/salmrel.htm (last visited Nov. 11, 2000) (citing declines of 40%, 50%, and 25%, respectively, in *Salmonella* contamination in HACCP-compliant plants that process ground beef, chicken, and pork). The USDA was recently enjoined, at least temporarily, from fully enforcing the *Salmonella* testing requirements of the HACCP regulation. A federal district court judge has prevented FSIS from withdrawing its inspectors from, and thus closing a meat processing plant that repeatedly failed *Salmonella* contamination tests. *See* Supreme Beef Processors, Inc. v. USDA, 113 F. Supp. 2d 1048 (N.D. Tex. 2000); Marion Burros, *Judge Gives Meat Plant a Reprieve from Closing*, N.Y. TIMES, Dec. 11, 1999, at A12.

[271] *See infra* note 273 and accompanying text.

[272] *See* OPPORTUNITIES TO REDIRECT FEDERAL RESOURCES, *supra* note 251, at 5 ("Most of the $271 million—over one-fourth of the food safety budget—spent annually on FSIS' organoleptic, carcass-by-carcass slaughter inspections could be spent more effectively on other food safety activities that better address food safety risks. Once HACCP is fully implemented, [food safety] funds could become available through the Congress's . . . eliminating the *legislatively mandated requirement for these federal inspections* . . . .") (emphasis added).

the USDA Under Secretary for Food Safety has stated:

> [W]hile the Federal Meat Inspection Act states that there is to be post mortem inspection of the carcasses of all animals prepared at a slaughtering or similar establishment, and the PPIA states that there is to be post mortem inspection of the carcasses of each bird processed, neither statute states how these inspections are to be conducted. *There is no statutory requirement that the inspections be accomplished as currently conducted under the FSIS' inspection program and regulations*.[273]

The FSIS' interpretation appears defensible. The statutes surely do not mandate the form of organoleptic inspection of meat and poultry products that is currently practiced, but they *do* seem to require more than a sampling of all carcasses. For meat products, the law mandates an "examination and inspection" of all "carcasses and parts thereof," and for poultry products, the PPIA prescribes "inspection" of "each" bird.[274] At the very least, this language would seem to require that an agent of the USDA visually, if only briefly, examine each carcass, as the Department has required for meat since 1906.[275]

D. The Environmental Protection Agency

The EPA's primary food safety responsibilities are licensing pesticides for on-farm use and establishing tolerance levels for residues on food. Both functions are performed by the agency's Office of Pesticide Programs (OPP) pursuant to the FIFRA and the FDCA, respectively. In 1998, the EPA's total budget for these activities was $181.9 million, nearly four-fifths of the FDA's total food safety budget of $222.6 million.[276] This is somewhat misleading, however, because the EPA's pesticide registration

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[273] Letter from Dr. Catherine E. Woteki, Under Secretary for Food Safety, to Mr. Lawrence J. Dyckman, U.S. General Accounting Office 2 (Jul. 7, 1998) (citations omitted and emphasis added), *reprinted in* OPPORTUNITIES TO REDIRECT FEDERAL RESOURCES, *supra* note 272, at 36-37.

[274] *See* 21 U.S.C. §§ 455(b), 604 (1994).

[275] An analogy can be made to the Supreme Court's recent rejection of the Department of Commerce's proposal to use statistical sampling to conduct the census for purposes of political reapportionment. In *Dep't of Commerce v. United States House of Representatives*, 119 S. Ct. 765 (1999), the Court held that an ambiguous statute that "might reasonably be read as either permissive or prohibitive" of sampling nevertheless prevented the Department's use of the statistical technique for reapportionment purposes. *Id.* at 777. Justice O'Connor, writing for the Court, reasoned that "the interpretation of the . . . [statute's] structure depends primarily on the broader context in which that structure appears. Here, the context is provided by over 200 years during which federal statutes have prohibited the use of statistical sampling where apportionment is concerned." *Id.* Similarly, in the case of meat and poultry inspection, the Court's contextual reading of the MIA and PPIA would have to take account of the 100-year history of carcass-by-carcass inspection.

[276] *See* ENSURING SAFE FOOD, *supra* note 6, at 182.

function also embraces efforts to control non-dietary risks to applicators, farm workers, and wildlife.[277] Of this funding, the EPA spent $19.7 million on activities to reduce the risk of agricultural pesticides and $36.8 million on reducing the use of pesticides that do not meet current safety standards.[278] Pursuant to the Food Quality Protection Act of 1996 (FQPA), the agency is currently engaged in reviewing the safety of nearly 10,000 previously established tolerances.[279]

The statutory scheme for controlling dietary pesticide risks is complex. Under the FIFRA, a pesticide may not be sold in the United States unless it has been registered by the EPA.[280] The FIFRA requires the manufacturer of a new pesticide to conduct tests and issue reports, which the EPA uses to evaluate the risks and benefits of the use of the chemical.[281] A pesticide may not be introduced into interstate commerce unless the Administrator of the EPA determines that the pesticide "will not generally cause unreasonable adverse effects on the environment."[282]

To control dietary exposure to pesticides, the EPA also establishes formal, binding upper limits, or tolerances, for residues left on food. This function is governed by the FDCA, as recently amended by the FQPA.[283] Pesticide tolerances are approved under a recently revised health-based safety standard that specifically requires consideration of aggregate pesticide exposure and the special sensitivities of children.[284] The EPA may grant a tolerance for a pesticide residue on raw or processed food only if it finds there is a "reasonable certainty" that no harm will result from

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[277] *See, e.g.*, U.S. ENVIRONMENTAL PROTECTION AGENCY, EPA OFFICE OF PESTICIDE PROGRAMS BIENNIAL REPORT FISCAL YEAR 1998 AND 1999 31 (1999), *available at* http://www.epa.gov/oppfead1/annual/98-99annual.pdf (last visited Nov. 11, 2000) (discussing EPA's programs to protect agricultural workers from pesticide risks). *See also* JOHN G. SPRANKLING & GREGORY C. WEBER, THE LAW OF HAZARDOUS WASTES AND TOXIC SUBSTANCES 38-58 (1997); JOHN APPLEGATE ET AL., THE REGULATION OF TOXIC SUBSTANCES AND HAZARDOUS WASTES (2000).

[278] *See* U.S. ENVIRONMENTAL PROTECTION AGENCY, SAFE FOOD, *available at* http://www.epa.gov/ocfopage/budget/1999/g03all.htm (last modified July 11, 2000) [hereinafter EPA FOOD SAFETY BUDGET].

[279] Pub. L. No. 104-170, 110 Stat. 1489. *See also 1999 FQPA Oversight Hearing*, *supra* note 66, at 67 (statement of James V. Aidala, Associate Assistant, Office of Prevention, Pesticides and Toxic Substances, EPA, and Keith Pitts, Special Assistant of the Deputy Secretary, USDA).

[280] *See* 7 U.S.C. § 136a(a) (1994).

[281] *See id.* § 136d.

[282] *See id.* § 136a(5)(D).

[283] *See* 21 U.S.C.A. § 346a (West Supp. 1999).

[284] *See id.* § 346a(b). *See generally* U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS, SUMMARY OF FQPA AMENDMENTS TO FIFRA AND FFDCA (1998), *at* http://www.epa.gov/oppfead1/fqpa/fqpa-iss.htm (last modified Aug. 19, 1999) [hereinafter FQPA SUMMARY].

aggregate exposure to the residue.[285] This activity requires elaborate risk assessments for each approved use, including analyses of individual exposure through diet, drinking water, and residence.[286] The EPA then consults with the USDA to develop risk management strategies that take into account the pesticide's value to farmers.[287]

The EPA also contributes indirectly to food safety by seeking to limit chemical and microbial contaminants in the water and air,[288] such as the pathogens *E. coli* or *Cryptosporidium*, which may infect food through local water supplies.[289] These functions are governed by, *inter alia*, the Clean Air Act[290] and the Safe Drinking Water Act.[291]

If consolidation of federal food safety functions were seriously contemplated, the EPA's pesticide residue program would seem a strong candidate for inclusion. It is the largest single federal unit responsible for evaluating the safety of chemicals added to food. Currently, approximately 680 EPA employees are involved in this activity,[292] but estimating the EPA resources devoted to assuring the safety of food residues is difficult because most of the same personnel are also involved in evaluating the underlying applications for FIFRA registration.[293] This raises the question of whether the EPA's pesticide registration function should also be encompassed by any consolidation. Separating these two pesticide activities would create inefficiencies, but relocating the EPA's entire pesticide program would disrupt important linkages with other EPA pollution control programs.

While the EPA establishes the allowable limits, the FDA and the FSIS are responsible for monitoring food to assure compliance with those limits.[294] These agencies also share responsibility for investigating on-farm compliance with EPA-prescribed limitations on pesticide use, limitations that are designed in part to assure that any residues on food are within safe limits. Since FDA and USDA inspectors are already monitoring food for

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[285] *See* 21 U.S.C.A. § 346a(b)(2)(A)(ii) (West 1998).

[286] *See 1999 FQPA Oversight Hearing*, *supra* note 66, at 64.

[287] *See id.* at 65-66.

[288] *See* ENSURING SAFE FOOD, *supra* note 6, at 27 (summarizing EPA's food safety responsibilities).

[289] *See* Natalie Pargas, *EPA's Office of Water Has a Role in Food Safety*, FOOD CHEM. NEWS, Jul. 5, 1999, at 10. *See also* Barstow, *supra* note 32.

[290] Act of July 14, 1955, ch. 360, 69 Stat. 322 (codified at 42 U.S.C. §§ 7401-7671q (1994)).

[291] Pub. L. No. 93-523, 88 Stat. 1660 (1974) (codified at 42 U.S.C. §§ 300f – 300j-26 (1994)).

[292] *See* EPA FOOD SAFETY BUDGET, *supra* note 278.

[293] *See* Interview with Jon Cannon, *supra* note 164.

[294] *See* discussion *supra* Part III.

other chemical contaminants, it makes sense for them to be responsible for checking for pesticide residues as well.

E. The Centers for Disease Control and Prevention

The FDA, the FSIS, and the EPA each seek to control foodborne risks through inspection, production surveillance, and product approval, but none of them systematically investigates the prevalence or causes of foodborne disease. At the federal level, this task falls to the CDC. The CDC surveys morbidity and mortality by causes and undertakes epidemiological investigations of many diseases, including foodborne illnesses.[295] The CDC has recently begun to devote more of its resources to food safety surveillance. The agency's spending in this area has risen from $2.9 million in fiscal year 1995 to $14.5 million in fiscal year 1998.[296] This rise is partially attributable to a new, more active surveillance of foodborne diseases via the FoodNet program, described below.[297]

1. The CDC's Basic Functions

The CDC obtains most of its data on disease incidence through the reporting of physicians nationwide.[298] The CDC's National Center for Infectious Diseases (NCID) maintains a list of "nationally notifiable" illnesses for which the agency maintains detailed records of reported morbidity and mortality.[299] Among the food-related diseases that the CDC monitors on a continuing basis are *Cholera*, *E. coli* 0157:H7, *Salmonella*, and *Shigella*.[300] The NCID analyzes data on specific diseases from state health agencies, laboratories, physician networks, hospitals, and national databases.[301] The reliability of this method of tabulation thus depends on patients seeking medical attention and on doctors making correct diagnoses

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[295] *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-91-19B, FOOD SAFETY AND QUALITY—WHO DOES WHAT IN THE FEDERAL GOVERNMENT 113-14 (1990).

[296] *See* ENSURING SAFE FOOD, *supra* note 6, at 183.

[297] *See* Sue Binder, et al., *The National Food Safety Initiative*, 4 EMERGING INFECTIOUS DISEASES 347 (1998).

[298] In an example of the federalist patchwork of the U.S. health structure, the CDC is required by Congress to collect morbidity and mortality information on specific diseases, however the states are not required to provide these data to the CDC. *See* U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL NOTIFIABLE DISEASE SURVEILLANCE SYSTEM, *at* http://www.cdc.gov/epo/dphsi/nndsshis.htm (last modified Oct. 28, 2000) (noting that reporting of nationally notifiable diseases by the states is voluntary).

[299] *See* U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, NCID SURVEILLANCE ACTIVITIES, *at* http://www.cdc.gov/ncidod/ncidsurv.htm (last modified July 6, 2000).

[300] *See Summaries of Notifiable Diseases in the United States, 1997*, MORBIDITY & MORTALITY WKLY. REP., Nov. 20, 1998, at 1, 3 (summarizing incidence and causes of nationally notifiable diseases).

[301] *See id.*

and reporting the illnesses and deaths they encounter.[302]

In 1996, the CDC, in cooperation with the FDA and the USDA, established FoodNet, an active foodborne illness surveillance network in several locations around the country.[303] FoodNet targets seven common foodborne pathogens that pose the greatest risks to public health: *Campylobacter*, *E. coli* 0157:H7, *Salmonella*, *Listeria*, *Shigella*, *Vibrio*, *Yersinia*, *Cryptosporidium*, and *Cyclospora*.[304] By active sampling of physicians and medical laboratories in several representative states, the CDC hopes to improve its assessments of the incidence of foodborne illness.[305]

The CDC has also conducted focused epidemiological investigations to determine the causes of morbidity and mortality in medical emergencies.[306] During outbreaks of food-related disease, the CDC generally works with state and local agencies.[307] Between 400 and 500 such outbreaks are reported to the CDC each year, accounting for upwards of 10,000 individual cases of food-related illness.[308] CDC personnel also work with the FDA or the USDA to determine the causes of large-scale cases of foodborne illnesses.[309] Both regulatory agencies have their own emergency response units for investigating and containing outbreaks of foodborne disease.[310]

2. Improving Active Disease Surveillance

The federal government's ability to combat foodborne illness has been limited by lack of good information about disease incidence. The CDC has recognized the limitations of relying on "passive" surveillance of reportable cases.[311] A major goal of the Clinton Administration's Food Safety Initiative was to enhance the government's capacity to assess the risks of

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[302] *See* David Satcher Congressional Testimony, *supra* note 33, at 21.

[303] FoodNet monitors clinical laboratories for specific foodborne pathogens in Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia—a total population of 20.5 million. CDC hope to include surveillance data from Maryland and New York in 1998. *See 1999 FoodNet Report*, *supra* note 43, at 191-93.

[304] *See id.*

[305] *See id.*

[306] *See* NCID SURVEILLANCE ACTIVITIES, *supra* note 173.

[307] *See* Binder, et al., *supra* note 297, at 347.

[308] David Satcher Congressional Testimony, *supra* note 33, at 22. This, of course, is only a small percentage of the cases of foodborne illnesses in the U.S. in many years.

[309] These cooperative efforts are resource constrained, however, for CDC has committed only some 50 employees to food safety. *See* OPPORTUNITIES TO REDIRECT FEDERAL RESOURCES, *supra* note 251, at 19 tbl. 1.1.

[310] *See* U.S. FOOD AND DRUG ADMIN. ET AL., FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE—REPORT TO THE PRESIDENT (1997) [hereinafter FOOD SAFETY FROM FARM TO TABLE].

[311] *See* Binder et al., *supra* note 297, at 347.

foodborne disease. One result was the FoodNet system. The Initiative also called on the CDC to help state health agencies better identify, investigate, and manage foodborne disease outbreaks.[312] In response, the CDC has provided training for state and local health officials in the recognition of foodborne diseases with the aim of creating a national early warning system for disease outbreaks.[313] The CDC is also involved in training epidemiologists in foreign countries, including several that are major exporters of food to the United States.[314]

F. Other Agencies with Food Safety Responsibilities

1. Federal Agencies

Several other federal agencies play roles in the loosely coordinated effort to make food safe. Each sits within an organization for which food safety is not a primary responsibility.

Within HHS, a non-trivial amount of food safety research is funded by the National Institutes of Health (NIH).[315] It is unclear, however, whether this research is coordinated with, or even complements, the research conducted by the USDA, the FDA, and the EPA. The Clinton Administration has established the Council on Food Safety and the Joint Institute for Food Safety Research, charging both with the responsibility to coordinate the research efforts of the various federal agencies.[316]

The National Marine Fisheries Service (NMFS), part of the Department of Commerce, has for many years operated a fee-based voluntary seafood inspection and surveillance service, which had a total budget of $18.5 million in 1998.[317] The Clinton Administration has proposed reassigning this program to the FDA,[318] a shift that would centralize federal seafood regulation. In anticipation of this relocation, the proposed Commerce Department budget for fiscal 1999 did not include

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312 *See id.*

313 *See id.*

314 *See id.* at 349.

315 *See* ENSURING SAFE FOOD, *supra* note 6, at 182. In 1998, the NIH funded $52.8 million of food safety-related research. *See id.*

316 *See* PRESIDENT'S COUNCIL ON FOOD SAFETY, ASSESSMENT OF THE NAS REPORT ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION 3 (1999) [hereinafter FOOD SAFETY COUNCIL NAS ASSESSMENT].

317 *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-91-19B, FOOD SAFETY AND QUALITY—WHO DOES WHAT IN THE FEDERAL GOVERNMENT 88-100 (1990); ENSURING SAFE FOOD, *supra* note 6, at 182.

318 *See* Joan Murphy, *NMFS, FDA Plan to Move Ahead with Seafood Inspection Consolidation*, FOOD CHEM. NEWS, Jan. 11, 1999, at 7.

funding for the NMFS program.[319] However, Congress has not approved this consolidation, and thus the FDA's budget request for fiscal 2000 repeated the request.[320]

Two units of the Treasury Department, the U.S. Customs Service and the Bureau of Alcohol, Tobacco, and Firearms (ATF), play important roles. Customs collaborates with several regulatory agencies, including the FDA and the USDA, to enforce federal laws at borders and ports.[321] The ATF oversees the production and marketing of alcoholic beverages and investigates cases of possible adulteration of domestic and foreign spirits.[322]

Finally, the FDA and FSIS share with the Federal Trade Commission (FTC) overlapping authorities to regulate food marketing practices. Oversimplified, the FTC has jurisdiction to prevent false or misleading advertising practices, while the FDA and FSIS retain authority over labels and labeling.[323]

2. State and Local Agencies

No description of the country's food safety "system" would be complete without at least a brief discussion of the state and local agencies that play important, and in some instances growing, roles in preventing or responding to foodborne illness. State and local officials, based in public health units or agriculture departments (or sometimes both), play the lead role in regulating retail food service establishments, including grocery stores.[324] As a consequence, the share of foodborne risk subject to state and local oversight is increasing. The changing dietary habits of American consumers continue to increase the percentage of meals prepared (and often consumed) away from home.[325] Simultaneously, as consumer demand for fresh fruits and vegetables has risen, local as well as federal officials have had to devote more attention to imported products.[326]

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319 *See id.*

320 *See* U.S. FOOD AND DRUG ADMIN., DESCRIPTION OF FIELD ACTIVITIES, *at* http://www.fda.gov/oc/oms/ofm/budget/fieldfoods.htm (last visited Nov. 11, 2000) [hereinafter DESCRIPTION OF FIELD ACTIVITIES].

321 *See* FOOD SAFETY: A TEAM APPROACH, *supra* note 174.

322 In yet another example of the patchwork organizational structure of the federal food safety agencies, FDA regulates wine coolers, while ATF retains jurisdiction over all other alcoholic beverages. *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-91-19B, FOOD SAFETY AND QUALITY—WHO DOES WHAT IN THE FEDERAL GOVERNMENT 115 (1990).

323 *See* 21 U.S.C. § 378 (1994) (providing FTC with authority to investigate food misadvertising claims).

324 *See* Taylor, *supra* note 209, at 16.

325 *See* Lin et al., *supra* note 41, at 213.

326 *See* Urbain Avernaete et al., *World-wide Impact of Horticulture*, paper presented at

While federal officials focus on major food production facilities, literally hundreds of state and local agencies inspect restaurants and supermarkets, as well as local plants and slaughterhouses. These state and local officials are the primary overseers of the approximately 750,000 restaurants, supermarkets, and other retail establishments nominally subject to FDA jurisdiction.[327] Twenty-five states now operate USDA-approved meat and poultry inspection programs that oversee about 3,000 slaughtering and processing plants and 7% of all domestically-produced meat and poultry.[328]

The FDA and the USDA must coordinate at many levels with state and local officials. The USDA's jurisdiction over meat and poultry products does not extend to retail establishments such as meat markets, grocery stores, and restaurants.[329] While meat and poultry are routinely processed in these facilities, the USDA depends on state inspection resources and the much more limited efforts of the FDA to monitor retail establishments. The FDA, on the other hand, officially has jurisdiction over restaurants, food vendors, and retail establishments.[330] The agency maintains and encourages state and local agencies to adopt a model food code.[331] It also contracts with state and local officials who provide much of the nation's milk and seafood inspection under federal authority.[332] The FDA's most ambitious reliance on local authority, however, involves the commissioning of state and local officials to conduct inspections and collect samples with the agency's authority.[333] Pursuant to 21 U.S.C. § 372(a), the FDA has commissioned over 600 state and local officials to conduct inspections traditionally performed by the federal government.[334]

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the World Conference on Horticultural Research, June 1998, *available at* http://pop.agrsci.unibo.it/wchr/wcl/faodoc1.html (last visited Oct. 28, 2000) (noting the rising demand and substantial cross-border trade in fresh fruits and vegetables).

