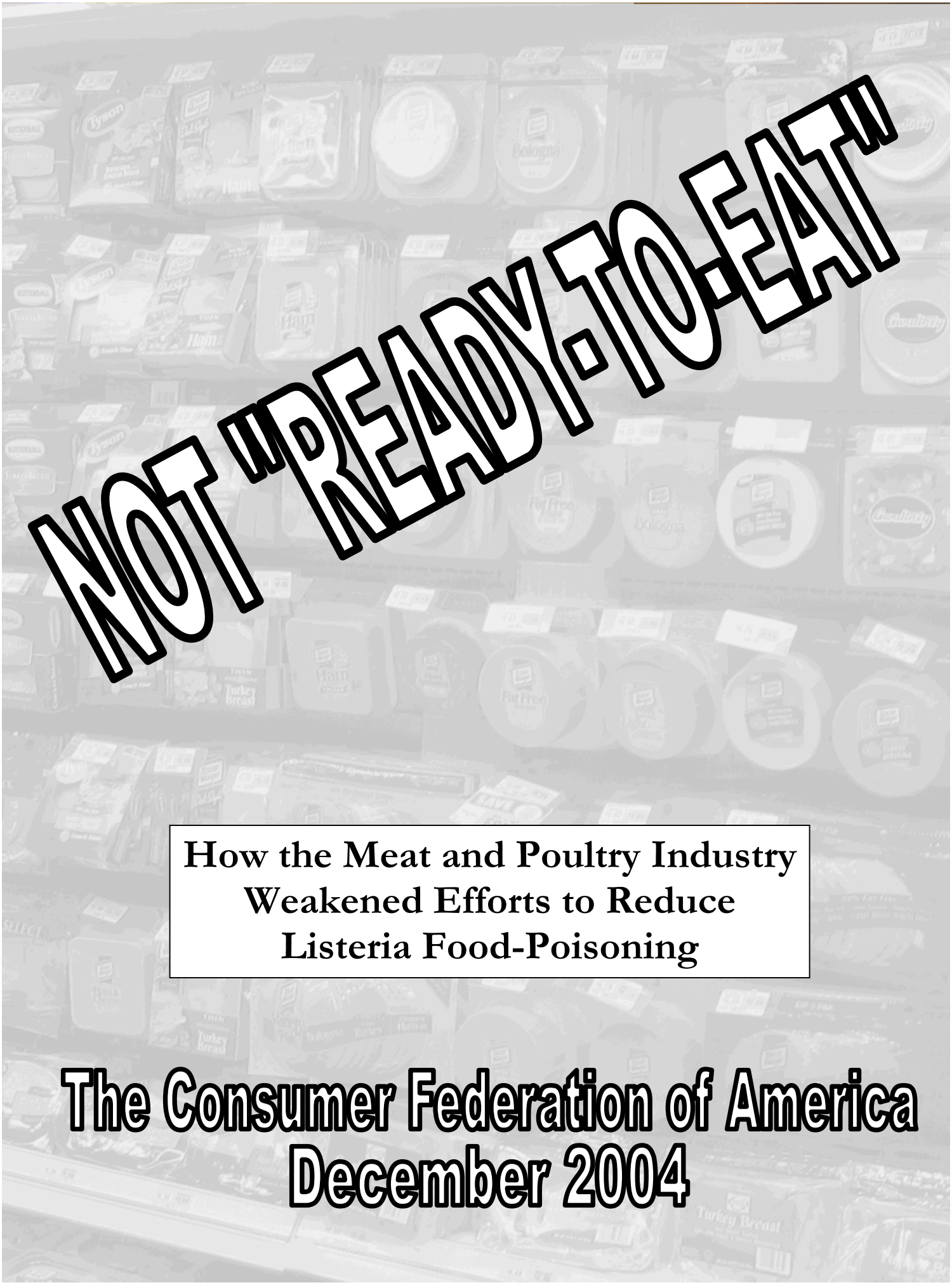

NOT "READY-TO-EAT"

How the Meat and Poultry Industry Weakened Efforts to Reduce Listeria Food-Poisoning

The Consumer Federation of America

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I. Executive Summary

This report focuses on the development of a rule and related policies to control *Listeria monocytogenes* (Listeria) in ready-to-eat meat and poultry products, and provides a case study of the role that industry plays in the crafting of government policies to protect the public from food poisoning. During the Bush Administration's first term, the approach taken by the U.S. Department of Agriculture (USDA) to controlling Listeria shifted significantly to favor positions taken by the regulated industry. The Department first delayed regulations to control Listeria contamination in ready-to-eat meat and poultry products and then revised them to reflect industry positions. During the same period, the government abandoned its pledge to reduce by 50 percent the number of Listeria food-poisoning (listeriosis) cases by 2005. These events raise the question of whether a 22 percent increase in Listeria food-poisoning cases in 2003 can be attributed, at least in part, to the change in USDA policy and approach.

Background

While the number of Listeria food-poisoning cases each year is not large, Listeria is among the most dangerous and lethal foodborne pathogens. The Centers for Disease Control and Prevention (CDC) estimates that Listeria causes close to 2,500 cases of food-poisoning annually; over 90 percent of the victims are hospitalized and 20 percent die. Listeria food poisoning results in the highest rate of hospitalization of any foodborne pathogen, and has the second-highest fatality rate.

The federal government first became aware of the danger posed by Listeria contamination in ready-to-eat meat and poultry products in the mid-1980s, and its first response was to initiate a government monitoring program in 1987 to test for the pathogen within meat and poultry plants. A major Listeria food-poisoning outbreak in the late 1990s, and consumer criticism of the Clinton Administration's slow response to it, led the Administration to announce initiatives to address the problem, including conducting a joint risk assessment by USDA and the Food and Drug Administration, and establishing food-safety standards for ready-to-eat products. In May 2000, the Clinton Administration set a new public health goal of cutting the rate of Listeria food-poisoning cases in half by 2005.

The Bush Administration's Relationship with the Meat and Poultry Industry

Three, notable factors illustrate the close relationship between George W. Bush and the meat and poultry industry:

1. *The amount and distribution of campaign contributions strongly favor the Republican Party.* According to the Center for Responsive Politics, agribusiness firms contributed a total of $59,431,422 to political candidates in 2000. Of this total, 74 percent of the money went to Republicans and 26 percent to Democrats. A similar breakdown was seen in the 2004 election.

Republicans have consistently received a larger share of the total agribusiness contributions than Democrats. With each presidential election cycle, the gap continues to

widen. Companies and trade associations connected to the meat and poultry sector have been especially generous to Republican candidates in general and to President Bush in particular. Individual employees of meat and poultry companies and trade associations contributed significantly more money to the Bush campaign as well. In particular, senior-level executives have donated extensively to industry association political action committees (PACs) as well as the PACs of their own companies.

Six of the top 20 meat and poultry processing companies and their chief executives, and the major trade associations, all of whom contributed to the Bush campaigns in 2000 and 2004, played an active role in shaping USDA's Listeria policy.

2. *There is evidence of an unusually close tie between the President and a meat company linked to a major outbreak of Listeria food-poisoning.* There is a special relationship between George W. Bush and Pilgrim's Pride, a Texas-based food processing company implicated in a major recall in 2002. Lonnie "Bo" Pilgrim, Chairman of the Board of Pilgrim's Pride Corporation, began supporting George W. Bush when Bush ran for governor in 1998, and continued to be a significant fundraiser in the 2000 and 2004 presidential campaigns.

3. *After the 2000 election, numerous meat industry alumni joined USDA in positions directly relating to food safety and nutrition.* The list begins with Deputy Secretary James Moseley, co-owner of a large hog farm, and moves on to Veneman's chief of staff, Dale Moore, who came to USDA directly from the National Cattlemen's Beef Association, where he was executive director for legislative affairs and Assistant Secretary for Congressional Affairs Mary Waters, a former ConAgra executive. Other former NCBA alumni and veterans of other meat related groups took over other top posts. In filling the key position of Under Secretary for Food Safety, the Bush Administration appointed Elsa Murano, a professor well known and liked by the industry. The Bush Administration also converted key positions, like that of FSIS Administrator, from career civil-service to political-appointee status.

Changes in USDA Listeria Policy under the Bush Administration

Consumer and public-health groups were optimistic when the Bush Administration decided to publish, without substantive change, the proposed rule on Listeria that had been developed by the Clinton Administration.

In the proposed rule, USDA said it intended to establish pathogen-reduction "performance standards" for all ready-to-eat products and, under some circumstances, require final-product testing for Listeria to ensure that the standards were being met. A performance standard generally limits the amount of a particular pathogen in the final product. The proposed rule spelled out in detail the Clinton Administration's view that performance standards were vital to protecting the public from Listeria in processed meat and poultry products.

Under the proposal, establishments producing ready-to-eat meat and poultry products also would have been required to test food-contact surfaces to verify that they are controlling Listeria within the entire processing environment. If an establishment found

contamination on one of its food-contact surfaces, it would have to take corrective action to demonstrate that its product was not adulterated with Listeria.

The optimism of the consumer and public-health groups was dampened, however, when FSIS decided to launch a second risk assessment, which it said was made necessary by the comments to the proposed rule. The additional risk assessment allowed FSIS to delay finalizing the Listeria rule. The final risk assessment was published in February 2003; it was roundly criticized by consumer groups because its scope was limited to deli meats and ignored hot dogs and other high-risk meat and poultry products, and because it did not include sampling of non-food contact surfaces in the risk model. The groups also took issue with FSIS's reliance on unpublished industry data.