[327] *See* Taylor, *supra* note 209, at 16 n. 12.

[328] *See* Letter of Transmittal Relating to Interstate Shipment of State Inspected Meat and Poultry Products from Dan Glickman, Secretary of Agriculture, to Albert Gore, Jr., President of the United States Senate 1 (Nov. 2, 1999), *available at* http://www.fsis.usda.gov/OA/congress/iship2.htm.

[329] *See* Applicability of the Federal Meat Inspection Act to Retail Establishments, 42 Op. Att'y Gen. 461 (1972).

[330] *See* HUTT & MERRILL, *supra* note 4, at 268 (describing FDA's jurisdiction over foods held for sale after shipment in interstate commerce).

[331] *See id.* at 266-69.

[332] *See id.*; U.S. FOOD AND DRUG ADMIN., FDA FOOD CODE, *available at* http://vm.cfsan.fda.gov/~dms/foodcode.html (last visited Oct. 22, 1999).

[333] *See* 21 U.S.C. § 372(a) (1994) (authorizing the FDA to conduct examinations and investigations "through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department").

[334] *See* U.S. FOOD AND DRUG ADMIN., FDA STATE-LOCAL COMMISSIONING PROGRAM, *at* http://www/fda.gov/ora/fed state/DFSR Activities/commissioning.htm (last modified Nov. 4, 1999).

State and local regulatory structures reflect as much fragmentation as the federal apparatus. For example, in a 1999 study, an Illinois Food Safety Task Force reported that more than 90 local health departments and 135 municipalities in Illinois alone provide food safety services by inspecting restaurants, schools, food stores, and caterers.[335] Indeed, the Illinois Department of Agriculture functions like a local USDA—preventing animal disease, monitoring slaughter, inspecting meat and poultry processing, and overseeing egg grading.[336] And the Illinois State Department of Public Health mimics the FDA—inspecting food processing and warehousing of all non-meat and poultry products, monitoring milk safety, and inspecting food retailers and restaurants.[337] Some other states, such as Texas and New York, combine the regulation of meat, non-meat, processed food, and retail operations in a single agency,[338] but this is by no means the universal pattern.

Inspection of retail food establishments is a critical element of local regulation. In New York, for example, the Division of Food Safety and Inspection has a budget of $6.3 million and is responsible for the regular inspection of over 28,000 establishments.[339] In 1996-1997, the Division of Food Safety and Inspection's 63 inspectors completed 17,918 inspections.[340] New York's Department of Environmental Conservation is responsible for seafood inspection, and local agencies such as the New York City Health Department inspect many retail food establishments whose primary business is prepared food.[341]

Some states spend comparable amounts on food safety. For example, California's Department of Food and Agriculture Division of Animal Industry (which encompasses responsibilities similar to the USDA's FSIS and APHIS) has an annual personnel budget of over $10 million.[342] Illinois

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335 *See* ILL. DEP'T OF AGRIC. & ILL. DEP'T OF PUB. HEALTH, FINAL REPORT OF THE ILLINOIS FOOD SAFETY TASK FORCE 3 (1999).

336 *See id.*

337 *See id.*

338 *See* TEX. DEP'T OF HEALTH, BUREAU OF FOOD AND DRUG SAFETY, *available at* http://www.tdh.texas.gov/bfds/bfds-hom.htm (last modified June 25, 2000) (listing divisions of the Texas Bureau of Food and Drug Safety); N. Y. STATE DEP'T OF AGRIC. AND MARKETS, FOOD SAFETY AND LABELING, *available at* http://www.agmkt.state.ny.us/Fsi/FSI1.html (last visited Nov. 11, 2000) (listing food safety functions of the New York State Department of Agriculture and Markets).

339 *See* STATE OF NEW YORK, OFFICE OF THE STATE COMPTROLLER, REP. NO. 98-S-15, DEPARTMENT OF AGRICULTURE AND MARKETS FOOD SAFETY PROGRAM 7 (1999).

340 *See id.* at 8.

341 *See id.* at 2. *See also* STATE OF NEW YORK, OFFICE OF THE STATE COMPTROLLER, REP. NO. A-6-95, NEW YORK CITY DEP'T OF HEALTH—FOLLOW-UP REVIEW OF MOBILE FOOD VENDORS (1995), *available at* http://www.osc.state.ny.us/audits (last visited Nov. 11, 2000) (noting New York City's difficulties regulating sidewalk food vendors).

342 *See* CALIFORNIA DEP'T OF FIN., 1999-2000 SALARIES AND WAGES SUPPLEMENT at GG27-GG28 (1999).

spends $1.7 million enforcing its state pesticide laws, $5 million on meat inspection, and $800,000 on non-meat food and drug regulation.[343]

G. The Challenge of Food Imports

In addition to monitoring the domestic products and suppliers of food, U.S. regulators must respond to the even greater challenge of assuring the safety of food produced beyond the country's borders. This challenge has grown as American demand for imported agricultural products has risen. To illustrate, in 1980, U.S. food manufacturers imported only 9% of their broccoli for use in processed foods. By 1995, 85% of broccoli for processing was imported.[344] On a broader scale, by 1995 more than half of all fish and shellfish consumed in the United States was imported, as was one-third of all fresh fruit.[345] In 1997, FDA inspectors physically examined just 1.7% of imported products under its jurisdiction; by contrast, FSIS inspectors visually inspected all of the products under its jurisdiction and performed physical inspections on 20% of them.[346]

A lack of inspectional resources hampers federal, and particularly the FDA, efforts to control the risks of imported food. Budgetary limits, however, are not the only constraint that the FDA faces. The USDA is required by law to verify that any country from which the United States imports meat or poultry maintains an inspection system that is functionally equivalent to the U.S. system.[347] Thus, the FSIS requires exporting countries to apply for meat and poultry importation eligibility, and FSIS personnel regularly visit these countries to verify the effectiveness of their respective meat and poultry safety regimes.[348] The FDA has no similar statutory authority to require that exporting countries maintain controls comparable to those it enforces domestically.[349] Moreover, even though

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[343] *See* ILLINOIS STATE COMPTROLLER, ILLINOIS DETAILED ANNUAL REPORT OF REVENUES AND EXPENDITURES 1998, 155, 156, 162 (1998) (detailing the budgets of the Illinois Departments of Agriculture and Public Health).

[344] *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-98-103, FOOD SAFETY—FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE 13 (1998).

[345] *See id.*

[346] *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/TRCED-98-271, FOOD SAFETY—WEAK AND INCONSISTENTLY APPLIED CONTROLS ALLOW UNSAFE IMPORTED FOOD TO ENTER U.S. COMMERCE 3 (1998) [hereinafter GAO UNSAFE IMPORTED FOOD REPORT].

[347] *See* 21 U.S.C.A. § 46(d) (West Supp. 1998) (mandating that imported poultry "shall . . . be subject to the same inspection, sanitary, quality, species verification, and the residue standards applied to products produced in the United States; and . . . [shall] have been processed in facilities and under conditions that are the same as those under which similar products are processed in the United States").

[348] *See* GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 346, at 21-22.

[349] *See id.* at 22.

the FDA has authority to negotiate voluntary equivalency agreements with foreign countries, it lacks the resources to confirm the effectiveness of their regulatory systems.[350]

The interdependence of the FDA, the USDA, and the U.S. Customs Service, presents another challenge to federal efforts to assure the safety of imported food. Because Customs, at the request of either agency, has the power to refuse entry of a product, coordination at ports is essential. A recent GAO report charges that due to lack of communication, Customs has been unaware of the FDA's refusal to accept certain shipments of food. Consequently, food that was refused entry by the FDA may have been allowed into commerce by the Customs Service.[351]

Finally, the participation of the United States in global efforts to harmonize food safety standards through the *Codex Alimentarius* (and derivatively through the World Trade Organization) requires that the various federal food safety agencies reach agreement on such controversial issues as the labeling of genetically modified foods and the use of hormones in raising beef.[352] *Codex* standards are especially significant, as they are considered by the World Trade Organization as a measure of international scientific consensus in its jurisdiction over trade cases involving food safety issues.[353] Thus, the movement toward international harmonization of food safety standards puts pressure on domestic regulators to coordinate in order to present a unified front in negotiations with other nations.

The foregoing sections make clear that the United States is far from operating an "integrated food safety system." Rather, Congress has allocated tasks among several agencies with discrete, though sometimes interfaced, authorities and responsibilities. These boundaries and connections are largely the result of legislative decisions made decades ago, when food production was almost exclusively domestic and the distinctions among producer sectors were much easier to discern. However, this fragmentation is not only embedded in statute; it is anchored in institutional traditions and political alliances that go back several decades. Any proposal to consolidate the federal food safety bureaucracy must take into account the statutory and institutional histories of the existing agencies, as well as the impact of such change at the federal level on domestic local governments and emerging international regimes.

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350 *See id.* at 22-23.

351 *See* U.S. GENERAL ACCOUNTING OFFICE, *supra* note 344, at 7-8.

352 *See generally*, FOOD SAFETY AND INSPECTION SERV., U.S. DEP'T OF AGRIC., CODEX ALIMENTARIUS (1999), *available at* http://www.fsis.usda.gov/OA/background/codex.htm (last visited Nov. 11, 2000).

353 *See id.*

IV. REORGANIZATION OF FEDERAL FOOD SAFETY REGULATION: AN OLD IDEA

Less than a decade after the FDA was moved out of the USDA, a commission chaired by former President Herbert Hoover recommended that food regulatory functions should be consolidated in a single agency—the USDA.[354] The Hoover Commission's report proved to be the first of more than twenty studies urging reorganization of federal food regulation. The following table lists the most prominent proposals.

Table 4.1[355]
Major Proposals for Reorganizing the Federal Food Safety Regulators Since 1949

Proposal	Year	Summary of Reorganization Recommendations
The Hoover Commission	1949	Transfer all food safety responsibilities to USDA.[356]
Department of Health, Education, and Welfare (HEW) Reorganization Directive	1968	FDA placed in the Public Health Service of HEW.
White House Conference on Food, Nutrition, and Health	1969	Create an interdepartmental committee to coordinate policy and consider the establishment of a single food safety agency.
Malek Report (House Commerce and Finance Subcommittee)	1969	Reorganize FDA into bureau for foods, pesticides, and product safety and bureau for drugs.

354 *See* THE HOOVER COMMISSION REPORT, *supra* note 138, at 250.

355 *See* DONNA U. VOGT, CONGRESSIONAL RESEARCH SERVICE, FOOD SAFETY: RECOMMENDATIONS FOR CHANGES IN THE ORGANIZATION OF FEDERAL FOOD SAFETY RESPONSIBILITIES, 1949-1997 (1998); INST. OF MED. & NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION 12-14 (1998).

356 Two of the twelve Hoover Commission members, James K. Pollack and James H. Rowe, Jr., dissented from the majority and advocated a unification of all food safety responsibilities within FDA, which would have remained a part of the FSA. *See* VOGT, *supra* note 15, at 137-38.

GAO (Need to Reassess Food Inspection Roles of Federal Organizations)	1970	Bureau of the Budget should undertake a detailed evaluation of the overlapping inspection activities of FDA, USDA, and other agencies to determine whether consolidation of some inspections would be feasible.
Ralph Nader (Sowing the Wind)	1972	Transfer USDA's meat inspection and chemical monitoring responsibilities and FDA's food inspection activities to a new, independent "consumer safety agency."
Consumer Safety Act (S. 3419)	1972	Create an independent Consumer Safety Agency that encompassed FDA's authority to regulate food and drugs; the CDC's licensing of certain clinical labs; and USDA's authority over meat and poultry inspection.[357]
Senate Government Affairs Committee Study on Federal Regulation	1977	Transfer USDA food safety activities to FDA.
President Carter's Government Reorganization Project (never released)	1978	Consolidation of all food safety activities. Final report did not resolve where this new organization would be located.
Lester Crawford	1980	Consolidation of all food safety functions within HHS; or transfer FDA's CFSAN and CVM to USDA; or merge CFSAN with CVM.

[357] *See id.* at 15-16. While S. 3419 passed in the Senate, the House was unwilling to transfer the FDA's responsibilities to an independent agency. *See id.* HEW Secretary Eliot Richardson opposed the bill, stating:

> I think . . . that if the Food and Drug Administration is going to have any problems of digestion of new responsibilities, the problems would be multiplied several fold by the effort to create a new agency duplicating administrative authorities and having to seek scientific capabilities and resources that are already within the Food and Drug Administration . . . . It is . . . much greater if we build upon the experience and capabilities of the Food and Drug Administration, than if we start all over again through the creation of [a] comparatively small, isolated outside body.

Id.

Sanford Miller	1989	Create special commission to recommend optimal food safety regulatory process (may include single agency).
Edwards Committee Report	1991	Remove FDA from PHS; FDA Commissioner would report directly to HHS Secretary.
GAO (Risk-based Food Safety Inspection)	1992	Congress should hold oversight hearings to examine options for reorganizing the federal food safety system, including creation of a single food safety agency that could administer a uniform set of statutes.
Food Safety and Inspection Agency Act (S. 1349)	1993	Place all federal food safety and inspection activities in a single, independent agency. Would set uniform risk-based inspection standards under the guidance of a 15-person expert commission. Introduced by Sen. Durenberger.
National Performance Review (Reinventing Government)	1993	Consolidate all federal food safety responsibilities under FDA.
Carol Tucker Foreman and the Safe Food Coalition	1993	Consolidate all federal food safety responsibilities under FDA.
Food Safety Reform Act	1993	Transfer to the Consumer Product Safety Commission all the food safety and inspection functions of USDA, FDA, EPA, Interior, and Commerce. Introduced by Sen. Metzenbaum.
Katie O'Connell Safe Food Act (H.R. 3751)	1994	Transfer USDA's meat, poultry, and egg inspection responsibilities to an independent Meat, Poultry and Eggs Inspection Agency. Introduced by Rep. Torricelli.

Safe Food Act	1997 1999	Consolidate all federal food safety, labeling, and inspection programs into a new independent Food Safety Administration.
National Academy of Sciences (Ensuring Safe Food)	1998	Presidentially-appointed leader would direct and coordinate federal activities, giving federal food safety efforts a single voice. New structure controls resources appropriated by Congress, and the structure would have a statutory foundation. Rejected White House-based "czar" and coordinating committee.

A. Major Reorganization Proposals

As Table 4.1 indicates, proposals to restructure federal food safety functions have embraced a wide spectrum of possible arrangements. Some would have consolidated all food safety duties in the USDA, on one extreme; others would have assigned them all to the FDA, on the other. Yet other proposals contemplated the transfer of current functions to a new "independent" unit or to an existing agency that currently exercises few food safety responsibilities. Several proposals refrained from offering a specific plan and simply endorsed the principle of consolidation.

1. The Hoover Commission: Consolidation in the USDA

One of the few government documents to become a best seller, the Hoover Commission Report of 1949 was remarkable in other ways as well.[358] The Commission's prominent membership, led of course by its chair, included Dean Acheson, Arthur Flemming, James Forrestal, and Joseph P. Kennedy.[359] Their report was a broad-ranging critique of the chaotic organization of a burgeoning bureaucracy and explored every major facet of the post-New Deal federal government.

The Hoover Commission specifically, but without elaboration, recommended that the FDA again be made part of the USDA. Finding that the statutory dispersal of food safety responsibilities among the USDA, the Federal Security Agency, the FTC, and the IRS "creates great overlap and also confuses the public," the Commission concluded that all federal food safety responsibilities should be transferred to the USDA.[360] Anticipating the criticism that the USDA's agricultural promotion role would dominate its

358 *See* THE HOOVER COMMISSION REPORT, *supra* note 138, at v-viii.
359 *See id.* at ii.
360 *See id.* at 250-51.

consumer protection mission, the Commission simply assured that "the Department of Agriculture will be vigorous in the protection of consumer interest."[361]

The formal allocation of food safety functions at the time the Hoover Commission was deliberating was not fundamentally different from the present structure. In 1947, the USDA devoted significant resources to inspecting meat products, spending over $9 million and employing about 3,000 field inspectors.[362] It also allocated $262,500 and 66 workers to regulating pesticides.[363] Overall, the USDA budgeted in excess of $20 million to the Bureau of Animal Industry, the departmental agency then chiefly responsible for food safety and the health of livestock.[364] The total FDA budget at the time was $4.2 million, which supported 1,000 employees, of whom nearly 700 were in the field.[365] The FDA's budget for regulating food sanitation, formulating food standards, and overseeing the safety of vitamin and dietetic products was approximately $2.5 million—less than one-third of the amount the USDA spent on meat inspection alone.[366]

2. The 1977 Senate Study: Consolidation in the FDA

Nearly thirty years after the Hoover Commission's report, the Senate Government Affairs Committee, under the chairmanship of Connecticut Democrat Abe Ribicoff, undertook a major review of "federal regulation." Over a two-year period, the committee staff studied a host of regulatory programs, including food safety regulation, and released their findings in December 1977.[367] Perhaps surprisingly, the committee—made up of senators as diverse as Edmund Muskie and Ted Stevens—was unanimous in its conclusions.[368] Among these was a recommendation that all federal food regulatory functions be consolidated in the FDA.[369] While acknowledging that the jurisdictional boundaries seemed "clearly drawn," the committee found that the relevant statutes—the FDCA, the MIA, and the PPIA—"form a patchwork of intricate inclusions, exclusions and interrelationships which frequently make a precise determination of where authority lies a most

361 *See id.* at 251.

362 *See* BUREAU OF THE BUDGET, THE BUDGET OF THE UNITED STATES GOVERNMENT FOR THE FISCAL YEAR ENDING JUNE 30, 1948, 288-89 (1947).

363 *See id.* at 355 (detailing the USDA budget to implement the Insecticide Act).

364 *See id.* at 257.

365 *See id.* at 159, 168-69.

366 *See id.* at 169.

367 *See* STUDY ON FEDERAL REGULATION, *supra* note 16, at iii.

368 *See id.* (noting in the report's transmittal letter that the committee had voted 16-0 to approve the report).

369 *See id.* at 140.

complicated matter."[370]

Portraying the FDA and the USDA as reflecting "two different worlds of inspection," the Ribicoff Report recommended the establishment of a single, unified food inspection force.[371] In an example chosen to support its finding that products were "falling through the cracks," the committee described a then-recent Consumers Union petition questioning the safety of meat and chicken pot pies and asking the FDA to establish tolerance levels for filth in these products.[372] The FDA had responded that it was forwarding the request to the USDA because pot pies were meat or poultry products and thus subject to the latter's regulation. A month later, the USDA wrote to Consumers Union stating that any filth in pot pies resulted from the pie shells and spices for whose regulation the FDA was responsible.[373] Later still the FDA acknowledged its jurisdiction over the pie shells, but after an exchange of letters lasting 18 months, the agency ultimately refused to initiate a survey of pot pies to determine tolerance levels for filth.[374]

The Ribicoff Report found similar problems of coordination in the USDA's voluntary inspection services, such as shell egg grading,[375] and in the two agencies' shared responsibilities for food labeling[376] and for chemical residues, and additives in meat and non-meat foods.[377] The committee summarized its assessment:

> [T]he current food regulation system results in duplication and inconsistency. As a result of the dual food inspection system, more than 2,000 plants [in 1977] are considered joint USDA-FDA responsibilities, and are subject to inspection by both agencies. The waste which stems from these duplicative inspections is undoubtedly excessive. Precious resources needed for effective food regulation are squandered.[378]

In sum, the committee concluded, the food safety system was "often duplicative, sometimes contradictory, undeniably costly, and unduly complex."[379]

Acknowledging that "[c]onsolidation of food regulation has been recommended by virtually every study of this area in recent years," the Committee nonetheless urged that this be achieved by transferring the

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370 *Id.* at 144-45.
371 *See id.* at 118-25.
372 *See id.* at 123.
373 *See* STUDY ON FEDERAL REGULATION, *supra* note 16, at 123.
374 *See id.*
375 *See id.* at 125-28.
376 *See id.* at 128-34.
377 *See id.* at 135-38.
378 *Id.* at 138.
379 STUDY ON FEDERAL REGULATION, *supra* note 16, at 139.

USDA's regulatory responsibilities to the FDA.[380] Its report addressed the familiar charge of conflict between the USDA's missions of agricultural promotion and public health protection, saying[381] "[w]hile recognizing that the USDA had remedied some of the practices which have subjected it to past criticism . . . . Nevertheless, we think it appropriate to separate the meat and poultry regulatory functions from the same agency whose duty it is to provide production of those products."[382] The committee also urged that the FDA's status within its parent Department be upgraded and that the FDA Commissioner be accorded greater independence.[383]

3. The National Performance Review: Consolidation in the FDA

Just seven years ago, the Clinton Administration's National Performance Review (NPR), headed by Vice President Gore, echoed the Ribicoff Report by proposing the transfer of the FSIS' meat and poultry inspection functions to the FDA.[384] Established to improve the efficiency and effectiveness of the departments and agencies, the NPR was the centerpiece of President Clinton's "reinvention" initiative.[385] The NPR argued that "[w]ith no fewer than 21 agencies engaged in research on food safety, often duplicating each other's efforts, we aren't progressing fast enough in understanding and overcoming life-threatening illness."[386] Finding that "[t]oo many items fall through the bureaucratic cracks" and that inter-agency referrals often failed to elicit cooperation, it proposed to give the FDA the dominant role in food safety.[387]

Despite the NPR's reformist rhetoric, the Clinton Administration never vigorously supported the transfer of the FSIS' responsibility to the FDA. Immediately after the release of the 1993 report, members of Congress began criticizing the plan.[388] By January 1996, the White House had jettisoned the

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[380] *Id.* at 139-40.

[381] *See id.* at 141 ("Indeed, one of the Department's primary missions is to promote agricultural production, and it properly does so. Unfortunately, the USDA has, in the past, been reluctant to take action that would discourage consumption, and numerous reports have found that the USDA has done an inadequate job of protecting the public health.").

[382] *Id.* at 141. In addition to recommending the consolidation of food safety responsibilities within the FDA, the Ribicoff Committee also urged upgrading the FDA's status in its parent department (then HEW) and increasing the independence of the FDA Commissioner. *See id.* at 143.

[383] *See id.* at 143.

[384] *See* ALBERT GORE, FROM RED TAPE TO RESULTS: CREATING A GOVERNMENT THAT WORKS BETTER & COSTS LESS: REPORT OF THE NATIONAL PERFORMANCE REVIEW 101 (1993).

[385] *See id.* at i.

[386] *Id*. at 101.

[387] *Id.*

[388] *See* Kenneth J. Cooper, *Hill Turf Fights May 'Reinvent' Gore Proposals; Long Loyalties, Parochial Politics Appear Likely to Reshape Recommended Changes*, WASH. POST, Sept. 13, 1993, at A19 (quoting then-Senator Dale Bumpers as saying that "political

NPR's plans for organizational change in favor of more easily attained goals, such as more widespread adoption of HACCP protocols in meat and poultry inspection.[389]

4. The 1998 NAS Report: Consolidation . . . Somewhere?

In the fall of 1997, Congress appropriated funds for the National Academy of Sciences to examine the "scientific and organizational needs for an effective food safety system . . . ."[390] In August 1998, the NAS panel formed to carry out this work released its report, *Ensuring Safe Food From Production to Consumption* (the NAS Report).[391]

Predictably, the NAS Report complimented the several federal agencies currently exercising food safety responsibilities for developing "many of the attributes of an effective system."[392] However, the report also found that the responsible agencies faced growing challenges on several fronts, including emerging pathogens such as *E. coli* 0157:H7, inspection of imported foods, the adequacy of inspection resources for commercial food processing facilities and larger food processors, and the increasing population at risk of foodborne illness.[393]

The NAS panel sought to define the attributes of an effective food safety system, stating that the government should have "one central voice at the federal level which is responsible for food safety and has the resources to implement science-based policy in all federal activities related to food safety."[394] According to the panel, an effective system should recognize the responsibilities of state and local regulators, and it should have adequate funding.[395] The NAS panel went on to identify several areas in which federal efforts fell far short of the ideal. It characterized federal food safety statutes as "[i]nconsistent, uneven and at times archaic . . . [that] inhibit use of science-based decision-making in activities related to food safety, including imported foods."[396] The panel found that "[a] lack of coordination on several levels seems to be one effect of the lack of strong focused leadership and the lack of a unified mission. The lack of coordination has resulted in a lack of national standards and a lack of focus

blood" would flow if the Clinton Administration attempted to close USDA field offices due to politicians' "parochial interest in those field offices").

389 *See* WILLIAM CLINTON & ALBERT GORE, REINVENTING FOOD REGULATIONS (1996).

390 *See* NAS Panel Appropriation, *supra* note 12, at H7518–H7519.

391 *See* ENSURING SAFE FOOD, *supra* note 6.

392 *Id.* at 2.

393 *See id.* at 4.

394 *Id.* at 7.

395 *See id.*

396 *Id.* at 9.

on food safety."[397] The NAS panel concluded that "[n]either routine surveillance programs, special projects, nor emerging issues are addressed in a coordinated interagency manner."[398] Coordination between federal and state officials was similarly lacking.[399]

Based on these findings, the NAS panel made five recommendations. Of immediate relevance, it recommended: "Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health."[400] Consistent with this reasoning, the panel also recommended elimination of carcass-by-carcass inspection of meat and poultry, establishment of a single set of inspection regulations for all foods, and acceptance of food only from countries with food safety controls equivalent to those in the United States.[401]

Most importantly, the NAS panel recommended that Congress restructure the federal food safety bureaucracy:

> Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.[402]

While it stopped short of recommending a single food safety agency, the panel emphasized that a successful food safety system requires unified leadership under a single official who can direct all federal food safety efforts and deploy resources as risks to food require.[403]

The NAS panel briefly surveyed possible organizational structures that might assure accountability. The options included: the creation of a food safety council with representatives from all responsible agencies under a presidentially-appointed chair; designation of one of the current federal agencies as the lead agency; creation of a single food safety agency reporting to a current cabinet-level secretary; and establishment of a new,

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397 ENSURING SAFE FOOD, *supra* note 6, at 87.

398 *Id.* at 88.

399 *See id.* ("Federal, state and local authorities must work with varied amounts of resources, skills, and legal authority. Lack of coordination and consistency between federal and state governments is problematic.").

400 *Id.* at 93.

401 *See id.* at 11.

402 *Id.* at 12.

403 *See* ENSURING SAFE FOOD, *supra* note 6, at 12. ("The key recommendation in this regard is that in order for there to be successful structure, one official should be responsible for federal efforts in food safety and have control of resources allocated to food safety.").

independent, cabinet-level food safety agency.[404] The panel quickly rejected two variants: appointment of a White House-based food safety "czar" and the establishment of a coordinating committee without line authority over personnel and resources.[405]

The NAS panel concluded by reemphasizing the impediments to effective regulation created by the "patchwork" of statutes and agencies that govern federal food safety efforts: "[R]egardless of the organizational structure chosen, a revamped federal food statute is critical to being able to reallocate resources toward risks that have or will have the greatest significance to the public's health."[406]

5. President Clinton's Council on Food Safety: Coordination In Lieu of Consolidation

Soon after publication of the NAS report, President Clinton established by Executive Order the Council on Food Safety.[407] Jointly chaired by the Secretaries of Agriculture and HHS and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy,[408] the Council's main purpose is:

> [T]o develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Science report 'Ensuring Safe Food from Production to Consumption' and other input from the public on how to improve the effectiveness of the current food safety system.[409]

The "principal goal" of the Council's strategic plan "should be the establishment of a seamless, science-based food safety system."[410] The President also charged the Council with the responsibility of supervising the agencies' creation of coordinated food safety budgets for submission to OMB and guiding federal food safety research.[411]

The Food Safety Council has taken steps toward each of the tasks set out in the President's Executive Order. In 1998, it held a series of public meetings and sought comments on the creation of its strategic plan for federal food safety regulation.[412] The principal agencies of HHS and the USDA have

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404 *See id.* at 13 Box ES-4.

405 *See id.*

406 *Id.* at 15.

407 *See* Exec. Order No. 13,100, 63 Fed. Reg. 45,661 (1998) [hereinafter FOOD SAFETY COUNCIL EXECUTIVE ORDER].

408 *See id.*

409 *Id.*

410 *Id.*

411 *See id.*

412 *See* Food Safety Initiative Strategic Plan, 63 Fed. Reg. 52,120 (1998) (announcing public meetings of the President's Food Safety Council to discuss the Council's strategic

created a unified presentation of federal food safety initiatives, though they have not yet produced a unified budget.[413]

In March 1999, the Food Safety Council released its assessment of the NAS panel's report.[414] The Council supported all of the panel's recommendations *except* the suggestion that Congress establish a unified structure for regulation with a single official in control of federal food safety resources.[415] The Council said that it "agrees with the *goal* of the NAS recommendation—that there should be a fully integrated food safety system in the U.S.,"[416] but it was not ready to endorse any politically treacherous institutional reorganization. The Council cautioned that "if not done carefully, separating food safety from non-food safety activities in each agency could act to weaken consumer and environmental protection overall."[417] Instead, it promised that its strategic report would include an assessment of "structural models and other mechanisms that could strengthen the federal food safety system through better coordination, planning, and resource allocation."[418]

Though he charged the Council with producing a unified food safety budget, President Clinton did not give it authority to veto individual agency budget requests.[419] Furthermore, the Council's structure does not yield a clear leader who can serve as the government's voice on federal food safety issues. As a result, the Council is basically a coordinating body. While the current White House and the agencies that it oversees seem committed to cooperation, the recent coordination measures are non-statutory. They do not respond to the NAS panel's observation that "[t]here appear to be no mechanisms to sustain expanding interagency coordination after the current national concern abates and the attention of Congress, the President, and agency leadership is directed to other issues."[420]

plan and seeking comment on the 1998 NAS report).

413 *See* U.S. DEP'T OF AGRIC. & U.S. DEP'T OF HEALTH AND HUMAN SERVS., BACKGROUNDER: 2000 PRESIDENT'S FOOD SAFETY INITIATIVE (2000), *available at* http://www.foodsafety.gov/~fsg/fsiback.html (last visited Nov. 9, 2000) (presenting food safety initiatives and multi-agency budgetary data).

414 FOOD SAFETY COUNCIL NAS ASSESSMENT, *supra* note 316.

415 *See id.* at ii–iii (indicating that the Food Safety Council "supports" the NAS panel's recommendations, except for NAS recommendation IIIa for which the Council "supports the goal" of the recommendation).

416 *Id.* at 13 (emphasis added).

417 *Id.* at 13–14.

418 *Id.* at 13.

419 *See* FOOD SAFETY COUNCIL EXECUTIVE ORDER, *supra* note 407.

420 ENSURING SAFE FOOD, *supra* note 6, at 87.

B. Arguments For and Against Consolidation

Congressional hearings have furnished contemporary advocates of reform a platform for criticizing the current organization of food safety programs and proclaiming the benefits of consolidation. In 1993 and 1994, subcommittees of the House Committee on Government Operations held hearings on the NPR recommendation that federal food safety responsibilities be consolidated within the FDA.[421] And within the year the Subcommittee on Governmental Management, Restructuring, and the District of Columbia of the Senate Committee on Governmental Affairs held a hearing on Senator Richard Durbin's proposal[422] to assign food safety functions to a new, non-cabinet agency.

At the opening of the 1993 House hearings, Representative Mike Kreidler of Washington acknowledged the NPR reorganization recommendation but stated, "*Frankly, getting the job done is more important to us than who does the job*."[423] Testimony at the 1999 Senate hearing illustrates what some reform proponents now believe the "job" is and how consolidation might help "get it done." Caroline Smith DeWaal of the Center for Science in the Public Interest (CSPI) and former USDA Assistant Secretary Carol Tucker Foreman, speaking for the Consumer Federation of America, have led the call for consolidation. Other supporters include Mark Silbergeld of Consumers' Union and former FDA Commissioner David Kessler.[424]

Critics of the government's efforts to mitigate foodborne risks identify many problems and reorganization would respond to some better than others. The chief criticisms focus on political accountability for major policy decisions, distribution of food safety resources, adequacy of safety standards and enforcement authority, and overlapping agency jurisdiction.

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421 *See Reinventing the Federal Food Safety System: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations and Joint Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations and the Subcomm. on Info., Justice, Transp., and Agric. of the House Comm. on Governmental Operations*, 103d Cong. (1994) [hereinafter *Reinventing the Federal Food Safety System Hearings vol. 1* and *Reinventing the Federal Food Safety System Hearings vol. 2*].

422 *See* The Safe Food Act, *supra* note 19.

423 *Reinventing the Federal Food Safety System Hearings vol. 1*, *supra* note 421, at 3-4 (statement of Representative Mike Kriedler) (emphasis added).

424 *See* ENSURING SAFE FOOD, *supra* note 6, at 173 (noting Silbergeld's support for a single food safety agency in a presentation to the 1998 NAS panel); Malcolm D. MacArthur, *Single Food Safety Agency is Debated But Unlikely to Pass*, PAPER, FILM & FOIL CONVERTER, Aug. 1, 1998, at 20 (noting Kessler's endorsement of a single food safety agency).

As Ms. Foreman elaborated at the 1999 hearing:

> The existing food regulatory system offends every rule of good organization and management. There is no clear statement of mission for protecting the public. Each agency operates under different statutes. There are no clear lines of authority and responsibility. Resources are not allocated according to need and priority. There is no clear standard for success.[425]

1. Diffuse Political Accountability

The NAS panel, echoing other critics, contended that the balkanized bureaucratic structure dilutes political accountability.[426] These critics point out that there is no executive officer—short of the President—whose responsibilities encompass all food products and the programs responsible for regulating them. As the panel noted,

> The multi-faceted federal framework of the U.S. food safety system lacks direction from a single leader who can speak for the government when confronting food safety issues and providing answers to the public. There is no single voice in the government to communicate with stakeholders regarding food safety issues. The lack of clear leadership at the federal level impedes the federal role in the management of food safety. Leadership is needed to set priorities, deploy resources, and integrate a consistent policy into all levels of the system.[427]

This critique implicates the ability of the federal executive to "speak with one voice" both domestically and internationally,[428] to allocate resources effectively, to direct responses to crises, and to accept responsibility for mistakes.

Other authorities have emphasized that dispersed leadership is more than a symbolic problem. Lack of official accountability, in their view, can obstruct vigorous management. Former FSIS Administrator Michael

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[425] *Hearing Before the Subcomm. on Government Management, Restructuring and the District of Columbia, U.S. Senate Committee on Governmental Affairs* 106th Cong. 81, 88 (1999) (statement of Carol Tucker Foreman) [hereinafter 1999 Carol Tucker Foreman Testimony].

[426] *See, e.g.*, ENSURING SAFE FOOD, *supra* note 6, at 8; CENTER FOR SCIENCE IN THE PUBLIC INTEREST, COMBINE ALL U.S. FOOD SAFETY FUNCTIONS INTO A SINGLE AGENCY, THE FOOD SAFETY ADMINISTRATION, *available at* http://www.cspinet.org/reports/hr2801.htm (last visited Nov. 11, 2000) [hereinafter CSPI SINGLE AGENCY POLICY STATEMENT].

[427] ENSURING SAFE FOOD, *supra* note 6, at 8.

[428] *See Hearing Before the Subcomm. on Gov't Mgmt., Restructuring and the Dist. of Columbia, Senate Comm. on Governmental Affairs*, 106th Cong. 131, 133 (1999) (statement of Sanford A. Miller) ("[G]iven the inexorable move towards a truly global food supply, there is need for a parallel global food safety structure. A single U.S. focus would make it far easier to speak in this arena with a single authoritative voice.") [hereinafter 1999 Miller Testimony].

Taylor, who previously served as the FDA's Deputy Commissioner, has observed: "There's no question that organizational fragmentation and inconsistency in statutory requirements are major obstacles to having the best possible food safety system . . . . Responsibility is widely diffused, making the system much more difficult to manage."[429]

Carol Foreman provided examples of the obstacles posed by the lack of unitary responsibility for food safety. She recounted that in 1992 the FDA and FSIS staff had advocated very different approaches for nutritional labeling of fat in ground beef. It took President Bush to break a deadlock over labeling format, which the USDA and HHS Secretaries and their respective staffs had been unable to resolve.[430] She also noted that in 1999 some FDA personnel had complained about Agriculture Secretary Glickman's comments on the labeling of genetically modified foods, suggesting that the FDA was trying to protect its turf.[431] According to Foreman, turf battles are a natural result of a regulatory system in which leadership is dispersed and "[p]rotecting the home turf will almost always outweigh all other considerations."[432] Former CFSAN Director Sanford Miller has noted that the absence of unitary leadership[433] makes interagency cooperation dependent on good personal relationships among agency officials.

Ms. Foreman also argues that lack of central authority, coupled with splintered jurisdiction, prevents the allocation of resources in accordance with risks. Foreman noted that despite concerns that the FDA may lack the resources to assure adequate inspection of shellfish, the agency may not borrow money or inspectors from the USDA's better-funded meat or poultry inspection programs.[434] Thus, in her view, lack of central accountability, as well as ineffective program control, may increase health risks.

The NAS panel argued that a reorganization that assigned accountability for federal food safety regulation in one agency, and ultimately one official, would provide communication as well as management benefits. The panel's

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[429] *See* Marian Burros, *Safety in Numbers? Hardly; Debate Fires Up For Merger of U.S. Food Inspection Agencies*, PITT. POST-GAZETTE, Apr. 17, 1997, at F1.

[430] *See* 1999 Carol Tucker Foreman Testimony, *supra* note 425, at 89. This episode proves that there is one person with true accountability over federal food safety—albeit a very busy one—the President.

[431] *See id.* at 90.

[432] *Id.*

[433] *See* 1999 Miller Testimony, *supra* note 428, at 133 (Aug. 4, 1999) ("In my experience, as long as the leadership has respect and good personal relations with each other, the system will work. When there are professional and personal conflicts, it will not.").

[434] *See* 1999 Carol Tucker Foreman Testimony, *supra* note 425, at 85.

report stressed the importance of creating a "*single* federal voice for food safety," a presidential appointee who will "speak to the nation, giving federal food safety efforts a single voice."[435]

We are persuaded that consolidation of responsibility for federal food safety functions *would* enhance political accountability. Collecting dispersed functions under a single administrator would allow one official to speak with authority. Central budgeting of food safety activities could enhance the ability of the administration, and perhaps of Congress, to allocate resources more rationally even if statutorily-driven inspection requirements remained unchanged. However, these benefits would come at a price and must be balanced against the disruption consolidation would produce. Indeed, this disruption, in our view, requires that the political feasibility of consolidation be assessed with skepticism.

2. Jurisdictional Overlaps and Gaps

Food safety program jurisdictions are typically defined by product category, resulting in some foods being regulated by more than one agency.[436] Critics of the current structure have charged that such jurisdictional overlap is inefficient.[437] More importantly, they contend that divided responsibility allows some food hazards to escape regulatory control. The National Performance Review's endorsement of consolidation begins with the stark conclusion: "Sometimes duplication among federal programs can make us ill—even kill us."[438] Senator Torricelli, co-sponsor of the 1997 Safe Food Act, stated, "[l]ack of coordination among the various agencies has unnecessarily endangered the health of millions of Americans, and it cannot be permitted to continue."[439]

In several reports and testimony before Congress, the CSPI has sought to spotlight food safety problems that "fall through the cracks of agency jurisdiction."[440] It has pointed out, for example, that both the NMFS and the AMS, which operate voluntary inspection programs (for seafood plants and

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[435] *See* ENSURING SAFE FOOD, *supra* note 6, at 13 (emphasis added).

[436] *See* discussion *supra* Part III.A.

[437] *See, e.g.*, U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-97-249R, FOOD SAFETY: FUNDAMENTAL CHANGES NEEDED TO IMPROVE FOOD SAFETY 2 (1997) (arguing that the structure of the federal food safety bureaucracy "necessitates extensive coordination efforts to minimize wasteful duplication of effort, prevent gaps in regulatory coverage, and avoid conflicting actions. However, as might be expected, our work has shown that the responsible agencies have not always been successful").

[438] GORE, *supra* note 384, at 101.

[439] *FDA and USDA Avoid Strong Stance on Single Food Agency Bill*, FOOD CHEM. NEWS, Nov. 10, 1997.