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In October 2002, nineteen months after the proposed rule was published, there was a major Listeriosis outbreak that infected 131 people and prompted a major recall. It took the agency another nine months to issue an "interim" final rule on Listeria and ready-to-eat products. To date, USDA has not issued a permanent final rule. An analysis of the positions advocated by the regulated industry reveals a startling symmetry between industry positions and changes ultimately adopted by the USDA in the interim final rule. Every aspect of the original USDA proposal that was opposed by industry was reversed in the interim final rule. Moreover, in every instance where consumer groups and industry took an opposing position, USDA rejected the consumer position and came down in favor of industry.

Most significantly, in the interim final rule, FSIS abandoned pathogen-reduction performance standards -- a core element of the proposed rule and the object of vociferous industry opposition -- because it determined that there was "insufficient scientific information" on which to base such standards. It opted, instead, for a more "flexible" approach to Listeria, giving plants three alternative approaches they could follow to reduce the likelihood of Listeria contamination.

FSIS had initially proposed requiring plants to include Listeria controls in their overall systems of preventive controls for pathogen reduction, an approach that involved greater government oversight. In the interim final rule, FSIS once again reversed itself, and determined that plants could address Listeria in their prerequisite programs. This approach limits FSIS authority over those programs and demotes the controls to little more than guidelines for sanitation.

In addition, consumer groups consistently urged FSIS to require information labels on ready-to-eat meat and poultry products that would alert at-risk consumers about the risks posed by the products and how to consume them safely. In the proposed Listeria rule, FSIS proposed only that the phrase "Refrigerate After Opening" be included on ready-to-eat product labels, and sent the consumer groups' labeling proposal to an advisory committee for further consideration. The interim final rule contained no discussion of FSIS's original proposal for refrigeration labeling or of the consumer group position that product labels should inform at-risk people. Instead, the agency announced a voluntary provision that allowed labels on ready-to-eat products to show that the products were processed in a manner to eliminate, reduce or limit the growth of Listeria.

Consumer and public-health groups have also faulted FSIS for its handling of recent Listeria-related recalls. More important, USDA's own Office of Inspector General (OIG) strongly rebuked the agency's handling of and response to a major Listeria food-poisoning outbreak in 2002 that covered eight states. The outbreak was ultimately linked to a ready-to-eat product -- cooked, sliceable turkey deli meat. Two companies produced the turkey products -- Jack Lambersky Poultry Company and Wampler Foods, a subsidiary of Pilgrim's Pride Corporation. The two companies recalled close to 30 million pounds of chicken and turkey products, some of which had been distributed through the National School Lunch Program.

The OIG reports found inadequate performance by federal inspection staff at the Lambersky plant and serious deficiencies at both plants regarding oversight of the recall process. The OIG noted that FSIS did adopt several of the revisions to the directive on recall verification procedures that it had recommended. The directive, however, did not address many other issues, in particular, how to better protect children and other participants in government feeding programs. Moreover, FSIS significantly diluted measures aimed at improving the testing procedures at ready-to-eat plants that had been promised by Secretary Veneman in the wake of the Lambersky/Pilgrim Pride recalls.

The continuing delays in finalizing the Listeria rule and the more accommodating attitude toward the meat industry have coincided with distressing signs that a steady decline in the rate of Listeriosis cases has ended. The rate of listeriosis increased by 22 percent in 2003. Equally disturbing but not surprising is the government's apparent abandonment of its goal of reducing by 50 percent the incidence of Listeria food-poisoning cases by 2005.

II. Introduction

Food poisoning is a major, public-health problem in the United States. According to the U.S. Centers for Disease Control and Prevention (CDC), each year, an estimated 76 million Americans are stricken with food poisoning; of these, 325,000 are hospitalized and 5,000 die.[1] The economic cost is enormous: illnesses from the five major bacterial foodborne pathogens cost at least $7 billion a year in medical expenses and time lost from work.[2] The costs of associated pain and grief are, however, incalculable.

The rise in food poisoning that began in the early 1980s can be attributed to a number of factors, including changes in food-production methods and food- consumption patterns. Since the death of four children in a 1993 outbreak of *E. coli* 0157:H7 spurred increased public attention to food poisoning, government and the food industry have invested more time, energy, and resources to reducing the problem.