[440] Natalie Pargas, *Optimum Food Safety Forum at IFT Segues to Consumer Education Issues*, FOOD CHEM. NEWS, July 6, 1998.

egg producers, respectively) have adopted policies to notify the FDA, which possesses formal regulatory authority, about unsanitary conditions found during inspections.[441] However, the GAO has reported that because inspectors and managers are often unaware of these referral requirements, during the period from 1988 to 1991 the NMFS failed to notify the FDA about conditions at 198 seafood plants that failed sanitation inspection.[442]

The CSPI has contended that miscommunication has similarly undermined the effectiveness of the FDA/USDA regulation of eggs. Egg regulation is now the shared responsibility of the FDA (shell eggs), the FSIS (processed egg products), and the AMS (registration of major commercial egg producers).[443] According to the CSPI, the USDA's shell egg graders and inspectors (employed by the AMS through that agency's voluntary egg grading service) often fail to notify the FDA of serious sanitation violations.[444] In one example, the USDA's APHIS (responsible for animal health) investigated a *Salmonella*-contaminated chicken flock but did not notify the FDA of its results for almost a month. By then, the FDA was unable to locate the *Salmonella*-contaminated eggs to attempt a recall.[445] Acknowledging difficulties in the regulation of eggs, the FSIS and the FDA have jointly sought comments regarding "how best to address the food safety concerns associated with shell eggs in the context of their mutual, HACCP-based, farm-to-table food safety strategy."[446] However, Senator Richard Durbin, claiming that the FDA's egg safety efforts are "almost non-existent," has called on the agency to relinquish its role in favor of exclusive USDA regulation.[447]

The CSPI's Caroline Smith DeWaal has presented examples of similar risks that are regulated inconsistently by different agencies. Ms. DeWaal cited the classic example of continuously inspected (FSIS) frozen pepperoni pizza and infrequently inspected (FDA) cheese pizza.[448] She also testified

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441 *See* U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-92-152, FOOD SAFETY AND QUALITY—UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY 48-49 (1992).

442 *See id.*

443 *See Salmonella Enteritidis* in Eggs, 63 Fed. Reg. 27,502, 27,508 (1998) (outlining current federal regulation of egg safety) [hereinafter *Salmonella Enteritidis* in Eggs].

444 *See* ELIZABETH DAHL & CAROLINE SMITH DEWAAL, SCRAMBLED EGGS: HOW A BROKEN FOOD SAFETY SYSTEM LET CONTAMINATED EGGS BECOME A NATIONAL FOOD POISONING EPIDEMIC (1997), *available at* http://www.cspinet.org/reports/eggs.html (last visited Nov. 11, 2000).

445 *See id.*

446 *Salmonella Enteritidis* in Eggs, *supra* note 443, at 27,509.

447 *See Durbin Tells FDA to Relinquish Control of Egg Regulation, Hand it to USDA*, FOOD CHEM. NEWS, July 5, 1999, at 19.

448 *See* Caroline Smith DeWaal, *Testimony Before the Subcommittee on Government Management, Restructuring and the District of Columbia, U.S. Senate Committee on*

that the FDA and the FSIS are implementing different versions of HACCP in their respective regulation of seafood and meat, products that present similar and significant risks:

> [B]oth frequent inspection and laboratory verification of product samples are essential to give the government appropriate oversight over plants utilizing HACCP. Otherwise, the HACCP program is little more than an industry honor system. While the USDA requires both on-site inspection by government inspectors and two levels of laboratory verification of meat and poultry products, the FDA requires neither for seafood products. The FDA inspects seafood plants once every one to five years and made laboratory testing for HACCP verification optional for seafood processors.[449]

Offering yet another example, DeWaal stated that the FDA and the EPA have implemented different limits on methylmercury in fish: The EPA has set a more stringent standard for recreationally caught fish than the FDA applies to commercially caught fish.[450]

Ms. DeWaal has also called attention to interagency differences in enforcement techniques and testing methods. Among her examples is the difference between the FDA's and the USDA's handling of imported foods: the USDA has the authority to investigate and approve as meeting U.S. requirements the standards and procedures followed by countries from which food is imported, a power the FDA lacks.[451] Ms. DeWaal also reported complaints by state agencies that federal officials have refused to adopt uniform testing and reporting requirements. Thus, local officials must often perform multiple tests on the same foods in order to report requested information to different federal agencies.[452]

Though skeptical of consolidation, the Administration's Council on Food Safety has acknowledged that the boundaries on agency jurisdiction have sometimes proved dysfunctional:

> There are numerous instances in the existing food safety system where the division of regulatory responsibility is not optimal. For example,

Governmental Affairs 106th Cong. 96, 104 (Aug. 4, 1999) [hereinafter 1999 DeWaal Testimony].

[449] *Id*. at 105-06. Perhaps as a consequence of FDA's method of HACCP implementation for seafood, DeWaal noted that in 1999 70% of seafood plants were not complying fully with the regulation. *See id.* at 113.

[450] *See id.* at 109. This apparent discrepancy could be justified, however, if recreationally caught fish were consumed in greater quantities, at least by some consumers, or if mercury were harder—and thus more costly—to avoid in commercial fish. *See id*. *See also* Mary Ellen Butler, *Harkin, Leahy Call on the FDA to Change Mercury Standard, Sample Fish*, FOOD CHEM. NEWS, Aug. 28, 2000 (describing legislative efforts to eliminate this disparity).

[451] *See* 1999 DeWaal Testimony at 107.

[452] *See id.* at 108.

> within the same plant, FSIS and FDA inspectors are often responsible for different foods. The FDA and the FSIS also share regulatory responsibility of eggs and egg products. Examples such as these create stakeholder confusion and inefficient allocation of resources. Any reorganization must consider areas where there is significant jurisdictional overlap.[453]

Advocates of consolidation emphasize the disadvantages of product-defined statutory boundaries. Such boundaries as the meat/non-meat distinction divide regulators along product rather than functional lines. Former FDA Commissioner David Kessler has argued that the current system fails to cover the "holes in the safety net."[454] The CSPI contends that the current bureaucratic organization, with its product-based distinction between inspectors, produces regulation that is "confusing, wasteful and highly ineffective."[455] Consolidation proponents argue that a consolidated system would improve food inspection by forcing currently separate inspection groups to work together.

The conclusion implied by these critiques seems plausible. If an integrated agency could field a unified inspection force, coordination problems would decrease and the inefficiencies of overlapping jurisdiction would diminish. A unified command structure might more easily marshal the efforts of inspectors, epidemiologists, physicians, and other professionals involved in food safety regulation.

Yet there is no guarantee that a consolidated structure would be more effective than the current dispersed structure. In the short term at least, the organization would rely on the same personnel who now staff the disparate agencies. The organization would face the challenge of managing a huge bureaucracy made up of employees drawn from several agencies with diverse histories and organizational cultures. Indeed, consolidation might impede efficiency. Secretary of Agriculture Glickman made his doubts emphatic: "To totally reorganize our food safety system and move to a single agency right now would wreak havoc."[456]

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[453] FOOD SAFETY COUNCIL NAS ASSESSMENT, *supra* note 316, at 14.

[454] Malcolm D. MacArthur, *Single Food Safety Agency is Debated But Unlikely to Pass*, PAPER, FILM & FOIL CONVERTER, Aug. 1, 1998, at 20.

[455] *See* CSPI SINGLE AGENCY POLICY STATEMENT, *supra* note 426. The CSPI states:

> Lettuce has caused a number of outbreaks from the hazardous strain of *E. coli* bacteria normally associated with hamburgers. Although we have USDA inspectors who visit farms, they don't inspect the crops for safety. FDA, the food safety agency most likely to regulate lettuce, doesn't inspect farms. *Lettuce falls through the cracks of our current food safety system. An independent Food Safety Administration could better address known hazards in the food supply*.

Id. (emphasis added).

[456] *See* Rick Weiss, *Food Safety Council Set; Panel is to Coordinate Federal Role*,

Consolidation could also sacrifice the benefits of competition among agencies. The NFPA's Kelly Johnston has argued, "by consolidating food safety under a single, presumably politically appointed individual, we eliminate the current checks and balances of the current system . . . ."[457] The Food Safety Council has asserted that in some areas interagency competition can be beneficial:

> [R]esearch and programs for food safety often do not operate as separate activities within the agencies, but rather draw significant strength from one another. While some projects are entirely focused on food safety, the food safety research portfolio includes many other projects in such areas as animal health and animal genetics.[458]

The Council has gone even further, contending that some problems can *only* be solved by distinct organizations, saying "[m]any food safety issues would be difficult to resolve by a reorganization. For example, some issues like bovine spongiform encephalopathy [mad cow disease] are both animal health issues and human health issues. Foodborne disease problems may also be waterborne disease problems."[459] Thus, unless a new structure were to encompass the USDA's animal health programs and the EPA's water quality programs, assuring safety would remain a multi-agency responsibility.

3. Misallocation of Resources

Several critics of the current structure, including the NAS panel and the GAO, have faulted the distribution of resources among the federal food safety agencies. The GAO, for example, recently questioned the cost-effectiveness of FSIS' meat and poultry inspection regime, comparing it with FDA's inspection of most other foods:

> More than one-fourth of the over $1 billion federal budget for food safety–about $271 million–could be used more effectively if most of these funds were congressionally redirected from the Food Safety and Inspection Service's organoleptic (seeing smelling, and touching), carcass-by-carcass slaughter inspections to a number of other food safety activities that need attention.[460]

Noting that the FSIS inspection budget—driven by the MIA and the PPIA mandates of carcass-by-carcass inspection—dwarfs the FDA's

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WASH. POST, Aug. 26, 1998, at A17.

[457] Remarks of Kelly D. Johnston, Remarks at the 1998 National Food Policy Conference (Mar. 23, 1998), *available at* http://www.nfpa-food.org/Speech/singlefoodagency.html (last visited Nov. 11, 2000).

[458] FOOD SAFETY COUNCIL NAS ASSESSMENT, *supra* note 316, at 15.

[459] *Id.* at 14-15.

[460] OPPORTUNITIES TO REDIRECT FEDERAL RESOURCES, *supra* note 251, at 2.

inspection budget, the GAO argues that this allocation erroneously implies that non-meat foods represent significantly lower risks.

Shrinking from controversy, the NAS panel did not call attention to the resource disparity between the FSIS and the FDA, but it did criticize the distribution of resources between the FDA and other agencies. "FDA's lack of resources to maintain adequate inspection and monitoring of commercial food facilities and of fresh fruits and vegetables, both domestic and imported, using statute-driven methods of monitoring and enforcement, increases the threat of foodborne disease and related hazards in the food supply."[461] The panel went on to observe that, in the face of increasing responsibilities, "FDA's shrunken inspection force is seriously over-extended, and FDA appears to have insufficient resources to meet its statutory obligations."[462]

In 1999 Senate testimony, the CSPI's DeWaal charged flatly that the FDA's food safety resources are inadequate. She presented data indicating that over three times as many outbreaks of foodborne illness have been traced to FDA-regulated foods as to USDA-regulated foods.[463] Yet, she observed, the FDA's food safety budget is approximately one-third that of the USDA, even though the latter is responsible for less than half of the food consumed by Americans.[464] "In essence, the FDA regulates more food with less money."[465] Narrowing her focus, DeWaal also complained that FDA food safety programs commanded less than 30% of that agency's total budget while, in her view, they represent more than half of the agency's responsibilities.[466] Speaking more generically, the NAS panel concluded that "resources currently identified for research and surveillance are inadequate to support a science-based program."[467]

Advocates of reform predict that programmatic consolidation would permit existing resources to stretch further. Carol Tucker Foreman has stated that "[r]esources now are not used efficiently." The new system she advocated would "rely on HACCP, and the government . . . [would] not have to have as many people inspecting."[468] Without other statutory changes, however, organizational consolidation might not affect the relative distribution of resources among food safety programs. The largest

461 ENSURING SAFE FOOD, *supra* note 6, at 8.
462 *Id.* at 87.
463 *See* 1999 DeWaal Testimony, *supra* note 448, at 99.
464 *See id.* at 101.
465 *Id.*
466 *See id.* at 101-02.
467 ENSURING SAFE FOOD, *supra* note 6, at 90.
468 *FDA and USDA Avoid Strong Stance on Single Food Agency Bill*, FOOD CHEM. NEWS, Nov. 10, 1997.

components of federal food safety expenditures are driven by the MIA and PPIA mandates for continuous carcass-by-carcass inspection.[469] The NAS panel recognized this obstacle to rebudgeting:

> Statutory revision is essential to the development and implementation of an effective and efficient science-based food safety system . . . . The meat and poultry inspection laws mandate a form of compliance monitoring that is largely unrelated to the magnitude or the types of risks that are now posed by those foods. This diverts efforts and perhaps resources from actual risks and other hazards.[470]

Thus, without amendment of the MIA and the PPIA, or a reinterpretation of these requirements to discover greater flexibility, it seems doubtful that organizational consolidation alone would lead to a major reallocation of resources.[471]

Even so, consolidation could cause program budgets to shift at the margins. With just one agency seeking funding, competition among programs for funds might prove easier to control.[472] While external constituencies would still lobby for increased (or reduced) funding for specific functions, a centralized process might yield a unified budget[473] that permitted allocation of resources in accordance with estimated risks.

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[469] *See* discussion *supra* Part III.C.2.

[470] ENSURING SAFE FOOD, *supra* note 6, at 7-8.

[471] Similarly, a statutory mandate that required the FDA to inspect the food processors within its jurisdiction either continuously or more periodically would cause a shift in the relative distribution of resources.

[472] As we discuss *infra* Part VII, the political battle over which, if any, congressional committees would be willing to give up oversight over the consolidated food safety agencies looms large. As NFPA President John R. Cady has stated:

> Right now, two House and two Senate committees share jurisdiction over the nation's food safety system. Each takes rightful pride in its expertise and role in the process and would be hard pressed to relinquish its responsibilities. This is a major hurdle to be overcome—perhaps the largest issue to be addressed.

John R. Cady, *Does America Really Need a Food Czar?*, Remarks to the Mid-America Food Processors Association (Dec. 1, 1997), on file with the Seton Hall Law Review.

[473] While President Clinton has proposed the creation of "unified food safety budget" within the current organizational framework of the federal food safety agencies, such a term is a misnomer. Such a "budget" would still be considered among the various congressional subcommittees that appropriate funding to the several federal food safety agencies. Thus, any rationalization of spending that may be conducted at the administration level would still be subject to the judgement of more than one set of appropriations subcommittees in the House and Senate. A truly unified food safety budget would be passed by the same congressional appropriation subcommittees in the House and Senate in order to preserve the value of rational balancing of risks and costs in a single budget.

4. Statutory Deficiencies

Advocates of food safety reform have criticized existing statutory standards and agency enforcement powers as insufficiently protective of public health. Notably, the NAS and the GAO have questioned the appropriateness of the FSIS' inspection methods for meat and poultry.[474] The NAS panel concluded:

> The sensory evaluation inspection methods used in FSIS inspections were appropriate when adopted 70 years ago, when major concerns included gross contamination, evidence of animal disease, and other problems that are no longer acute concerns. Those methods are not appropriate or adequate to detect the major microbial and chemical hazards of current concern.[475]

President Clinton expressed his own skepticism about the FSIS's approach:

> I was literally stunned when I came here to find out that we were inspecting meat in the United States in the same way we had inspected it since 1910—and in the same way that dogs inspect it today, by smelling it and touching it. We're doing a little better now.[476]

Carol Tucker Foreman has contended that the FDA's regulation of fruits and vegetables is likewise deficient. Citing CSPI data indicating that these products are among the most likely to be linked to foodborne illness outbreaks, Foreman testified, "Raw fruits and vegetables are terribly susceptible to bacterial contamination. They are subject to the most cursory inspection. The FDA has issued a 'guidance' for these products. There are no regulations, no HACCP, no performance standards for limited bacterial contamination."[477] Ms. Foreman's criticism implies a failure of regulators to take real threats seriously, a recurrent theme among critics of federal food safety efforts.

The critics also contend that agency officials, even when appropriately inspired, lack legal authority to correct known deficiencies. It is a matter of debate, however, whether apparent statutory limits on agency authority are as firmly anchored, and thus difficult to escape, as officials contend.[478]

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474 *See* discussion *supra* Part III.C.2.

475 ENSURING SAFE FOOD, *supra* note 6, at 27.

476 Clinton, *supra* note 5, at 375.

477 *See* 1999 Carol Tucker Foreman Testimony, *supra* note 425, at 85.

478 The D.C. Circuit has recently opined on this issue, holding that FSIS inspectors may not delegate their statutory inspection obligations to industry employees under the HACCP regulations. *See* Am. Fed. of Gov't Employees v. Glickman, 215 F.3d 7 (D.C. Cir. 2000) ("Delegating the task of inspecting carcasses to plant employees violates the clear mandates of the FMIA and PPIA.").

Supreme Court decisions have made clear that administrators have broad discretion to interpret, and where appropriate revise their interpretations of, their statutory authority.[479] We have not studied the text or history of the various statutory provisions that are often claimed to be impediments to effective regulation. We accept such claims as sufficient to establish that substantive statutory reforms *may* be necessary to place regulation on a sound footing. Accordingly, we assume that any serious reform initiative will require congressional approval of substantive as well as organizational changes in current law.

Some complaints about statutory inflexibility clearly seem well-grounded. In the last year alone legislators have introduced several proposals to modernize the FDA's and the USDA's inspection and enforcement authority, where it was clear that the FDCA, the MIA, or the PPIA needed to be amended to provide the missing instrument. For example, legislators have proposed an amendment to the FDCA that would give the FDA two powers currently held by the USDA: foreign equivalency authority and the power to destroy adulterated imports.[480] Bills have also been introduced to provide the USDA with recall authority, in addition to its current ability to withdraw continuous inspection.[481] Legislators have further proposed mandatory quarterly inspections by the FDA (a version of the continuous inspection required of the USDA), annual registration of FDA-regulated food producers, and statutory recall authority.[482]

We should not overlook the controversies over the standards that

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[479] *See* Chevron, U.S.A., Inc. v. Natural Res. Defense Council, Inc., 467 U.S. 837 (1984) (holding that a court must defer to an administrative agency's reasonable interpretation of an ambiguous statute). *See also* Regions Hosp. v. Shalala, 522 U.S. 448 (1998) (applying *Chevron* deference to HHS interpretation of the Medicare Act); Sullivan v. Everheart, 494 U.S. 83 (1990) (applying *Chevron* analysis to HHS interpretation of Social Security Act); Patricia M. Wald, *Judicial Review in Midpassage: The Uneasy Partnership Between Courts and Agencies Plays On*, 32 TULSA L.J. 221, 241-44, 247 (1996) (stating that "Chevron was a preemptive strike to force courts out of the business of telling agencies what they could do, or could not do, when the law itself was not clear," and concluding "[t]he Supreme Court said, in effect, we will find a general congressional intent to leave it to the agency where there is any doubt about what the law means."); Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984, 1057 (1990) (presenting empirical evidence that *Chevron* has had the effect of increasing judicial deference to administrative agencies).

[480] *See* Imported Food Safety Improvement Act, S. 1123, 106th Cong. (1999) (providing for FDA equivalency authority, authority to destroy adulterated imports, and authority to prohibit port shopping).

[481] *See* Safe and Fair Enforcement and Recall for Meat and Poultry Act, S. 48, 106th Cong. (1999); H.R. 983 (providing for USDA meat and poultry recall authority).

[482] *See* Consumer Food Safety Act of 1999, S. 908, 106th Cong. (1999); H.R. 1612, 106th Cong. (1999) (providing for FDA recall authority, annual registration of FDA-regulated food producers, and quarterly inspection mandate).

agencies are to apply in deciding whether a practice, a food, or a food-use chemical, is safe. For example, debate continues over the standard the FDA is to apply in deciding whether to approve new food additives, and particularly over the notorious Delaney Clause, which purports to forbid approval of any additive that has been shown to cause cancer in animals.[483] Congress narrowed the reach of that provision in the 1996 Food Quality Protection Act, which established a new standard for approving pesticide residues in food. The Act also opened a new debate by mandating that the EPA take special measures to protect children against even small risks.[484]

In other contexts, critics contend, current law permits the use of substances in food that increase risk to consumers. Debate persists over the approval of macro-additives and substances derived through genetic engineering. The EU and the United States are still engaged in economic warfare over the issue of hormone-treated beef,[485] and the exploding controversy over genetically modified food crops may yet provoke fundamental changes in the statutory standards for testing, approval, and label disclosure of new food technologies.[486]

These examples have not dominated the current debate over federal food safety regulation or its bureaucratic organization. The revival of demands for consolidation has been fueled largely by concerns about pathogenic organisms in food and the apparent failure of governmental efforts to prevent them.[487] But if, as seems clear, organizational consolidation would require congressional action, and if consolidation without substantive statutory reform would represent only a partial victory for its proponents, we must contemplate a much larger arena of policy debate. Proponents of consolidation must not only entertain the possibility of statutory reforms that they might oppose, they must also reckon with the

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[483] *See, e.g.*, STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE (placing the Delaney Clause in a class of statutes that if applied literally, may be unreasonably and pointlessly strict); Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 YALE J. ON REG. 1 (1988); Edward Dunkelberger & Richard A. Merrill, *The Delaney Paradox Reexamined: Regulating Pesticides in Processed Foods*, 48 FOOD & DRUG L.J. 411 (1993); Lars Noah & Richard A. Merrill, *Starting from Scratch? Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 395-401 (1998).

[484] *See* Kenneth Weinstein et al., *The Food Quality Protection Act: A New Way of Looking at Pesticides*, 28 ENVTL. L. REP. 10,555 (1998).

[485] *See* David Aboulafia, *Pushing RBST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin to America*, 15 PACE ENVTL. L. REV. 603 (1998).

[486] *See supra* Part I.A.4.

[487] *See, e.g.*, Burros, *supra* note 429 ("Following an outbreak of the hepatitis A virus from contaminated strawberries, an increasing number of food safety experts are questioning whether it is time to retire the federal government's fragmented system of regulation and start all over again.").

likelihood that obstacles to agreement on an expanded policy agenda will ultimately doom any chance for consolidation. Achieving agreement on consolidation might facilitate the consideration of substantive changes in safety standards and enforcement authority. It is equally possible, however, that substantive reforms would prove even *more* difficult. After the heroic investments of political capital that would be necessary to achieve organizational consolidation, it is quite conceivable that neither the President nor members of Congress would retain any zest for food safety reform.

V. THE ENVIRONMENTAL PROTECTION AGENCY: A PRECEDENT FOR CONSOLIDATION?

In an effort to broaden our assessment of the possible gains from, and likely impediments to, consolidating federal food safety functions, we searched for historical parallels. The closest recent example that we found was the creation of the EPA by President Nixon's Reorganization Plan of 1970.[488] Nixon assembled in the EPA the environmental protection functions of ten separate programs previously based in the Departments of the Interior, HEW, and Agriculture, as well as the Atomic Energy Commission.[489] This was a genuine confederation of existing activities and the bureaucracies that performed them. As Mark Landy and his co-authors have emphasized, the "new" EPA was largely staffed with personnel who brought with them the "concepts, attitudes, and skills that had served their former agencies."[490] More importantly, these personnel, though covered by a new letterhead and on a new payroll, continued to operate under their original statutory charters.[491]

Since its creation, the EPA's programs have undoubtedly improved environmental quality. Even after thirty years, however, the agency still has not fully integrated its constituent parts and it continues to administer a series of separate media-specific statutes. These characteristics have hampered, though not defeated, the EPA's ability to regulate environmental risks in a consistent and coordinated manner—which was one of the primary goals of its creation. This does not mean that consolidation was a mistake, only that full integration remains a long-term and elusive goal.

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488 *See* Reorganization Plan No. 3, *supra* note 156.

489 *See id.*

490 MARK K. LANDY ET AL., THE ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS FROM NIXON TO CLINTON 34 (1994) ("For example, the pesticide group from Agriculture had long been more interested in promoting productivity than in protecting human health and the environment.").

491 *See* Reorganization Plan No. 3, *supra* note 156, at § 2 (noting the transfer to EPA of statutory responsibility for enforcing portions of at least fourteen statutes, including the Federal Water Pollution Control Act, the Atomic Energy Act, FIFRA, and the FDCA).

A. Rationale For the EPA's Creation

The history of the EPA's creation illustrates the political sensitivities, and consequent difficulties, exposed by any effort to assemble a new federal agency out of existing bureaucratic units. Following the publication of Rachel Carson's *Silent Spring*, public awareness of environmental pollution grew rapidly through the 1960s.[492] Facing the prospect of a 1972 reelection battle against the likely Democratic nominee, Senator Edmund Muskie, a prominent spokesman for environmental regulation, President Nixon felt pressure to act.[493] A presidential task force had already recommended the establishment of a Department of Environment and Natural Resources (DENR) that would be the fifth largest cabinet department after Defense, HEW, Agriculture, and the new Department of Transportation.[494] This proposed department would have combined almost all of the current responsibilities of the EPA with other functions that remain in the Departments of Energy and the Interior.[495]

In 1969, Nixon asked the Ash Council, a group he had appointed to study governmental reorganization, to design a plan to implement the DENR concept.[496] However, after study the Ash Council members resisted the massive consolidation that creation of the DENR would have required. Notably, they feared not only that Congress would not accept the resulting disruption of legislative committee arrangements, but also that the new Department would not be sufficiently integrated to permit effective management. The Council also objected to combining resource development activities and environmental protection functions in the same agency,[497] echoing the long debate over the FDA's location within the USDA. After the incumbent Secretaries of Commerce, Agriculture, and HEW also refused to endorse the proposal to create the DENR, President Nixon backed a more modest plan, embodied in the modern EPA.[498] Accordingly, the EPA was inspired by the anticipated impact of

[492] *See* JOHN C. WHITAKER, STRIKING A BALANCE 8-15, 24 (1976) (citing polling data on awareness of environmental issues and the impact of SILENT SPRING).

[493] *See* LANDY ET AL., *supra* note 490, at 28-30 .

[494] *See id.* at 30-31; ALFRED A. MARCUS, PROMISE AND PERFORMANCE: CHOOSING AND IMPLEMENTING AN ENVIRONMENTAL POLICY 40 (1980).

[495] *See* MARCUS, *supra* note 494, at 39.

[496] *See* LANDY ET AL., *supra* note 490, at 31.

[497] *See id.*

[498] *See id.* at 32. President Nixon created the EPA by Reorganization Plan No. 3, authorized by 5 U.S.C. § 901(a)(1), which obligated the Executive "to promote the better execution of laws, the more effective management of the executive branch and of its agencies and functions, and the expeditious administration of the public business." Reorganization Plan No. 3, *supra* note 156 (reproducing the President's Message to Congress). Nixon also cited the Executive's obligation under section 901(a)(3) "to increase the efficiency of the operations of the Government to the fullest extent practicable." *Id.*

environmental issues on the 1972 election but structured to take account of perceived political and bureaucratic obstacles.

In the planned reorganization, the President collected the primary federal water quality, air quality, solid waste, pesticide, and radioactive waste protection programs.[499] Specifically, his plan transferred to the EPA the following agencies: (1) from the Interior Department, the Federal Water Quality Administration; (2) from HEW, the National Air Pollution Control Administration, the Bureaus of Solid Waste Management, Water Hygiene, and Radiological Health of the Environmental Control Administration and the FDA's Office of Pesticides Research; and (3) from the USDA, the Plant Protection Division and the Pesticides Regulation Division of the ARS.[500] In addition, the EPA absorbed the Federal Radiation Council and the Division of [Radiation] Protection Standards of the Atomic Energy Commission.[501] In all, the EPA aggregated programs whose 1971 budgets totaled over $1.1 billion and which employed 5,176 civil servants.[502] Today, the agency employs over 11,000 people and has a budget of over $2 billion.[503]

President Nixon's message to Congress proclaimed that combining these diverse programs would enable the new EPA to launch a "coordinated attack" on pollution.[504] He specifically found that the existing multi-agency response to interrelated problems of environmental degradation was inadequate:

> [T]he present governmental structure for dealing with environmental pollution often defies effective and concerted action. Despite its complexity, for pollution control purposes the environment must be perceived as a single, interrelated system. Present assignments of departmental responsibilities do not reflect this interrelatedness. *Many agency missions, for example, are designed primarily along media lines–air, water, and land. Yet the sources of air, water, and land pollution are interrelated and often interchangeable.*[505]

Nixon's assessment of the fragmentation of federal environmental regulation in 1970 parallels contemporary criticisms of federal food safety programs.

The solution to the problem of divided regulatory responsibility was

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499 *See id.* at § 2.

500 *See id.*

501 *See id.*

502 *See* MARCUS, *supra* note 494, at 45 tbl.6.

503 *See* FY99 FEDERAL BUDGET APPENDIX, *supra* note 230, at 878-80.

504 Reorganization Plan No. 3, *supra* note 156 (reproducing the President's Message to Congress).

505 *Id.* (emphasis added).

the creation of "a strong, independent agency."[506] Nixon's conception of an "independent" agency was a body that would be outside of the existing cabinet structure but still very much under the authority of the President. The EPA was to study, monitor, and regulate pollutants "irrespective of the media in which they appear."[507] Moreover, the new agency would set "consistent standards covering the full range of . . . waste disposal problems."[508] Thus, perhaps the most significant programmatic goal of the EPA's creation was to facilitate integration of research, standard-setting, and enforcement across the assertedly artificial boundaries of air, water, and land.[509]

B. Assessments of the EPA's Performance

Despite the difficulties inherent in its formation and the enormity of the challenges that it faces, the EPA has made important progress in reducing environmental pollution. The GAO recently concluded:

> Substantial progress has been made in addressing the nation's environmental problems since the [EPA] was created in 1970. Among other improvements, some of our most serious air and water quality problems have been alleviated, dangerous pesticides have been banned, and health threats posed by lead in gasoline and paint have been reduced.[510]

One crude measure of the EPA's achievement is the amount by which industrial waste has been reduced since 1970. By this measure, the EPA has made gains in cleansing each of the media that it regulates.

Air pollution has declined significantly since 1970. By 1991, the regulatory strategies of the Clean Air Act—controlling outdoor sources such as smokestacks and curbing combustion by-products from mobile sources—had substantially reduced concentrations of five of the six pollutants for which the EPA has established National Ambient Air Quality Standards.[511] Since then, the number of metropolitan areas out of

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[506] *Id.*

[507] *Id.*

[508] *Id.*

[509] In fact, Douglas Costle, director of President Nixon's EPA transition task force, envisioned an EPA organization that would eventually discard media-based divisions (*e.g.*, water, air, pesticides) in favor of functional (*e.g.*, planning, standard-setting, and research) that would oversee regulation of all pollutants. *See* MARCUS, *supra* note 494, at 37.

[510] U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/RCED-97-155, ENVIRONMENTAL PROTECTION—CHALLENGES FACING EPA'S EFFORTS TO REINVENT ENVIRONMENTAL REGULATION 16 (1997).

[511] *See* COMM. ON ADVANCES IN ASSESSING HUMAN EXPOSURE TO AIRBORNE POLLUTANTS, NAT'L RESEARCH COUNCIL, HUMAN EXPOSURE ASSESSMENT FOR AIRBORNE POLLUTANTS: ADVANCES AND OPPORTUNITIES 1 (1991). *But see* COMM. ON TROPOSPHERIC OZONE FORMATION AND MEASUREMENT, NAT'L RESEARCH COUNCIL, RETHINKING THE

compliance with air quality standards has dropped from 199 to fewer than 70.[512] Since 1970, emissions of airborne particulate matter have decreased by 78% and emissions of lead have declined by 98%—leading to a 75% reduction in the average blood-lead levels in children since 1978.[513] Total emissions of smog-causing nitrogen oxides, however, have increased by 14% since 1970, due primarily to automobile usage and the operation of coal-powered energy plants.[514]

The same period has also seen significant improvements in surface water quality. Finding the vast majority of publicly-owned wastewater treatment plants to be in compliance with the Clean Water Act, a NAS panel in 1993 reported that "[w]here they were once elevated, concentrations of lead, DDT, and PCBs in coastal fish, shellfish, and sediments are decreasing."[515] Regulations that require industrial dischargers to pretreat waste before releasing into local sewers have reduced toxic discharges by an estimated 75%.[516] Improved sewage treatment reduced discharge of oxygen-consuming wastes by 36% between 1970 and 1992.[517] Despite these gains, however, some 40% of the nation's lakes, rivers, and streams remain too dirty for fishing and swimming.[518]

The EPA has also been able to report major decreases in the release of hundreds of toxic pollutants. Between 1988 and 1993, the volume of chemicals on the EPA's Toxic Release Inventory released into the environment dropped by 43%.[519] Releases of seventeen of the EPA's high priority toxins decreased by more than 46% from 1988 to 1994.[520]

Nonetheless, it is difficult to know to what extent these gains in pollution

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OZONE PROBLEM IN URBAN AND REGIONAL AIR POLLUTION 41 (1991) (finding significant incidence of non-compliance for ambient ozone concentrations throughout the United States).

512 *See* U.S. ENVTL. PROT. AGENCY, TWENTY-FIVE YEARS OF ENVIRONMENTAL PROGRESS AT A GLANCE, *available at* http://www.epa.gov/ngispgm3/nrmp/history/topics/25year/intro.pdf (last modified Sept. 8, 2000) (discussing national environmental trends from 1970–1995) [hereinafter TWENTY-FIVE YEARS OF ENVIRONMENTAL PROGRESS].

513 *See id.*

514 *See id.*

515 COMM. ON WASTEWATER MGMT. FOR COASTAL URBAN AREAS, NAT'L RESEARCH COUNCIL, MANAGING WASTEWATER IN COASTAL URBAN AREAS 33 (1993) (finding improvements in Puget Sound, New York Harbor, and the Delaware River Estuary, but noting that many urbanized bays and estuaries are not experiencing similar recoveries).

516 *See* TWENTY-FIVE YEARS OF ENVIRONMENTAL PROGRESS, *supra* note 512 (noting that more than 30,000 major industrial dischargers are now covered by pretreatment regulations).

517 *See id.* (finding reduced discharges of oxygen-consuming waste into national waters from 6,700 metric tons per day in 1970 to 4,300 metric tons per day in 1992).

518 *See id.*

519 *See id.*

520 *See id.*

reduction are attributable to Nixon's 1970 decision to consolidate previously dispersed programs. The creation of the EPA was not primarily an effort to improve the management of long-established programs that already enjoyed broad political support. Rather, it marked the first in a series of dramatic steps by which the federal government elevated environmental protection to a high place on the nation's agenda. Many more important steps were to follow, of which the most significant were the successive legislative revisions of the Clean Air Act in 1970,[521] 1977,[522] and 1990,[523] and of the Water Pollution Control Act in 1972, 1977, and 1990.[524] In addition, Congress substantially broadened the reach of the EPA's regulatory authority through the enactment of new laws such as the Toxic Substances Control Act, the Resource Conservation and Recovery Act of 1976,[525] and a series of strengthening amendments to the pesticide laws.[526]

Thus, the regulatory tools available to the modern EPA look very different from those President Nixon was able to assign to the agency in 1970. Moreover, the budgets for the various programs for which the EPA was given responsibility also grew dramatically during the 1970s and 1980s, even as successive administrations began to lose enthusiasm for environmental protection. For example, in 1970 the Federal Water Quality Administration had a budget of $1 billion;[527] the EPA's spending on state assistance for clean water programs alone is now about $2 billion.[528] Budgets in other program areas have at least doubled.[529] EPA spending on food safety activities—nearly all of which relates to pesticide regulation—has quadrupled.[530]

It would be naïve to attribute the EPA's successes solely to the decision to consolidate environmental programs in 1970. Yet it would also be wrong to conclude that that decision was not important. That decision surely facilitated, and may even have inspired, some of the dramatic legislative reforms that appear more critical today. It is also quite possible that the EPA's visibility, coupled with its comprehensive jurisdiction, attracted more

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521 Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676 (1970).

522 Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685 (1977).

523 Clean Air Act Amendments, Pub. L. No. 101-549, 104 Stat. 2399 (1990).

524 Federal Water Pollution Control Act, Pub. L. No. 95-217, 91 Stat. 1566 (1977).

525 Pub. L. No. 94-580, 90 Stat. 2795 (1976).

526 *See, e.g.*, Federal Insecticide, Fungicide, and Rodenticide Act, ch. 125, 61 Stat. 163 (1947); Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

527 *See* MARCUS, *supra* note 494, at 45 tbl.6.

528 *See* FY1999 FEDERAL BUDGET APPENDIX, *supra* note 230, at 881.

529 *Compare* FY1999 FEDERAL BUDGET APPENDIX, *supra* note 230, at 881 (detailing 1998 federal environmental spending on state aid by EPA program) *with* MARCUS, *supra* note 494, at 45 tbl. 6 (detailing 1971 environmental spending by agency).

530 *See* MARCUS, *supra* note 494, at 45 tbl. 6 (showing $16 million of spending on federal pesticide activities in 1971); FY1999 FEDERAL BUDGET APPENDIX, *supra* note 230, at 878 (showing $60 million of EPA food safety spending in 1998).

funds for environmental protection than could have been assembled by its various component programs had they remained separate. To the extent that reducing the risks associated with food consumption depends on increased appropriations for existing programs, assembling them in the same agency may attract aggregate funding at levels they could not independently expect.

C. Lessons for Food Safety

The mere possibility of increased funding for food safety regulation, however, would not justify consolidation if it would not also improve efficiency, reduce duplication, and bridge gaps in the structure. Accordingly, it is also useful to explore the impact of the EPA's creation in these areas.

While EPA efforts have reduced emissions in many media, the agency has not achieved *integrated* control of pollution across the land, sea, and air. The EPA has never found it possible to escape the media-based structure that it inherited when its constituent programs were assembled.[531] Most of the statutes that the agency administers, including the Clean Air Act,[532] the Clean Water Act,[533] the RCRA Superfund,[534] are still media-based.[535] Some authorities claim that the lack of an integrated law obstructs efforts to evaluate and regulate pollutants in a coordinated, rational fashion.[536] Former EPA

[531] *See* U.S. ENVTL. PROT. AGENCY, EPA ORGANIZATIONAL STRUCTURE, *at* http://www.epa.gov/epahome/organization/ (last modified Nov. 6, 2000) (depicting within the EPA organization the Assistant Administrators for Air and Radiation; Prevention, Pesticides, and Toxic Substances; Solid Waste and Emergency Response; and Water).

[532] Act of July 14, 1955, ch. 360, 69 Stat. 322 (codified at 42 U.S.C. §§7401-7671q (1994)).

[533] Water Pollution Control Act, ch. 758, 62 Stat. 1155 (1948), *amended by* the Clean Water Act, Pub. L. No. 95-217, 91 Stat. 1566 (1977) (codified at 33 U.S.C. §§ 1251-1387 (1994)).

[534] Pub. L. No. 96-510, 94 Stat. 2767 (1980) (codified at 42 U.S.C. §§ 9601-9675 (1994)).

[535] *See* U.S. ENVTL. PROT. AGENCY, ENVIRONMENTAL LAWS THAT ESTABLISH EPA'S AUTHORITY, *at* http://www.epa.gov/history/org/origins/laws.htm (last modified Oct. 10, 2000) (listing major environmental statutes enforced by EPA: the Clean Air Act; the Clean Water Act; the Comprehensive Environmental Response, Compensation and Liability Act; the Emergency Planning and Community Right-to-Know Act; the Endangered Species Act; the Federal Food, Drug and Cosmetic Act; the Federal Insecticide, Fungicide and Rodenticide Act; the National Environmental Policy Act; the Occupational Safety and Health Act; the Oil Pollution Act of 1990; the Pollution Prevention Act; the Resource Conservation and Recovery Act; the Safe Drinking Water Act; the Superfund Amendments and Reauthorization Act; and the Toxic Substances Control Act).

[536] *See, e.g.*, NAT'L ACAD. OF PUB. ADMIN., RESOLVING THE PARADOX OF ENVIRONMENTAL PROTECTION 65 (1997) ("Fragmentation makes it harder to protect the environment. Statutes and regulations which focus on one form of pollution in one media [sic]–air, water, or land–typically fail to recognize the interactions among different pollutants from one medium to another."); Robert M. Sussman, *An 'Integrating' Statute*, ENVTL. F., Mar./Apr. 1996, at 16 (arguing that Congress' failure to integrate EPA's statutes is a "major failing" of the federal environmental protection system).

Deputy Administrator Robert Sussman has observed:

> Taken as a whole, the laws EPA implements do not communicate clear environmental goals or provide effective tools for measuring progress. They lack rational mechanisms for allocating resources to the greatest environmental challenges. They establish differing and often conflicting decision-making criteria from one law to another. And they discourage multimedia strategies that integrate and streamline requirements across programs.[537]

The "integrating statute" that Sussman calls for would not replace existing media-specific statutes.[538] Rather, it would provide an overarching legal framework within which the agency could prioritize competing goals, allocate resources according to the seriousness of environmental risks, and promote multi-media solutions to environmental pollution.[539]

While the EPA budget and staffing levels have risen markedly since 1970, the increases have not always produced coherent regulation. As Alfred Marcus has argued, much of the EPA remains "a coalition of small fiefdoms" divided by distinct statutory programs, regional offices, and staffs:

> [F]or the first twenty years of EPA's existence, [its environmental] goals remained unattainable as the narrow perspectives of bureaucrats worked against achieving such broad principles. Program managers were tied to specific laws, functions, and appropriations that perpetuated longstanding pollution control distinctions. Regional administrators had local connections and enough independence not to act in concert with Washington.[540]

Thus, in addition to the statutory boundaries that define its programs, bureaucratic divisions within the EPA—some regional and some programmatic—continue to present obstacles to cohesive, multidisciplinary regulation of environmental pollution.

For us, the relevant question remains whether the EPA experience could serve as an instructive model for possible consolidation of federal food safety functions. The similarities between the announced goals of the Nixon Administration and those of current advocates of food safety consolidation are striking. Nixon claimed to be seeking a structure that could enlist the federal government's disparate environmental programs in a "coordinated attack" on pollution.[541] Proponents of food safety reform seek a resource-enriched, politically visible agency to coordinate the federal government's efforts to

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[537] Sussman, *supra* note 536, at 16.