Government monitoring shows that, from 1996-2003, the estimated incidence of infections caused by some foodborne pathogens declined.[3] However, there has been no sustained decrease in cases of *E. coli* O157:H7 and several types of *Salmonella,* and the overall toll of deaths and illnesses from foodborne pathogens remains unnecessarily high. One pathogen, *Listeria monocytogenes* (Listeria)[4] is especially troublesome. Though not as familiar to the public as the more infamous *E. coli* O157:H7, Listeria poisoning results in the highest rate of hospitalization of any foodborne pathogen, and the second-highest fatality rate (i.e., twenty percent of Listeria victims die).[5] Moreover, this pathogen is particularly deadly to a fetus: a pregnant woman who contracts Listeria food-poisoning will almost always suffer miscarriage or stillbirth or bear a child with severe disabilities. The costs of acute illness from foodborne Listeria poisoning alone are estimated to be $2.3 billion per year.[6]

The development of a rule and related policies to control Listeria in ready-to-eat meat and poultry products provides a case study of the role that industry plays in the crafting of government policies to protect the public from food poisoning. Hardly the only example,[7]

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[1] Paul S. Mead, et al, *Food-Related Illness and Death in the United States,* 5 Morbidity and Mortality Weekly Report (Sept.-Oct. 1999) at 1 (electronic version) available at http://www.cdc.gov/ncidod/EID/ vol5no5/pdf/ mead.pdf. These estimates are considered conservative for two reasons: 1) foodborne illness is underreported; and 2) there are many pathogens yet to be identified that cause additional undiagnosed foodborne illness. *Id.*

[2] Economic Research Service, U.S. Department of Agriculture, *Briefing Room: Economics of Foodborne Disease*, available online at http://www.ers.usda.gov/Briefing/FoodborneDisease/.

[3] *See* D. Vugia, MD et al., *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly through Food --- Selected Sites, United States, 2003*, 16 Morbidity and Mortality Weekly Report 338 (April 30, 2004) available online at http://www.cdc.gov/mmwr/preview/ mmwrhtml/ mm5316a2.htm. During 1996 -2003, no substantial changes were observed in the incidence of infection caused by *Listeria*, *Shigella*, and several common *Salmonella* serotypes (*S*. Enteritidis, *S*. Newport, and *S*. Heidelberg). By contrast, The incidence of *Vibrio* and *S*. Javiana infection increased.

[4] Unless otherwise specified in this report, "Listeria" will mean *Listeria monocytogenes*.

[5] U.S. Center for Disease Control and Prevention, *Listeriosis*, available at http://www.cdc.gov/ncidod/dbmd/ diseaseinfo/listeriosis_g.htm

[6] Economic Research Service, U.S. Department of Agriculture, *Briefing Room: Economics of Foodborne Disease*, *Listeria Monocytogenes,* available online at http://www.ers.usda.gov/briefing/FoodborneDisease/listeria/.

[7] We chose to focus on *Listeria Monocytogenes* given the high mortality rate associated with this pathogen, as well as the fact that Listeria contamination is found in meat and poultry products that are considered "ready to eat." Other groups have done similar studies focusing on other pathogens. *See*, e.g., Safe Tables Our Priority, *Why*

it is a clear case of the public interest losing out to the interests of the food industry during the first term of George W. Bush's presidency.

Government food-safety regulation, like other health and safety regulations, exists because market mechanisms do not work: there is no way for a consumer to determine, independently, that a food product is safe. This "market failure" is particularly evident in the case of food poisoning, because the pathogens or chemicals that may contaminate a food product are not visible, and it is almost always impossible for an individual consumer to trace a particular illness to a specific food product. At the same time, a company cannot recoup the costs of building safety into their products, so they have had little incentive to spend the money on their own and generally oppose government efforts to make them do so. As a result, industry representatives are a constant presence in the government decision-making process, arguing that they should be allowed to deal with food-safety problems through voluntary, industry-initiated measures that involve less government intrusion and may be less costly to them. They strongly oppose all proposals that involve compliance with strict government-set standards (such as limits on microbiological contamination) and rigorous verification requirements (such as final product testing).

While government food-safety officials are charged with protecting public health, in practice they balance competing interests -- balancing the competing consumer desire for safe food against food processors' interest in keeping their costs low and minimizing government interference in their daily operations.

This report begins by providing some background on the pathogen, *Listeria monocytogenes*, and the disease it causes, listeriosis (Listeria food-poisoning). It then describes the regulatory structure for meat and poultry products, and presents a chronology of efforts by the U.S. Department of Agriculture (USDA) to control Listeria contamination in ready-to-eat meat and poultry products.

USDA's approach to controlling Listeria contamination in meat and poultry products underwent substantial change after George W. Bush became president. Republican Administrations traditionally have tended to be less inclined to impose strict regulations on business, and have historically had closer ties to meat producers and processors. This report explores two factors that have contributed to the change in Listeria policy. First, both agribusiness generally and meat and poultry producers, processors and retailers specifically make substantial campaign contributions and an increasing percentage of the monies go to Republican candidates. One of the biggest contributors to President Bush's campaigns has been the Chairman of Pilgrim's Pride, a Texas company with a history of violations of safety regulations at its Wampler Foods plant in Franconia, Pennsylvania.[8] This plant was forced to undertake one of the largest recalls of meat and poultry products in history after its products were associated with a major Listeria food-poisoning outbreak in 2002.