[538] *See id.* at 17.

[539] *See id.*

[540] Alfred A. Marcus, *EPA's Organizational Structure*, 54 LAW & CONTEMP. PROBS. 5, 30 (1991).

[541] Reorganization Plan No. 3, *supra* note 156 (reproducing the President's Message to Congress).

combat foodborne illness through a "farm-to-table" strategy.[542] They lament that disaggregated regulators separately administer a collection of statutes that address different products, prescribe different modes of enforcement, and set different standards of performance.[543]

There are, however, important contextual differences that weaken the predictive value of the EPA experience. First, the political constituencies that supported the EPA are quite different from those that now endorse food safety consolidation. The creation of the EPA was driven by a popular movement sparked by Rachel Carson's *Silent Spring* and embraced by a President who feared a strong election opponent.[544] Environmental organizations remain vocal and politically influential. Concerns about food safety, however, have not yet catalyzed a vigorous political movement. The constituency for "food safety" may be populous, but its voice is weak. Although Agriculture Secretary Dan Glickman argued that the 1993 *E. coli* outbreak that killed four children and sickened thousands started a "tidal wave of public interest,"[545] this supposed interest has thus far failed to propel the cause of regulatory consolidation or produce stronger tools for either the USDA or the FDA.

In 1970, the Nixon Administration argued that a major benefit of consolidating environmental regulation would be the ability to determine the total environmental exposure to pollutants *regardless of media* and minimize aggregate exposure to the most serious risks.[546] Thus, the goal of managing multi-media risks through total exposure estimates drove the scientific community's support of an effort to consolidate media-specific programs. No similar technology-based rationale has yet been advanced to support the

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[542] *See, S.T.O.P.—Safe Tables Our Priority: Hearing Before the Subcomm. On Gov't Mgmt., Restructuring and the Dist. Of Columbia, Senate Comm. On Governmental Affairs*, 106th Cong. 92, 94 (1999) (statement of Nancy Donley) ("Consolidating food safety activities into a single independent agency would elevate food safety, prevent duplication and fill in gaps that currently exist in our multiple agency system.") [hereinafter 1999 Donley Testimony].

[543] *See, e.g.*, DYCKMAN, *supra* note 18, at 1, 3. The author noted:

> Twelve different agencies administer as many as 35 laws that make up the federal food safety system . . . . Programs emerged piecemeal, typically in response to particular health threats or economic crises. The laws not only assigned specific food commodities to particular agencies but also provided the agencies with different authorities and responsibilities, reflecting significantly different regulatory approaches.

Id.

[544] *See* discussion *supra* note 473 and accompanying text..

[545] *See* Glickman, *supra* note 5 (arguing that the 1993 outbreak caused "[a] tidal wave of public interest [that] tips the political scales—uniting industry, . . . consumers, government and public health officials behind a food safety revolution").

[546] *See* Reorganization Plan No. 3, *supra* note 156 (reproducing the President's Message to Congress) (outlining a "more effective approach to pollution control" that would assess all pollutants and regulate by total exposure including multi-media interactions).

consolidation of federal food safety functions. Despite frequent calls for "farm-to-table" food safety regulation and the need for improved risk assessment, reform advocates have not yet been able to portray a new system that could model total foodborne risk and calibrate regulatory requirements accordingly.

Other salient differences make the EPA experience a weak predictor of the effects of consolidating food safety functions. Most of the programs that President Nixon combined to form the EPA were relatively new federal initiatives. With the exceptions of pesticide regulation and radiation control, an original task of the Atomic Energy Commission, regulation of environmental pollution had been viewed as a federal responsibility for little over a decade.[547] Few of the relocated units had long histories, deeply rooted traditions, or strong institutional coherence. By contrast, the two primary components of a consolidated food safety agency, the FDA and the FSIS, have been in business for nearly a century and responsible for administering statutes that in key respects look much as they appeared at the beginning of World War II.[548] Their established practices and institutional memories could present durable impediments to program integration and unified management.

VI. CONSTRUCTING A PLAN FOR FOOD SAFETY CONSOLIDATION

However one assesses the success of the EPA "experiment," this example of consolidation is both a reminder of the challenges facing such organizational initiatives and evidence that integration of previously dispersed programs is a long-term project. It also demonstrates the need for a kind of concrete analysis and advance planning that few proponents of consolidating food safety functions have so far shown. No proponent of consolidation has offered a detailed description of the organization she envisions. None identifies all of the current government functions they would assemble or examines the formal steps that would be required to achieve the goal.[549] The advocates of consolidation do, however, share two

[547] *See* ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION 106-11 (2d ed. 1996) (indicating that most significant federal environmental legislation was not enacted until the 1970s).

[548] *See* discussion *supra* Part II.

[549] The most concrete proposal is outlined in the Safe Food Act, *supra* note 19. The bill calls for the creation of an independent establishment as defined in 5 U.S.C. § 104 (a non-cabinet department) to be known as the Food Safety Administration (FSA). *See id.* The FSA would implement the food safety provisions of the FDCA, PPIA, MIA, Egg Products Inspection Act, and "such other laws and portions of laws regarding food safety, labeling, and inspection as the President may designate by Executive order . . . ." *Id.* The FSA would assume the food safety budget and responsibilities "as determined by the President" of the FSIS, CFSAN, CVM, NMFS, and "such other offices, services, or agencies as the President may designate by Executive order . . . ." *Id.* Thus, the President at the time of the adoption of the Safe Food Act would have quite a bit of discretion to pick and choose agencies and

assumptions and most express firm (albeit differing) views about where in the federal bureaucracy the combined entity should be located.

Consolidation proponents obviously believe that regulatory performance will improve if the appropriate program elements are clustered in one organization, whether in a new or existing entity. They see other gains as well, possibly in aggregate resources for food safety, and more certainly in public visibility and political accountability. But the core of their case is a belief that unitary management can bridge gaps, avoid duplication, and deploy existing resources more effectively than the currently splintered programs now do—even when they agree to cooperate.[550]

Proponents also appear to assume that Congress would have to approve any consolidation plan by passing new legislation. The lapse of statutory reorganization authority means that currently no President could bring about even a partial consolidation by Executive Order.[551] Generally, however, they do not explore the implications of this assumption, either for the likelihood of success or for more practical issues, such as the timetable for achieving the elusive goal. Many proponents appear to believe that the self-evident benefits of consolidation will inspire members of Congress from both parties to join in supporting the essential legislation.

Finally, though some advocates of consolidation (including the 1998 NAS panel) appear agnostic on the matter of bureaucratic location, most express a clear preference about which part of the existing structure should house the combined programs. The Hoover Commission recommended

statutes for the FSA to encompass.

[550] *See* discussion *supra* Part IV.B.

[551] During much of the period since World War II, Congress had established a mechanism for sharing reorganization duties with the President. *See* 5 U.S.C.A. § 901(d) (West Supp. 1999) ("The President shall from time to time examine the organization of all agencies and shall determine what changes are necessary . . . ."); *id.* § 906 (mandating House and Senate approval of reorganization plans submitted by the President under authority of 5 U.S.C. § 901). In 1949, Congress passed the Reorganization Act, ch. 226, § 2, 63 Stat. 203, to implement the recommendations of the Hoover Commission. This statute was later reauthorized and codified in the Reorganization Acts of 1966. Pub. L. No. 89-554, 80 Stat. 394 (1966). The Reorganization Acts permitted the President to develop and submit reorganization plans to both houses of Congress. *See* 5 U.S.C.A. § 903(b) (West Supp. 1999). Congress was required to approve or disapprove the President's plan without amendment within ninety days of its transmission. *See id.* § 906(a). Each of the successive versions of reorganization authority carried an expiration date or sunset. Congress extended the expiration date five times between 1966 and 1984, and ignored the expiration altogether in 1995, but then allowed the authority to lapse. *See* 5 U.S.C.A. § 905(b) (West Supp. 1999) ("A provision contained in a reorganization plan may take effect only if the plan is transmitted to Congress . . . *on or before December 31, 1984.*") (emphasis added). There appears to be no immediate prospect of renewal. Accordingly, any plan to consolidate some or all of the federal government's current food safety functions would require legislative approval.

returning the FDA to the USDA, and dismissed concerns that combining regulatory and promotional functions would compromise the former.[552] More recent advocates of consolidation have been skeptical of such an arrangement for the very reasons that the Hoover Commission dismissed.[553] Their caution may not demonstrate that the risk of conflict has risen. Rather it may simply reflect heightened sensitivity to the practical pressures that regulators are believed to face. In any event, those who favor extracting the USDA's food safety programs and combining them with the FDA's programs—either within HHS or outside it—may now reflect the dominant view.[554]

Beyond these generalizations, it is surprising how little attention proponents have given to the specifics of consolidation. We believe that one cannot realistically assess the merits of consolidation, much less its political prospects, without greater attention to specifics. In this part, we explore a series of questions that anyone who seriously entertains the idea of consolidation should want addressed. These questions are not mere matters of detail; their analysis reveals the complexity of translating an appealing concept into an organizational reality. Their resolution will affect the magnitude of the challenge and perhaps determine the prospects of success.

A. Identifying Programs To Be Consolidated

In discussions about consolidation of food safety programs, the obvious leading candidates are the FSIS' meat and poultry inspection programs, and the food sanitation activities of the FDA's CFSAN. The working assumption is that the combination would include both headquarters officials and the field inspection forces of the two agencies. FSIS inspectors comprise a highly specialized force devoted exclusively to meat and poultry inspection, whose oversight probably could be shifted

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[552] *See* discussion *supra* Part IV.A.1.

[553] *See, e.g.*, U.S. GENERAL ACCOUNTING OFFICE, PUB. NO. GAO/T-RCED-94-223, FOOD SAFETY—A UNIFIED, RISK-BASED FOOD SAFETY SYSTEM NEEDED 4-5 (1994) (statement of John W. Harmon). Mr. Harmon stated:

> We also still believe, as we testified in 1972, that it is important for the food safety mission to be housed in an agency that is not charged with responsibilities that might conflict, or appear to conflict, with its willingness to aggressively administer its public health protection responsibilities . . . . While there are a number of proposals to reorganize USDA to separate its food safety and agriculture promotion responsibilities, they would still be housed under a department with conflicting roles.

Id.

[554] *But see* Allison Beers, *Senators Say USDA Should Be the Single Food Safety Agency*, FOOD CHEM. NEWS, Aug. 9, 1999 (noting that two congressional supporters of a single food safety agency advocate consolidation within USDA).

without disrupting field operations.[555] Most of the FDA's smaller corps of inspectors, however, are not narrowly specialized and many visit facilities that span the agency's regulatory responsibilities.[556] Their service is budgeted by case or project, for example, the inspection of food warehouses. Each FDA center has a claim on a portion of the total inspection time that the agency has been given resources to support. While it may be possible to identify some FDA inspectors whose regular work is exclusively food safety-related, most display the versatility of street policemen, responsible both for investigating gang violence and issuing speeding tickets.

The FDA's multipurpose inspection force would not be a significant impediment to consolidation of those FSIS and CFSAN activities devoted to the production of major food products, but other agency programs would need to be considered. A notable example is the FDA's program for regulating chemicals used in food production—food ingredients (either food additives or GRAS substances), coloring agents, and packaging materials (so-called indirect additives)—or found to contaminate food.[557] These activities rest in the CFSAN's Office of Premarket Approval. They could be moved, along with the rest of the Center, to a new agency, but this would leave behind another food safety-related program housed within the FDA, the Center for Veterinary Medicine, which is responsible for approving and policing the use of veterinary drugs. The rationale for this unit rests on the same scientific foundation that underpins the CFSAN's premarket approval program. Indeed, the two programs share certain facilities, as well as research and analytical methods. If it makes sense to combine programs that target foodborne pathogens with programs aimed at chemicals in food, it would be difficult to justify omitting the CVM's drug residue program.

This logic, however, leads to a larger question: What about the EPA's pesticide program, one of whose main functions is to set limits on pesticide residues on food—limits that the FDA or the USDA then enforces?[558] This activity was once housed within the FDA because it was governed by provisions of the FDCA, which also governed the agency's regulation of other food-use chemicals. We do not challenge the 1970 decision to make the EPA responsible for both tolerance setting and premarket review of

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555 *See* discussion *supra* Part III.C.2.

556 *See* DESCRIPTION OF FIELD ACTIVITIES, *supra* note 320 ("With a highly trained staff versed in all of FDA's product responsibilities, the Agency can respond rapidly to various types of emergencies, and can also redirect field efforts from time to time during the year among FDA's different programs as inspection and product testing needs change.").

557 *See* discussion *supra* Part III.B.

558 *See* discussion *supra* Part III.D.

pesticides, for the same toxicological data underlie both types of decisions. But the present arrangement is surely open to question if the goal now would be to combine the major *food safety* programs in a single organization.

A moment's reflection will reveal that some of the relocations suggested by the foregoing discussion would sever other programmatic linkages, some of which reflect an independent logic. For example, if one were to shift the CVM's drug residue program from the FDA, would it make sense to leave the reminder of the Center's veterinary drug approval program behind? After all, many of the same scientists who evaluate the safety of possible residues for human consumers are involved in determining whether a drug will be safe for animals. It might in theory seem feasible to separate responsibilities for drugs used on animals produced for human food from those for drugs for use on companion animals, but the same therapeutic agents are often useful in both. Does this suggest that the CVM's entire operation accompany the CFSAN in any reorganization?[559]

So far we have focused on programs whose primary functions or organizational location make them logical candidates for inclusion in a single food safety agency, but the possibilities do not stop there. Other federal agencies perform functions that contribute to the national government's efforts to keep food safe. A prime example is the CDC. Proponents of consolidation must confront the question whether personnel at the CDC who are now involved in monitoring and investigating outbreaks of foodborne disease should be moved into the new organization. And if they should not, they must explain how these still-separate functions are to be coordinated.

Similar decisions would also have to be made about the Department of Commerce's remaining seafood safety activities, the Customs Service's port-of-entry monitoring of food imports, and the Department of Justice's responsibility for court enforcement activities initiated by the FSIS or the CFSAN. The Department of Commerce's claim to a continuing role in this area strains credulity. Accordingly, the Clinton Administration's plan to relocate its seafood safety functions in the FDA seems logical. By contrast, it would seem foolish to consider separating Customs' responsibility for food imports from its oversight of all other imports, or to make reorganization of food safety programs the occasion for renewing the debate over the Department of Justice's monopoly over federal court litigation.

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[559] This question is made more difficult by the FDA's recent decision to regulate genetically engineered animals as animal drugs. *See* Rebecca Osvath, *FDA to Regulate Genetically Engineered Animals as Animal Drugs*, FOOD CHEM. NEWS, Aug. 7, 2000.

There is a more important point lurking here, however. Any consolidation plan will inevitably exclude some federal programs that must work cooperatively with officials whose primary responsibility is food safety. Moreover, no plausible consolidation plan could encompass the numerous state agencies that play critical roles at the retail and local levels. No one has seriously suggested that food safety regulation should be entirely federalized. Hence, success in controlling foodborne risks will always depend on collaboration among several federal agencies as well as across multiple levels of government. The "seamless" structure that advocates of consolidation envision is a mirage.

B. Federal Regulation of Food Extends Beyond Safety

So far we have mentioned only programs that contribute to making food safe. Even with this narrow focus, we have shown that it would be impossible to avoid difficult decisions about which federal functions to include and which to leave untouched. But yet more difficult choices are presented by the current responsibilities of the two agencies that would comprise the core of the new structure—the FSIS and the CFSAN.

We take the CFSAN as illustrative. The Center's activities are focused on food safety—even more intensely in recent years because of the heightened concerns about foodborne pathogens—but they also include other important programs that have no obvious relationship to the safety of food as that concept is conventionally understood. One of these programs is concerned with food labels (and other food "labeling" in the vernacular of the FDCA). Since the FDCA's passage, FDA personnel have devoted major efforts to prescribing and enforcing requirements for food labels. Before its recent attempt to regulate tobacco, the agency's two most ambitious rulemakings involved attempts to improve and standardize the information provided on the labels of food. The more recent attempt, a rulemaking to implement the requirements of the Nutrition Labeling and Education Act of 1990,[560] took eighty-five full-time-equivalent employees over two years just to establish the ground rules.[561] More recently, and as a sequel to this effort, the CFSAN has developed major resources for establishing and defending regulations governing the labeling of dietary supplements.[562]

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[560] Pub. L. No. 101-535, 104 Stat. 2353 (1990).

[561] *See* M. Elizabeth Magill, *Congressional Control Over Agency Rulemaking: The Nutrition Labeling and Education Act's Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 178 (1995) (detailing CFSAN resources dedicated to promulgating the NLEA final rule).

[562] *See FDA Works on Strategy for Regulating Dietary Supplements*, CHEM. MARKET REP., June 14, 1999, at 1 (noting that dietary supplement regulation is on CFSAN's "A" list of priorities).

Many of the CFSAN's food labeling activities may appear to have little to do with the safety of food, but this distinction is not always clear. For many years after the enactment of the FDCA, for example, the FDA used its authority to dictate the contents of so-called standardized foods as a means of assuring the safety of new food ingredients.[563] The agency continues to view food labels as a way of warning allergic consumers about the risks posed by some food ingredients.[564] Indeed, the FDCA's requirement that all ingredients be listed on the label of food has been justified as safety-related.[565]

CFSAN officials have always seen a close connection between the content of food labels and the nutritional quality of the food supply. As research has elucidated the relationship between dietary choices and the risk of chronic diseases, such as cancer and heart disease, the line between economic regulation and safety regulation has become blurred.[566] The FDA's approval of so-called disease prevention claims for foods whose long-term consumption has been shown to reduce health risk demonstrates the futility of sharp distinctions in this area.[567] This example is also a reminder of the CFSAN's third main activity, which involves research into, and regulation of, contents to protect the nutritional quality of food.

In the most recent fiscal year, the CFSAN allocated over $19 million (19% of the Center's budget) to nutrition-related and food labeling activities.[568] Even if one concluded that their functional connection with food safety efforts was not close, it would be odd to exclude them from any relocation of the CFSAN's programs, leaving them a dangling appendage to an FDA then almost exclusively concerned with medical products. Understandably, the advocates of consolidation appear to assume that all of

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563 *See* HUTT & MERRILL, *supra* note 4, at 96-117.

564 *See, e.g.*, 21 C.F.R. § 172.804(d) (1999) (establishing specialized labeling for food products containing aspartame).

565 *See* 21 U.S.C. § 343(q)(2)(A) (1994) (permitting FDA to require by regulation that certain nutrients be included on food labeling to "assist consumers in maintaining healthy dietary practices").

566 *See, e.g.*, Levi et al., *supra* note 40 (discussing relationship between diet and cancer risk); 21 U.S.C. § 343(r) (1994) (providing standards for the regulation of health claims made in food marketing and labeling).

567 *See* 21 C.F.R. § 101.72—88 (1999) (establishing approved health claims for food labeling including, *inter alia*, the relationship between intake of fruits and vegetables and cancer and the relationship between dietary fat and cancer).

568 *See* U.S. FOOD AND DRUG ADMIN., DISTRIBUTION OF RESOURCES—PROGRAM LEVEL (BA + USER FEES), *available at* http://www.fda.gov/oc/oms/ofm/budget/net162-3.htm (last modified May 21, 1999) (detailing FDA nutrition and labeling budget); U.S. FOOD AND DRUG ADMIN., ALL PURPOSE TABLE—TOTAL PROGRAM LEVEL, *available at* http://www.fda.gov/oc/ofm/budget/netapt25.htm (last modified May 21, 1999) (detailing CFSAN budget).

the CFSAN's functions would be included in or shifted to the new structure.

They appear to make the same assumption about the FSIS' major program for regulating the labels on meat and poultry products. In the last decade, the FSIS has devoted efforts, often in tandem with the FDA, to reforming the content of meat and poultry labels. Its main labeling responsibility is a product of a long-standing interpretation of the MIA and the PPIA.[569] Before any new meat or poultry product may be marketed, the FSIS must approve its label, and changes to the label of any marketed product must likewise be approved.[570] One result of this prior approval regime is that, unlike the FDA, the FSIS need not spend significant resources monitoring labels in use. Correspondingly, however, it supports a label approval program that requires significant resources.

The USDA has sometimes defended its label approval requirement as a means of protecting the safety of meat and poultry products because it assures that no ingredient that has not been approved will be used.[571] This activity and the FSIS's inspectional activities are not so closely integrated, however, that they could not be separated. But such a separation would disrupt established work patterns and probably disturb long-established relationships between the agency and the industry.

In sum, the implicit logic of the proponents of consolidation is that *all* current functions of the FSIS and the CFSAN should be combined within the new organization. As to what other programs might be included with them, the proponents have been silent.[572]

C. Bureaucratic Location

Many proponents of consolidation have expressed clear views about the appropriate location within the federal government of a unified food safety agency.[573] This is not surprising, since both members of Congress and executive officials have always viewed the issue of location as important.[574] The enactment in 1906 of separate statutes governing meat production and commerce in other foods suggests that the original Congress saw the domains as distinct. The decision to lodge *both* functions

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569 *See* discussion *supra* Part III.C.2.