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are People Still Dying from Contaminated Food? (2003) available at http://www.safetables.org/pdf/STOP_Report.pdf (Report focused on *E. coli* O157:H7).

[8] *See* Oliver Prichard and Aparna Surendran, *Food plant cited before outbreak: "Corrective actions" were not taken at a Franconia poultry processor linked to seven listeria deaths*, Philadelphia Inquirer, Nov. 03, 2002, available at http://www.philly.com/mld/inquirer/4429354.htm.

Two years after Pilgrim's Pride's products were implicated in that outbreak, which killed seven people and caused three miscarriages/stillbirths as well as dozens of hospitalizations and illnesses, the record of problems within the plant remain sealed. The USDA's Office of Inspector General (OIG) was unable to fully investigate that recall because of an ongoing criminal investigation.[9] CFA has been unable to obtain any further information about the investigation except that it remains open.

The second major change at USDA in early 2001 came in the form of new personnel. A flock of former meat-and-poultry industry trade association executives migrated to high-ranking political appointments (and policy-making positions) at the Department. As a result, industry lobbyists gained increased access to USDA officials.

USDA's top food-safety officials have chosen to conceal just how much access industry officials had to them during the formulation of the Listeria rule. They have refused to release the public calendars detailing their meetings held over the past four years with industry groups that were advocating a change in USDA's approach to reducing illness from Listeria. By contrast, officials at the U.S. Food and Drug Administration (FDA) – as well as at other agencies --publish their calendars on their agency's website each week so that the public can be informed about who is seeking to influence policy. In fact, the decision to withhold public calendars is inconsistent with the practice of other USDA officials who have released their calendars in response to Freedom of Information Act requests.[10]

Against this backdrop, the Department's Listeria policy took a decidedly pro-industry tilt. The industry-friendly approach of the Listeria rule, eventually encompassed in an interim final rule in June 2003, was foreshadowed by a number of agency actions during the first two years of the Bush Administration: USDA's decision to delay regulatory action by undertaking a second risk assessment; its decision to limit the scope of the risk assessment as well as its reliance on data from an industry-sponsored study rather than data developed by government scientists; its hasty revisions to a Listeria directive after a major Listeria food-poisoning outbreak in 2002; and the Department's inadequate response to that outbreak and associated product recalls.

An analysis of the positions advocated by the regulated industry regarding the proposed Listeria rule reveals a startling symmetry between industry positions and changes ultimately adopted by the USDA in the interim final rule. Every aspect of the original USDA proposal that was opposed by industry was reversed in the final rule. Moreover, in every instance where consumer groups and industry took an opposing position, USDA rejected the consumer position and came down in favor of industry.

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[9] *See* USDA, Office of Inspector General, Northeast Region, *Audit Report: Food Safety and Inspection Service Oversight of the Listeria Outbreak in the Northeastern United States* (USDA/OIG-AUDIT No. 24601-02-Hy) (June 2004) at i., available at http://www.usda.gov/oig/webdocs/24601-02-HY.pdf.

[10] CFA has filed a suit aimed at compelling release of the withheld public calendars.

III. Background

A. Listeria Monocytogenes

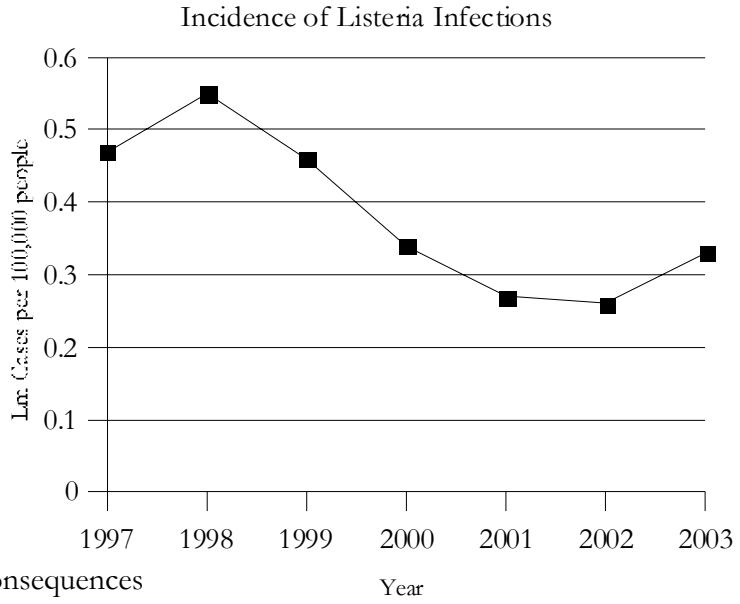
Listeria monocytogenes (Listeria) is a pathogenic bacterium found in the environment, both outdoors (in soil, water and on vegetation) and inside buildings (on the surfaces of equipment, floors, and walls). It also lives in the intestinal systems of animals, which carry the pathogen without ever becoming sick. Listeria can be transmitted from any of these sites to meat and poultry products.

Listeria is a particularly challenging pathogen because it spreads easily upon contact with a contaminated surface. Like most foodborne pathogens, Listeria bacteria cannot be detected by sight, smell or touch. However, unlike most other foodborne pathogens, Listeria can thrive and even continue to multiply in the low-oxygen and low-temperature atmosphere of refrigerators, surviving for weeks, even months.[11]

Food products can become contaminated with Listeria in a number of ways: if they are formulated using contaminated ingredients; if a cooked, sterilized product comes into contact with a tainted product or surface; or even if that product is exposed to Listeria-contaminated water from a non "food-contact" surface (i.e., dripping from pipes on the plant's ceiling).

B. Listeria Food-Poisoning

Listeria infection in humans causes listeriosis (Listeria food- poisoning), a disease with flu-like symptoms, including fever and upset stomach. The infection may spread to the nervous system, resulting in serious headache, stiff neck, confusion, loss of balance, or convulsions. Like most infectious agents, Listeria can be most dangerous for people with weaker immune systems: the very young, people over 60 years of age,[12] individuals undergoing cancer treatments, transplant patients, and those suffering from AIDS, diabetes or kidney disease.[13]



Source: CDC

Listeria food-poisoning can have serious consequences for pregnant women. Some experts estimate that one-third of all Listeria food-poisoning cases occur in pregnant women.[14]

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[11] *See* Brian D. Sauders et al, *Distribution of Listeria monocytogenes Molecular Subtypes among Human and Food Isolates from New York State Shows Persistance of Human Disease-Associated Listeria monocytogenes Strains in Retail Environments*, 67 Journal of Food Protection 1417 (2004).

[12] *See* Bruce Gellin and Claire Broome et al., *Listeriosis*, 261 JAMA 1313 (1989).

[13] *Listeriosis, supra* note 5.

[14] *See* Lawrence Slutsker and Anne Schuchat, *Listeriosis in Humans*, in Listeria, Listeriosis, and Food Safety 87 (Elliot Ryser and Elmer H. Marth, eds., 1999).

An infected pregnant woman may experience only mild symptoms, but the infection creates a substantial risk to her fetus, frequently leading to miscarriage, stillbirth, or serious health problems for a newborn.

The number of Listeria food-poisoning cases each year is not large, but Listeria is among the most dangerous and lethal foodborne pathogens. The CDC estimates that Listeria causes close to 2,500 cases of Listeria food-poisoning annually; over 90 percent of the victims are hospitalized and 20 percent die.[15] Listeria food-poisoning has a long incubation period (2-6 weeks),[16] and this fact can make it difficult to link a specific infection to a particular food product.

In 2003, CDC reported that there had been a decrease in Listeria food-poisoning cases from 1996-2002, and noted that the nation might be on track to reaching the objective of reducing Listeria infections by half (to .25 cases per 100,000 people).[17] However, in 2004, CDC data show that, in 2003, the decline not only stopped, it actually reversed, with the incidence of Listeria food-poisoning back up to .33 per 100,000.[18]

C. Listeria Contamination in "Ready-to-Eat" Meat and Poultry Products

In addition to its high fatality rate, Listeria is especially dangerous because it is frequently associated with foods that people assume are sterile and safe to eat directly from the package. These so-called "ready-to-eat" meat and poultry products include hot dogs, luncheon meats, cold cuts, fermented or dry sausage, and other deli-style meat and poultry products.

The labels on these products typically state "cooked," and "ready-to-eat," and may also have "use-by" date labeling. Consumers reasonably assume that the label means what it says. Neither restaurants nor individual consumers ordinarily heat or fry bologna or liverwurst before serving or eating it. The fact remains, however, that healthy pregnant women, along with people over sixty years of age and others who have less than optimal immune function, may get sick if they do not heat these so-called "ready-to-eat" foods to steaming hot in order to kill any possible Listeria bacteria.