570 *See generally* Frank & Johnson, *supra* note 254 (summarizing FSIS food labeling activities).

571 *See FSIS Begins Generic Labeling Audit; Considers Additional Safety Information on Labels*, FOOD CHEM. NEWS, Dec. 23, 1998 (describing safety rationale for FSIS labeling audit and possible food preparation directions on labels).

572 *See, e.g.*, Safe Food Act, *supra* note 19.

573 *See, e.g.*, *supra* notes 553-554 and accompanying text.

574 *See* discussion *supra* Part II.

within the USDA, however, does not negate this conclusion because the existing federal apparatus did not offer many other options. No other cabinet department would have seemed plausible, and the first "independent" agency—the Interstate Commerce Commission (ICC)—was still a unique organizational experiment.[575] Several decades later, however, Franklin Roosevelt's removal of the FDA from the USDA apparently reflected some concern that the agency's law enforcement activities were in tension, if not incompatible, with the Department's overriding task of reviving American agriculture.[576] It may also have reflected a judgment that the FDA would be more effectively administered if it were outside the USDA.

As one considers the possible locations for a consolidated food safety program in 2000, the options are more numerous than in 1906. For many proponents, however, the choice is apparently binary: Either merge the FSIS (and any other appropriate USDA activities) into the FDA, or merge the CFSAN into the FSIS.[577] Advocates for the latter option appear in the minority, perhaps because of concerns about compatibility with the promotional responsibilities of the USDA.[578] There is stronger support among reformers for consolidating food safety functions within the FDA, an agency with a more robust consumer protection reputation.[579]

The case for making the FDA home to all federal food safety functions has serious weaknesses. To be sure, the CFSAN's key programs can be described as designed to reduce the risk posed by foreign materials, including pathogens, in food while preserving the nutritional quality of American diets.[580] But one should simultaneously ask whether the CFSAN fits comfortably within the FDA—a diminished part of an agency whose prominent functions are now focused on technologies marketed for use in

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[575] *See* MARVER H. BERNSTEIN, REGULATING BUSINESS BY INDEPENDENT COMMISSION 17-19 (1955) (recounting the establishment of the ICC in 1887 and summarizing the further development of independent commissions starting with the FTC in 1914).

[576] *See* Roosevelt, *supra* note 127.

[577] *See, e.g.*, GORE, *supra* note 384, at 101 (calling for consolidation of USDA's food safety responsibilities into FDA).

[578] *See, e.g.*, HARMON, *supra* note 553; 1999 Carol Tucker Foreman Testimony, *supra* note 425, at 87 ("The Department of Agriculture was established to protect and assist food producers, and its institutional bias remains true to that goal . . . . The Department's food safety programs are overseen by the congressional agriculture committees, whose members' first concern is *not* food safety.") (emphasis in original).

[579] *See* HARMON, *supra* note 553; GORE, *supra* note 384, at 101; 1999 Carol Tucker Foreman Testimony, *supra* note 425, at 87 ("The FDA benefits from being within the human health bureaucracy . . . . ").

[580] *See* ENSURING SAFE FOOD, *supra* note 6, at 26 ("FDA's Center for Food Safety and Applied Nutrition (CFSAN) seeks to ensure that . . . [non-meat, non-poultry] foods are safe, sanitary, nutritious, wholesome, and honestly and adequately labeled.").

the delivery of medical care.[581] One measure, cruder to be sure, of the importance FDA leaders attach to food safety is the number of agency press releases issued on the subject. Since 1994, fewer than one-third of the agency's press releases have discussed food-related issues, and only some of these dealt with "safety" as conventionally defined.[582]

In selecting a location, one should consider more than the compatibility of program responsibilities. Another factor to be weighed, surely, is the prominence of the resulting organization. Following a recent departmental reorganization, food safety enjoys greater prominence within the USDA than it might within the FDA, or within the FDA's parent department, HHS. The creation of the office of Under Secretary for Food Safety provides some assurance that food safety issues get attention at the USDA's highest levels.[583] The CFSAN, in contrast, is one of five product-focused centers within the FDA, whose head (customarily a physician) ranks two levels below the Secretary of HHS.[584]

If prominence is a prime criterion, of course, neither of the obvious options is ideal. Consolidation advocates should want a new arrangement that would assure that the organization's important work attracted the attention and the resources they believe it deserves. The possibilities are

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[581] *See* discussion *supra* Part III.B.4. *See also* 1999 Carol Tucker Foreman Testimony, *supra* note 425, at 87 ("Food safety is often the poor stepsister at FDA, with most of the attention and resources devoted to concerns over drugs and medical devices.").

[582] *See* U.S. Food and Drug Administration, *FDA Press Releases—1999*, *available at* http://www.fda.gov/po/indexes/99news.html (last modified Jan. 5, 2000) (listing all FDA press releases from January 1 – October 14, 1999 and indicating that ten out of twenty-four were related to food safety); U.S. Food and Drug Administration, *FDA Press Releases—1998*, *available at* http://www.fda.gov/po/indexes/98news.html (last modified Jan. 5, 2000) (listing all FDA press releases for the year and indicating that twenty out of sixty-one were related to food safety); U.S. Food and Drug Administration, *FDA Press Releases—1997*, *available at* http://www.fda.gov/po/indexes/97news.html (last modified Oct. 26, 2000) (listing all FDA press releases for the year and indicating that sixteen out of sixty-two were related to food safety); U.S. Food and Drug Administration, *FDA Press Releases—1996*, *available at* http://www.fda.gov/po/indexes/96news.html (last modified Oct. 26, 2000) (listing all FDA press releases for the year and indicating that six out of twenty-six were related to food safety); U.S. Food and Drug Administration, *FDA Press Releases—1995*, *available at* http://www.fda.gov/po/indexes/95news.html (last modified Oct. 26, 2000) (listing all FDA press releases for the year and indicating that seven out of seventeen were related to food safety); U.S. Food and Drug Administration, *FDA Press Releases—1994*, *available at* http://www.fda.gov/po/indexes/94news.html (last modified Oct. 26, 2000) (listing all FDA press releases for the year and indicating that eight out of thirty-one were related to food safety).

[583] *See supra* notes 232-33 and accompanying text.

[584] *See* HUTT & MERRILL, *supra* note 4, at 15-17 (describing FDA's organizational structure and positioning within HHS). The FDA's positioning within HHS (and before that HEW) has been a source of contention for decades, as noted by the Ribicoff Committee in 1977. *See* STUDY ON FEDERAL REGULATION, *supra* note 16, at 144-45 ("We believe it is time to upgrade the status and independence of the FDA within HEW.").

numerous, though perhaps not unlimited. There do not appear to be any constitutional limits on the structure Congress could prescribe for a new agency, or the prominence assigned it, so long as it adhered to the few conditions embodied in Articles I and II of the Constitution.[585] Thus Congress could create a new "Department of Food Safety" and provide for a presidentially-appointed "Secretary" or other titled official to head it. Another option, perhaps differing only cosmetically, would be to create a new "executive agency," similar to the EPA, standing outside of, but perhaps on a par with, existing cabinet departments, whose head could be given the title of "Administrator" or any other that Congress chose.[586]

So far, such formal distinctions have not attracted attention from the proponents of consolidation, but they do stress the importance of operational independence. Several have suggested that food safety functions should be consolidated in a new "independent agency," though they generally have left the implications of this term unexplored.[587] To anyone schooled in American administrative law, the label "independent agency" conjures up two often overlapping images. One is of an agency, often titled a "commission," or occasionally a "board," which is presided over by a tribunal of three or more members, each of whom has a vote on

[585] *See* U.S. CONST. art. I, § 8 (providing broad legislative powers to Congress); U.S. CONST. art. II (providing the President with the "executive Power" and the obligation to "take Care that the Laws be faithfully executed"); McCulloch v. Maryland, 17 U.S. 316, 421 (1819) (reading the Necessary and Proper Clause broadly and declaring, "Let the end be legitimate, let it be within the scope of the constitution, and all means which are appropriate, which are plainly adapted to that end, which are not prohibited, but consist with the letter and spirit of the constitution, are constitutional"). *See also* JERRY L. MASHAW, RICHARD A. MERRILL, & PETER M. SHANE, ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM 4-28, 169 (4th ed. 1998) (illustrating Congress' broad powers to create diverse forms of administrative agencies).

[586] *See* MASHAW ET AL., *supra* note 585, at 24-25 (describing EPA's creation as an executive agency outside of the departmental structure). This is the organizational structure preferred in the Safe Food Act. *See* Safe Food Act, *supra* note 19, at § 4(a) (defining the proposed Food Safety Administration as an "independent establishment" as specified in 5 U.S.C. § 104: "an establishment in the executive branch (other than the United States Postal Service or the Postal Rate Commission) which is not an Executive department, military department, Government corporation, or part thereof, or part of an independent establishment . . . ").

[587] *See, e.g.*, 1999 Donley Testimony, *supra* note 541, at 94 ("Consolidating food safety activities into a single independent agency would elevate food safety, prevent duplication and fill in gaps that currently exist in our multiple agency system."); Caroline Smith DeWaal, *Time to Create a Single, Federal Food Safety Agency*, HOUS. CHRON., Aug. 27, 1999, at 35 ("A single food safety agency would . . . have the power and the flexibility to enforce food safety regulations from farm to table."); Burros, *supra* note 429 ("Following an outbreak of the hepatitis A virus from contaminated strawberries, an increasing number of food safety experts are questioning whether it is time to retire the federal government's fragmented system of regulation and start all over again.").

major policies and decisions.[588] The other image is that of an agency head or heads who are appointed by the President but serve not at the President's pleasure, but for a term of years.[589] In the U.S. government there are several examples of each model, most of them illustrations of both simultaneously.[590]

We find it hard to believe that advocates of an "independent food safety agency" have either model in mind. The challenges that currently confront food safety regulators rarely precipitate the kind of formal proceedings that the New Deal commissions were established to adjudicate. Furthermore, the history of most multi-member commissions does not suggest that this structure facilitates the kind of nimble, vigorous regulation that proponents of consolidation claim is now lacking.[591] The notion that a Food Safety Administrator should enjoy political independence is not unthinkable, but presidential interference, or even indifference, has not been among the central criticisms of the government's performance in this area.[592] Even if either had been, it is doubtful that Congress could create an office to perform the paradigmatic executive functions required of the head

[588] *See* ROGER G. NOLL, REFORMING REGULATION 5 (1971) (describing independent commissions: "In charge of the agency is a tribunal of essentially co-equal commissioners, responsible for establishing agency policies, making final decisions in specific cases coming before the agency, and managing the activities of the staff . . . ").

[589] *See* STUDY ON FEDERAL REGULATION, *supra* note 16, at 35 ("The traditional independent regulatory agency is a commission of multiple members, nominated by the president and confirmed by the Senate, who are appointed for set terms which expire at staggered intervals.").

[590] *See id.* at 35-36 (finding at least eleven independent federal regulatory commissions in 1977 including, *inter alia*: the Federal Reserve, Commodity Futures Trading Commission, Consumer Product Safety Commission, Federal Communications Commission, Federal Trade Commission, the ICC, and the Securities and Exchange Commission).

[591] *See, e.g.*, THE HOOVER COMMISSION REPORT, *supra* note 138, at 431-39 ("Administration by a plural executive is universally regarded as inefficient. This has proved to be true in connection with these commissions."); MARVER H. BERNSTEIN, REGULATING BUSINESS BY INDEPENDENT COMMISSION 293 (1955) ("Commissions have shown little understanding of the need for promotion of voluntary compliance with, and for vigorous enforcement of, their regulations."); THE PRESIDENT'S ADVISORY COUNCIL ON EXECUTIVE ORGANIZATION, A NEW REGULATORY FRAMEWORK: REPORT ON SELECTED INDEPENDENT REGULATORY AGENCIES 3-7 (1971) (summarizing findings critical of the independent regulatory agencies, including, *inter alia*: "Inherent deficiencies in the commission form of organization prevent the commissions from responding effectively to changes in industry structure, technology, economic trends, and public needs") [hereinafter THE ASH COUNCIL REPORT]. *But see* STUDY ON FEDERAL REGULATION, *supra* note 16, at 80 (concluding that "the independent status of the regulatory commissions should be continued"); NOLL, *supra* note 588, at 12-14 (critiquing the analysis of the Ash Council Report).

[592] Recent outbreaks of foodborne disease have focused the President's attention on food safety. *See, e.g.*, FOOD SAFETY FROM FARM TO TABLE, *supra* note 310 (outlining federal efforts to address food safety problems at the request of President Clinton).

of a food safety agency, and at the same time constitutionally shelter its occupants from close presidential oversight or removal.[593] Moreover, if lack of political accountability is a defect of the current arrangements, an "independent" agency would hardly be a cure.[594]

The advocates of independence have not explained their reasoning in any detail, but we assume their objective is to create an agency that is not subordinate to, or anchored in, any existing department or program. If we are correct, an "independent" food safety agency would be one that combined the existing functions of the FSIS and the CFSAN (and perhaps other functions as well) in an organization outside both the USDA and HHS. The modern EPA would thus appear to be a better model than any of the multi-member agencies to which the label "independent" has commonly been applied.

D. Agency Leadership

The previous discussion has touched on another issue that any concrete proposal for consolidation would have to address: Who should head the new organization? We reject the option of a multi-member commission, though not because proponents of consolidation have ruled it out. As far as we can tell, few of them have thought about the issue. Once one settles on an organization headed by a single, presidentially-appointed (and removable) officer, the choice of title would appear to be largely a matter of taste. Whether that official was titled "Secretary" of a new department or "Administrator" of a non-cabinet executive agency could have implications for the occupant's social calendar, but probably would not affect her influence with the President or with Congress. In these critical arenas, two other factors, neither subject to the control of statutory architects, would matter a great deal more.

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[593] *See* Humphrey's Ex'r v. United States, 295 U.S. 602 (1935) (holding that the Federal Trade Commission Act limits the power of the President to remove members of the FTC and that any "executive" power that is exercised by the FTC is done in furtherance of its "quasi-legislative or quasi-judicial powers." *But cf.* Myers v. United States, 272 U.S. 52 (1926) (holding that the President may remove all "purely executive" officers of the United States); Morrison v. Olson, 487 U.S. 654, 689-90 (1988) (limiting the importance of the categorization in *Humphrey's Ex'r* of "quasi-legislative" and "quasi-judicial" Commission powers in the context of the Independent Counsel). The *Morrison* Court held:

> [t]he analysis contained in our removal cases is designed not to define rigid categories of those officials who may or may not be removed at will by the President, but to ensure that Congress does not interfere with the President's exercise of the 'executive power' and his constitutionally appointed duty to 'take care that the laws be faithfully executed under Article II.

Id.

[594] *See* BERNSTEIN, *supra* note 591, at 293 ("The commissions' record of political responsibility is unsatisfactory . . . . [T]heir political accountability is seriously deficient.").

One would be the personal standing (and certainly the political skill) of the individual appointed to head the organization.[595] The visibility of the job and the resources allocated to it would surely reflect and affect congressional views of the agency's importance. Different heads of the same agency, however, have enjoyed widely varying influence with Congress, based on résumé or personality.[596] Congress, through the Senate confirmation process, can make it more or less difficult for Presidents to appoint influential agency heads, but it cannot assure that effective candidates will be nominated.[597]

The President and his staff have greater influence over the quality of the candidates who get considered for the kind of job we imagine. The President can significantly influence the power of successful nominees not only by his original selection but also by his willingness to support their decisions and to accord them personal access, rather than forcing them to deal through subordinates.[598] Some EPA Administrators and many cabinet secretaries rarely met with the Presidents whom they served, while others had close ties to, and thus often ready backing from, the White House.[599]

E. Geographic Dispersal

The foregoing discussion highlights many of the major issues of organizational design that any serious plan to consolidate food safety functions would have to resolve. There are additional issues as well. While perhaps not as fundamental, they are nonetheless potentially

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[595] *See* JAMES Q. WILSON, BUREAUCRACY 217 (1989). Mr. Wilson states:

> A few gifted political executives are able to fuse the maintenance of their own position with that of their organizations. Because of their exceptional talents combined with their good fortune in holding office at a time when their political environment is unusually malleable, these individuals manage to make that environment so supportive that in effect it becomes a universal constituency.

Id.

[596] *See id.* at 205 ("Reputation—for influence, style, and access—is a key part of the relationship between executive and constituency."). *See also* CHRISTOPHER H. FOREMAN, JR., SIGNALS FROM THE HILL 94-97 (1988) (describing the political give and take of the congressional appropriations process and noting that "[s]ometimes by necessity, opportunistic extended bargaining and mutual adjustment take place").

[597] *See id.* at 77-82 (describing the often unexpected results of the "bargaining, second-guessing, and delay" in the Senate confirmation process).

[598] *See, e.g.*, ROBERT B. REICH, LOCKED IN THE CABINET 301 (1997) (recounting the experience of former Secretary of Labor Robert Reich wandering the corridors of the West Wing "like an itinerant peddler" trying to sell his ideas to people who saw the President more than the Secretary did).

[599] *See, e.g.*, Michael Riley et al., *"Silent Sam" Speaks Up*, TIME, Sept. 18, 1989, at 24 (describing the relationship of former Secretary of Housing and Urban Development Samuel Pierce with President Reagan who once famously failed to recognize Pierce at a reception).

significant practical impediments.

One of these—already an obstacle to effective coordination—is geography. FDA units are already dispersed among some three dozen buildings in the greater Washington, D.C. area. The CFSAN is less splintered than other centers, as it currently occupies fewer than half a dozen buildings in the Washington area, with its two major operations at 200 C Street, N.W., Washington, D.C., and Beltsville, Maryland.[600] Even this division makes hands-on supervision by the Center Director (not to mention the Commissioner's office—located elsewhere, in Rockville, Maryland) difficult.[601] The USDA's food safety functions are headquartered in just three buildings in the nation's capital but over 75% of its workforce, made up of the resident inspectors of meat and poultry processing facilities, is based at several thousand facilities around the country.[602]

The dispersal of FSIS, and to a lesser extent FDA, personnel is inescapable so long as continuous and immediate access to food processing and storage facilities is an essential part of effective regulation. Consolidation of the FSIS and the CFSAN might not exacerbate already challenging problems of vertical coordination, but the different inspection duties and philosophies of the two agencies would present a separate organizational challenge. Increasing the number of Washington-based facilities that are subject to the direction of a single administrator would not be an additional challenge.

Our main purpose in this part has not been to show that consolidation could not work. On that point we remain agnostic, albeit skeptical. Rather, our aim is to identify key issues of organizational design and program management that any consolidation plan would have to address before it could be taken seriously. Few contemporary advocates of consolidation have acknowledged these issues, and none has outlined a concrete plan that purports to resolve them.

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600 *See* Interview with Michael R. Taylor, who heads the Center for Risk Management, at Resources for the Future in Washington, D.C. (October 23, 2000).

601 *See id.*

602 *See id.*

VII. THE POLITICAL OBSTACLES TO CONSOLIDATION

Protecting the safety of the food supply is an enormous and increasingly complex challenge notwithstanding the plausible claim that Americans enjoy food that is as safe as any in the world.[603] We have not attempted here to resolve how the individual agencies that now share responsibility for food safety must modernize their methods and improve their performance. Our central focus has been the recurrent suggestion that these programs should be combined in a single organization. In Part VI we explored the major programmatic implications of that suggestion. In this part we take up questions about its practical and political feasibility.

A. Consolidation as an Ideal

We are persuaded that if one could now organize federal food safety functions without reference to history, and unconstrained by existing structures, there would be advantages in combining many of these functions in one organization directed by a single presidentially-appointed head. Such a structure would promote political accountability by linking the President with the agency's duties and identifying the administration with *the* official responsible for their performance. That official could be the government's spokesperson on food safety, responsible for explaining its response to inevitable crises and for marshalling public support for new regulatory initiatives and self-protection measures. If Congress were able to begin with a clean slate, it could allow a unified agency greater discretion in its choice of methods to identify, prevent, and respond to foodborne hazards than either the FSIS or the FDA enjoys. It could also authorize the reprogramming of appropriated funds in response to shifting public health priorities. Moreover, if all relevant personnel worked for the same agency, administrative directives could replace delicate negotiation as the chief means of enlisting the cooperation of entities scattered around the country.

In short, we are willing to stipulate that a unified agency headed by a single administrator would have assets that the current balkanized structure lacks. But this is not an ideal world, and it is unrealistic to expect members of Congress or executive branch architects to view the existing structure as irrelevant or to ignore its evolution.