D. U.S. Department of Agriculture

Most Americans are familiar with the FDA, part of the Department of Health and Human Services (DHHS), and probably assume that it is responsible for ensuring the safety of the nation's food supply. They are partially correct: FDA does regulate the safety of most

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[15] *Listeriosis, supra* note 5.
[16] CDC, Diagnosis and Management of Foodborne Illness: A Primer for Physicians MMWR, Vol. 50, No. RR-2 (Jan. 26, 2001) available at http://www.cdc.gov/mmwr/PDF/rr/rr5002.PDF.
[17] *See* D. Vugia, MD et al., *Preliminary FoodNet Data on the Incidence on the Incidence of Foodborne Illnesses --- Selected Sites, United States, 2002*, 15 Morbidity and Mortality Weekly Report 340 (April 18, 2003) available at.http://www.cdc.gov/mmwr/PDF/wk/mm5215.pdf.
[18] *See* Vugia et al., *supra* note 3.

food products, including some that are susceptible to Listeria contamination.[19] The safety of meat, poultry and processed egg products, however, is the responsibility of the USDA's Food Safety and Inspection Service (FSIS). To fulfill this responsibility, FSIS inspects the approximately 6,500 plants in the U.S. that slaughter animals and/or process meat and poultry products.[20]

USDA's primary mission is to promote the production and sale of agricultural commodities. At the same time, Congress has assigned to the Department the additional responsibility of a major public-health program -- assuring the safety of meat and poultry products. These dual mandates are often in conflict, requiring the agency to resolve incompatible priorities. Every time the agency must decide whether to inform the public about health threats related to meat and poultry products, it also must consider the possible impact this information might have on meat and poultry sales. Over the years, USDA has been criticized for being overly solicitous to the interests of meat and poultry producers.[21]

This conflict is exacerbated by the fact that many of the political appointees assigned responsibility for meat and poultry inspection over the past few decades have had close ties to the regulated industry.[22] Indeed, a number of Congressional and Executive-branch studies have criticized USDA's food safety regulators for being too close to the industry they regulate. Some studies have recommended that meat and poultry inspection be moved out of USDA and into FDA, part of the DHHS, where protecting public health is the major focus and not an adjunct to making agricultural products more appealing.[23] In response to these criticisms, Congress created the position of Under Secretary for Food Safety in 1994 to separate the Department's food safety responsibilities from its marketing functions.[24]

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[19] FDA regulates soft cheeses such as feta, brie, camembert, blue-veined and Mexican-style cheese, as well as raw, unpasteurized milk and products made from it, all of which be contaminated with Listeria.. This report, however, focuses only on USDA-regulated products and the Department's Listeria policy.

[20] Federal meat inspection began with the enactment of the Meat Inspection Act in 1906. The law was prompted by the tremendous public outcry regarding horrible conditions in meatpacking houses depicted in Upton Sinclair's novel, *The Jungle*. Congress passed the Poultry Products Inspection Act (PPIA) in 1957 in response to the rapidly expanding market for dressed, ready-to-cook poultry and processed poultry products.

The Federal Meat Inspection Act was amended as the Wholesome Meat Act of 1967, which provided for state inspection of the nation's meat supply. When the PPIA was amended in 1968, meat and poultry inspection programs, which had been separate, were merged into one program at the time of enactment. Authority over the inspection program bounced between different agencies within USDA until 1977, when it was assigned to the Food Safety and Quality Service, which was redesignated as the Food Safety and Inspection Service (FSIS) in 1981. FSIS, USDA, Agency History, available at http://www.fsis.usda.gov /about/ agency_history/index.asp.

[21] *See*, e.g., U.S. Senate, Committee on Governmental Affairs, *Study on Federal Regulation: Regulatory Organization* 95th Congress (1977); 140 Cong. Rec. H9967 (daily ed. Sept 13, 1994) (Remarks by Congressman Robert Torricelli); Eric Schlosser, *Fast Food Nation: The Dark Side of the All American Meal* (2001).

[22] William McMillan, Assistant Secretary for Marketing and Inspection in the Reagan Administration, was the former Director of Washington office of the National Cattlemen's Beef Association (NCBA); George H.W. Bush appointed Jo Ann Smith, Immediate Past President of the NCBA. Richard Lyng, who was responsible for meat inspection in the Nixon Administration, became President of the American Meat Institute and returned to USDA in the Reagan years, first as Deputy Secretary and then Secretary of the Department

[23] *See, e.g.,* Vice President Albert Gore's National Performance Review, Chapter 4, *Cutting Back to Basics* 1993, available at http://govinfo.library.unt.edu/npr/library/nprrpt/annrpt/redtpe93/2272.html.

[24] *See* Department of Agriculture Reorganization Act of 1994, Pub. L. No.103-354.

In the period following the creation of the position of Under Secretary for Food Safety, USDA embarked on the most significant change in its approach to product inspection since passage of the original Meat Inspection Act. Up until that time, federal inspectors followed an "organoleptic" approach, relying on sight, touch, and smell to evaluate the safety of meat and poultry products. Since microbiological contamination cannot be detected organoleptically, this approach was largely ineffective in controlling pathogens.

In 1996, FSIS adopted a new approach to the way slaughter and processing plants ensure the safety of their products called the Hazard Analysis and Critical Control Point (HACCP) system.[25] The HACCP system was originally developed not for use by a government, public-health regulatory agency but, rather, as a means by which an individual company could assure it was meeting its own safety standards. FSIS's version of HACCP puts responsibilities on food companies, as well as the government, for assuring that contaminated meat and poultry products do not reach the public. .