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[603] *See* Clinton, *supra* note 5, at 375 ("The Vice President has told you about some things our administration has done to modernize food safety, to keep our food supply the safest in the world.").

B. Historical and Political Impediments

Even if the proponents could convince program managers and external constituents that the gains from combining the government's major food safety functions would outweigh the costs, we suspect they would have difficulty persuading the political actors whose support is indispensable. At least this is the teaching of history. The idea of consolidation is hardly new. Since the Hoover Commission's report to President Truman, the concept has received repeated endorsements.[604] Yet no concrete proposal to combine the FDA's food programs with the FSIS's activities has ever reached first base in the political arena. Despite the concept's distinguished pedigree, no consolidation plan has gained the endorsement of any President or come to a vote in either House of Congress.

The Hoover Commission's plan to consolidate food safety regulation failed for at least two reasons. First, the Commission's other recommendations addressed to the USDA called for controversial closings of many local field offices serving farmers, thus ensuring the opposition of representatives from agricultural districts and states.[605] Second, and perhaps more importantly, there was never a true consensus within the Commission in favor of its final recommendation to consolidate regulation in the USDA.[606] The Commission's Agriculture Task Force recommended that all food safety responsibilities rest in the USDA, but its Medical Services Committee and a contemporaneous Brookings Institution study advocated that the FDA remain in a public welfare agency.[607] The Commission's report led to the passage of the Reorganization Act of 1949, which enhanced the President's ability to shuffle programs with congressional consent.[608] But, when President Eisenhower eventually addressed the location of the FDA, he placed it within the new Department of Health, Education, and Welfare.[609]

Later endorsements also failed to elicit strong political support. Even with a Democratically-controlled Congress, President Carter made no effort to pursue Senator Ribicoff's recommendation that the FDA take over responsibility for all food safety functions. Instead, Carter devoted his

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604 *See* discussion *supra* Part IV.A.

605 *See* RONALD C. MOE, THE HOOVER COMMISSION REVISITED 43 (1982).

606 *See* BRADLEY D. NASH & CORNELIUS LYNDE, A HOOK IN LEVIATHAN: A CRITICAL INTERPRETATION OF THE HOOVER COMMISSION REPORT 186-87 (1950).

607 *See id.*

608 *See* MOE, *supra* note 605, at 56-57; *see also supra* note 551 (describing features of the Reorganization Act).

609 *See* HUTT & MERRILL, *supra* note 4, at 5; MOE, *supra* note 605, at 58 (describing the creation of the HEW).

energy in the regulatory arena to reforms designed to minimize the cost of regulation and exert White House oversight of administrative rulemaking.[610]

More recently, congressional reaction to the Clinton Administration's NPR proposal to consolidate food safety responsibilities in the FDA revealed the slim prospects for implementation. Within one week of the final NPR report, the Democratic Speaker of the House, and the House Agriculture Committee chair endorsed consolidation—but within the USDA.[611] Senator Dale Bumpers, then chair of the Senate Agriculture Appropriations subcommittee, betrayed his skepticism when he stated, "I don't know that the FDA's track record on food inspection is all that hot."[612] Congressman Richard Durbin, who as Senator later introduced legislation to combine functions in the FDA, predicted that the USDA would retain its turf because "Agriculture has its friends from different regions of the country."[613]

Nor do the early reactions to the NAS panel's report (which conspicuously avoided addressing where, much less how, food safety functions should be centralized) provide evidence that the prospects for consolidation have improved. Scattered bills to make a single agency responsible for federal efforts have been introduced, but only one has been the subject of committee hearings. No bill has won the support of any committee, much less made its way to the floor of either house. Notably, moreover, President Clinton's Food Safety Council expressly refrained from endorsing what without doubt was the centerpiece of the NAS report.[614]

An examination of Congress' committee structure, coupled with an appreciation of its customary mode of operation, reveals why the prospects for consolidation are bleak. The several agencies with food safety functions are currently overseen by an even larger number of congressional committees, which could be expected to protect their alliances in any exploration of reorganization. The USDA, FDA, and EPA pesticide programs, and Commerce's NMFS fall under the jurisdiction of more than a dozen authorizing and appropriation committees and subcommittees in the House and Senate. The two lead agencies, the USDA and the FDA,

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610 *See Regulation; Carter Starts to Turn a Supertanker*, ECONOMIST, Apr. 14, 1979, at 14; Timothy B. Clark, *New Approaches to Regulatory Reform—Letting the Market Do the Job*, 11 NAT'L L.J. 1,316 (both describing President Carter's approaches to regulatory reform).

611 *See* Cooper, *supra* note 388, at A19.

612 *Id*.

613 *Id*.

614 *See* Food Safety Council NAS Assessment, *supra* note 316 and accompanying text.

answer to four different authorizing committees and two appropriating subcommittees in the House and Senate. The USDA reports to the Agriculture Committees in the House and in the Senate.[615] The FDA is authorized and chiefly overseen by the House Commerce Committee and the Senate Committee on Health, Education, Labor, and Pensions.[616] The FDA budget, however, is approved by the Agriculture Appropriations Subcommittees in the two chambers. Agricultural interests thus have an opportunity to exert influence over the FDA through the members of these committees.[617] The EPA, which is chiefly responsible for pesticide regulation, is authorized by the House Commerce and House Science Committees, and the Senate Environment and Public Works Committee.[618] The EPA's budget, however, is approved by the House and Senate Veterans Administration, HUD, and Independent Agencies Appropriations Subcommittees.[619] Finally, proposals for executive branch reorganization must come before the Senate Government Affairs Committee and the House Government Reform and Oversight Committee, as well as before the committees overseeing the programs whose status and location are under consideration.[620]

In short, the dispersal of food safety responsibilities within the executive branch mirrors an even more complex distribution of congressional committee jurisdiction. Any proposal to consolidate federal

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[615] *See* CHARLES W. JOHNSON, CONSTITUTION, JEFFERSON'S MANUAL AND RULES OF THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES, H.R. DOC. NO. 104-272, at 375-76 (1997) (describing the jurisdiction of the House Agriculture Committee) [hereinafter HOUSE RULES MANUAL]; LANA R. SLACK, SENATE MANUAL, S. DOC. NO. 104-1, at 24-25 (1995) (describing the jurisdiction of the Senate Agriculture Committee) [hereinafter SENATE MANUAL].

[616] *See* HOUSE RULES MANUAL, *supra* note 615, at 386-88 (describing the jurisdiction of the House Commerce Committee); SENATE MANUAL, *supra* note 615, at 32-33 (describing the jurisdiction of the Senate Labor and Human Resources Committee); U.S. Senate, *Jurisdiction*, *at* http://www.senate.gov/~labor/juris/body_juris.htm (last modified Jan. 29, 1999) (showing the jurisdiction of the renamed Senate Health, Education, Labor and Pensions Committee).

[617] *See* FOREMAN, *supra* note 596, at 99-101 (noting the concern for farmers shown in FDA appropriations reports by the House and Senate Agriculture Appropriations Subcommittees).

[618] See HOUSE RULES MANUAL, *supra* note 615, at 386-87 (describing the jurisdiction of the House Commerce Committee); *id.* at 412-13 (describing the jurisdiction of the House Science Committee); SENATE MANUAL, *supra* note, 615 at 28-29 (describing the jurisdiction of the Senate Environment and Public Works Committee).

[619] *See* FOREMAN, *supra* note 596, at 104-08 (assessing the EPA appropriations processes by the House and Senate appropriations subcommittees on Housing and Urban Development and Independent Agencies).

[620] *See* SENATE MANUAL, *supra* note 615, at 31 (describing the jurisdiction of the Senate Government Affairs Committee); HOUSE RULES MANUAL, *supra* note 615, at 392-93 (describing the jurisdiction of the House Government Reform and Oversight Committee).

food safety functions would have to gain the support of the respective chairs (and ranking members) of the above-named committees. As James Q. Wilson has written:

> Congress is exceptionally sensitive to the implications of any reorganization for its own internal allocation of power. Taking a bureau out of one department and putting it into another often means shifting oversight responsibility for that bureau from one committee (or subcommittee) to another. A willingness to surrender turf is as rare among members of Congress as it is among cabinet secretaries.[621]

Professor Wilson's observation should chasten advocates for consolidation of federal food safety functions. And this is to say nothing about the difficulty of persuading current Republican majorities in the House and Senate of the merits of a plan whose goal would be to make *regulation* more effective.

We do not assert that the campaign cannot be won, but the obstacles are surely formidable. Not only would the responsible leaders of the House and Senate majorities have to agree on the merits of reorganization, they would also have to negotiate a new set of legislative arrangements for overseeing and funding the new organization. If either house simply retained its current jurisdictional assignments—requiring the combined agency and its single head to seek funding and statutory authorization from the several committees that now exercise authority—many of the potential benefits of consolidation would never accrue.

C. The EPA "Model"

Given this picture of congressional control, readers may find it astonishing that President Nixon's creation of the EPA was successful. There are several features of the EPA story that in our view make it a poor predictor of the political fate of proposals to reorganize food safety functions.

One is an accident of timing. Even though President Nixon faced Democratic majorities in both the House and Senate in 1970, partisan animosities were not yet the obstacle to agreement that they have since become. In addition, President Nixon's initiative promised to strengthen federal environmental controls, a goal likely to have greater appeal for the President's congressional adversaries than for many of his Republican allies. Furthermore, and this is by no means a trivial distinction, President Nixon was able to invoke previously conferred reorganization authority and thus force the issue of consolidation onto the legislative agenda. That authority lapsed during President Carter's term and has not been renewed.

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[621] WILSON, *supra* note 595, at 268.

Probably the most significant distinction between the creation of the EPA and current proposals to reorganize food safety functions lies in the age and history of the programs involved. It would be wrong to suggest that the several pollution control programs that President Nixon collected from HEW, Agriculture, and Interior were not appreciated by their parent departments, but, with the possible exception of the USDA's pesticide registration program, they were not prized. None was very large, either in personnel or budget, and none was yet a major source of grant funding for local government or private organizations. Furthermore, none could claim a history comparable to that of the FSIS or the FDA—spanning a century during which each has accumulated constituencies outside Washington and defenders among members of both parties of Congress. Proposals to combine their functions at the very least create uncertainty about the continuity of long-established regulatory patterns and even worse may threaten alliances that date back to before World War II.

D. Costs of Consolidation

Even if a political consensus in favor of consolidation could be achieved, we should ask what costs might accompany success. The USDA Secretary Glickman recently left no doubt about his view, when he declared that any effort to combine the FSIS and the FDA would "wreak havoc."[622] We can imagine reasons for his skepticism. In the short term, formal consolidation of organizationally dispersed programs would disrupt current work and decision-making patterns and possibly weaken employee morale. The experience of private firms in the wake of a merger suggests that these effects are real and often harmful, even when they prove transitory.[623] We would expect a transition to take longer within government, partly because loyalties and work arrangements are more deeply entrenched and partly because most civil servants do not operate in a world where organizational transformation is expected or common.[624]

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[622] *See* Weiss, *supra* note 456, and accompanying text (quoting Glickman).

[623] *See* Rosabeth Moss Kanter, *Collaborative Advantage: The Art of Alliances*, HARV. BUS. REV., Jul.-Aug. 1994, at 96, 108. Professor Kanter discusses the hazards of private sector collaborative relationships and notes:

> The potential value of the relationship must be weighed against the value of all the other company activities, which also make demands on its resources—including the time and energy of executives. Even when relationships have high value, an organization can handle only so many before demands begin to conflict and invest requirements (management time, partner-specific learning, capital, and the like) outweigh perceived benefits.

Id.

[624] *See* Peter Szanton, *So You Want to Reorganize Government?*, *in* FEDERAL REORGANIZATION—WHAT HAVE WE LEARNED 1, 9 (Peter Szanton ed., 1981). Mr. Szanton observed:

In this regard, the EPA experience may again be instructive. While the EPA may appear to be reasonably unified in 2000, it has taken three decades to accomplish this feat. Those who are familiar with the agency's internal operations attest to the continuing influence of old loyalties, abandoned policies, and long-established alliances with congressional staff.[625] The EPA undoubtedly possesses assets that its several parts could not separately have acquired, but in many respects it remains a collection of parts, a confederation. Furthermore, the designers of the EPA had one advantage that architects of food safety consolidation might not have: In the creation of the EPA no constituent program was an obvious "loser." Most of the programs assembled to create the EPA were not integral parts of their departments, and their relocation did not imply the superiority of any one component. The return of the FDA's food programs to the USDA, however, would imply failure in their present location or, at the very least, the belated correction of a New Deal mistake. The removal of the FSIS from the USDA after over ninety years would represent an even greater failure.

Indeed, any consolidation plan, even one that contemplated the creation of a new agency, would imply that existing food safety programs and their managers had failed. In 1970, the challenge presented by environmental pollution was new, or at least recently discovered. While environmental advocates shared a conviction that existing institutions were inadequate, the main target of criticism was Congress and the legal tools that it provided to federal officials. The enactment of the National Environmental Policy Act, the creation of the EPA, and the passage of the Clean Air Act within a single year represented a new public commitment to attack a new set of problems. Except for the USDA's pesticide program, criticism of official performance was muted.

By contrast, the challenge of keeping food safe is ancient and recognition that the federal government has a critical role to play in meeting this challenge is a century old.[626] The responsible institutions have been in business for nearly as long and today employ thousands of workers and collectively spend over a billion dollars on the task. The very notion

> Reorganization has traditionally focused on structural change, whose dominating principle is that related programs should be placed cheek by jowl within the same institution. But the issues government now addresses . . . cause widely separated programs to be related, and each with different sets of others, depending on the issue. *Structural change is far too difficult and slow-moving to manage such shifting and multiple relations.* Processes of coordination, far more flexible, are the only devices that can serve.

Id. (emphasis added).

625 *See* discussion *supra* V.C; *see also* Interview with Jon Cannon, *supra* note 164.

626 *See* Hutt, *supra* note 1.

that their functions should be reorganized represents a judgment that, in fundamental ways, they have not been doing their job. Accordingly, we would expect employee resentments over relocation of food safety programs to be deeper and last longer than those that must have accompanied the creation of the EPA.

In addition, for any of the consolidated programs, relocation would threaten linkages with external constituencies that are not only the source of professional friendships but often the lubricant of effective government. It is not surprising that all of the major associations of food producers—groups such as the National Food Processors Association and the Grocery Manufacturers Association—have opposed the concept.[627] One can be skeptical of their motives (imagining worries that once-friendly officials might no longer be in a position to act on their sympathies) but effective regulation often depends upon good personal relationships between officials and those whose conduct they seek to influence. In any reorganization, such relationships could be threatened or destroyed.

We do not mean to exaggerate the institutional costs of consolidation. While disruption and uncertainty would be inevitable, the gains from reorganization might eventually offset them. Yet in the current discussions of the benefits of consolidation, however, such costs have largely been ignored.

VIII. CONCLUSION

Although we are likely to witness some modest reorganization of food safety functions, such as the Commerce Department's surrender of seafood jurisdiction to the FDA, we are skeptical that any move to combine the FSIS with the CFSAN, either within an existing department or in a new organization, will ultimately appeal to the political decision-makers. Thus, we expect the major federal food safety functions to remain organizationally dispersed, though perhaps more effectively coordinated. Even if a centralized organization replaces the present balkanized structure at the federal level, however, protecting food safety will inevitably remain a multi-agency activity. Food is grown and processed locally and since many of the hazards that most concern public health authorities emerge at

627 *See, e.g.*, *Hearing Before the Subcomm. on Gov't Mgmt., Restructuring and the Dist. of Columbia, Senate Comm. on Governmental Affairs*, 106th Cong. 124, 129 (1999) (statement of Stacey Zawel, Ph.D., Vice President, Scientific and Regulatory Policy, Grocery Manufacturers of America, Inc.) ("America's food safety system needs the right focus, not a new structure."); *Hearing Before the Subcomm. on Gov't Mgmt., Restructuring and the Dist. of Columbia, Senate Comm. on Governmental Affairs*, 106th Cong. 119, 123 (1999) (statement of Rhona Applebaum, Executive Vice President for Scientific and Regulatory Affairs, National Food Processors Association) ("The architecture of the nation's food safety system is not so flawed that the building needs to be gutted.").

this stage, critical responsibilities will continue to rest with state and local officials.[628] This is not simply a statement of political reality, it is a description of sensible management. There are good reasons for federal authorities to deal with, support, and rely upon local partners, and equally sound reasons for states and localities to retain their independence. Similarly, the internationalization of the U.S. food supply will make American consumers and domestic regulators increasingly dependent on the performance of foreign authorities.[629]

Because a unitary "farm-to-table" system of food regulation is not realistically achievable, there will continue to be "seams" between participants in a multi-agency collaboration. The question that advocates of consolidation, as well as legislators, must address is whether the long-term gains from consolidation of functions at one level of this complicated structure would justify the immediate struggle and the short-term costs. We do not believe that the EPA example provides a clear answer. If one considers the EPA's performance to have been largely successful, as we do, it is possible to conclude that the example proves that consolidation will not make matters worse and could make them better. But the struggles that EPA managers face in their efforts to regulate comprehensively, foster internal cooperation, assure cross-agency consistency, and design integrated pollution control programs should make consolidation advocates cautious in their predictions.

We have sketched a pessimistic picture of the prospects for organizational consolidation of the federal food safety programs. Moreover, we have suggested that such consolidation would not solve, and might not even address, some of the most serious challenges to the safety of the U.S. food supply. It is a fair question, then, whether there are other intermediate measures that could improve regulatory performance.

President Clinton's Council on Food Safety represents an effort to enhance coordination and improve cooperation among the primary federal food safety agencies.[630] The establishment of high-level coordinating groups is a familiar presidential response to bureaucratic turf battles.[631] Yet orchestrated and encouraged coordination can yield benefits at a relatively low cost. For example, the Food Safety Council may aid in creating coordinated budget proposals and identifying areas of redundancy or gaps in regulatory efforts. In 1997, at the urging of the White House,

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628 *See* discussion *supra* Part III.F.2.

629 *See* discussion *supra* Part III.G.

630 *See* discussion *supra* Part IV.A.5.

631 *See, e.g.*, Exec. Order No. 12,631, 53 Fed. Reg. 9,421 (1988) (establishing during the Reagan Administration the Working Group on Financial Markets to address jurisdictional deficiencies found after the stock market crash of 1988).

representatives of the CDC, the FDA, the EPA, and the FSIS, as well as state and local food safety agencies, formed the Foodborne Outbreak Response Coordinating Group (FORC-G) to strengthen interagency coordination during food-related emergencies.[632] Co-chaired by the USDA's Under Secretary for Food Safety and HHS' Assistant Secretary for Health,[633] FORC-G has a three-part role: enhance coordination and communication among the cooperating agencies; assist resource allocation during food-related emergencies; and improve preparation for new foodborne threats.[634] These efforts may lay the groundwork for better future coordination of routine operations. Given the political obstacles to real organizational reform, this may be the most feasible means of stitching the "seams" in the regulatory apparatus.

Coordinating bodies such as the Food Safety Council should be recognized for what they are: Palliative care, not reconstructive surgery. By their nature, such instruments are weak. They are usually grounded in Executive Orders rather than statutes. Moreover, they must work within the limits of existing statutes and abide by statutorily-driven resource allocations. Furthermore, the Food Safety Council specifically lacks clear leadership. The group is chaired jointly by the Secretaries of Agriculture and HHS and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, all of whom have other, arguably higher, responsibilities and none of whom has authority to resolve disagreements.[635] The Council may improve the executive's ability to bridge jurisdictional gaps and avoid overlaps, but it cannot assure political accountability or correct Congress' allocation of resources.

As with most vexing problems, there are no easy solutions to the problems created by the organization of federal food safety regulation. Neither reorganization nor orchestrated coordination among agency leaders is likely to assure political accountability, reallocate resources or bridge jurisdictional gaps while preventing overlaps. Moreover, even if a unified federal food safety system could improve regulatory effectiveness, policy

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[632] *See* U.S. DEP'T OF AGRIC. & U.S. DEP'T OF HEALTH AND HUMAN SERVS., FACT SHEET: FORC-G—FOODBORNE OUTBREAK RESPONSE COORDINATING GROUP, *at* http://www.cfsan.fda.gov/~lrd/tpforc-g.html (last visited Nov. 11, 2000) (listing the agencies and responsibilities of FORC-G).

[633] Other members of FORC-G include representatives of the CDC, FDA, FSIS, EPA, Association of Food and Drug Officials, National Association of City and County Health Officials, Association of State and Territorial Public Health Laboratory Directors, Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture. *See id.*

[634] *See id.*

[635] *See* Food Safety Council Executive Order, *supra* note 407.

makers must balance the benefits against the physical, bureaucratic, and political costs of consolidation today. Congress should not be fooled into believing that statutory reorganization alone can meet the challenge of managing the risks of a diverse and dispersed food supply.