Under the HACCP approach as adopted by USDA, an establishment must first undertake a hazard analysis to identify the food-safety hazards that are "reasonably likely to occur" in its production processes. A food-safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. An establishment must also determine the "critical control points" (CCPs): the points, steps, or procedures in a food process at which controls can be applied and, as a result, food-safety hazards can be prevented, eliminated, or reduced to an acceptable level.[26] Among other things, a plant's written HACCP plan must specify controls for each hazard identified.

In some instances, FSIS has established performance standards that establishments must meet. Such a standard could, for example, set a maximum limit on, or a required reduction in, the number of specific pathogenic organisms in a product. The standard may apply to the actual pathogen that is making people sick. Alternatively, as is often the case when it is difficult to measure that pathogen, the standard may apply to an "indicator" or "reference" organism (i.e. a non-pathogenic form of a bacteria whose elimination or reduction most often indicates the elimination of or reduction in the pathogen of concern). Here, *Listeria spp.* is an indicator organism that can be indicative of serious sanitation problems in a plant, while *Listeria monocytogenes* is the pathogenic organism that causes foodborne illness in humans.

While establishments must have HACCP plans in place, FSIS gives each plant the flexibility to choose the process control or treatment that it believes will allow it to control contamination and meet any relevant standards. Establishments are required to verify that their HACCP systems are working to control pathogens in their products. However, they are generally given discretion to determine how to verify compliance, whether through product testing or other means.

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[25] *See* 9 CFR Part 417. FSIS began implementing its HACCP rule for large plants in January 1997; implementation of the rule was completed by January 2000.

[26] FSIS, *Key Facts: The Seven HACCP Principles* (1998) available at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oa/background/keyhaccp.htm.

Under HACCP, federal inspectors oversee each plant's implementation of its HACCP plan, and conduct their own testing to monitor compliance with the plan and any applicable performance standards. While inspectors can review plants' HACCP plans, these plans are not pre-approved by FSIS before they are implemented. More significantly, when a plant does perform its own verification testing, it is not required to notify the federal inspector when it has found a positive result in its pathogen testing. This means that a plant could find pathogens on a regular basis and choose not to revise its HACCP plan to control them, as long as an inspector does not discover that there is a problem.

IV. The Government's Initial Response to Listeria

The federal government first became aware of the danger posed by Listeria contamination in ready-to-eat meat and poultry products in the mid-1980s. USDA's first response to the problem was to initiate a monitoring program in 1987 to test for the pathogen within processing plants. Then, in 1989, the agency established a restrictive "zero-tolerance" standard for Listeria in ready-to-eat products. Under the zero-tolerance standard, any amount of Listeria in a ready-to-eat meat or poultry product renders it "adulterated"[27] and subject to a voluntary recall.[28] The zero-tolerance standard for Listeria in ready-to-eat products reflected a policy decision that the consequences of Listeria food-poisoning are too severe, and the available data regarding the pathogen's infectious dose and other characteristics too limited, to define a safe level of contamination.

Despite the zero-tolerance policy for Listeria, a nationwide outbreak of Listeria food-poisoning occurred in 1998 that heightened government attention to this pathogen. Contaminated hot dogs and other ready-to-eat meat products manufactured by Bil Mar Foods, a subsidiary of the Sara Lee Corporation, resulted in 21 deaths (including six miscarriages/stillbirths) and 100 illnesses in 22 states.[29] In response to the severity of the Bil Mar outbreak and the surrounding publicity, FSIS developed a more comprehensive approach to Listeria contamination in ready-to-eat products. These actions, however, focused only on the role of the government in controlling Listeria contamination of ready-to-eat products and imposed no additional regulatory obligations on producers.

First, FSIS issued a directive in August 1998 that governed the government's microbial sampling of ready-to-eat products produced in HACCP plants.[30] A directive applies only to federal inspectors, and imposes no responsibility directly on the regulated company or its employees. With a directive, there is no requirement that an opportunity for public comment be offered, and the agency is not required to justify its action. For the public, a directive has only one advantage over a regulation: because it is not subject to the notice-and-comment requirements of a rulemaking, a directive can be developed or revised

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[27] The applicable laws (the Federal Meat Inspection Act and the Poultry Products Inspection Act) prohibit companies from selling "adulterated" (i.e. "unsafe") meat or products. *See* 21 U.S.C. §§601(m) and 453(g).
[28] Unlike other federal agencies, USDA has no authority to mandate a product recall.
[29] *See* CDC, Press Release, *Update: Multistate Outbreak of Listeriosis* (Mar. 17, 1999) available online at http://www.cdc.gov/od/oc/media/pressrel/r990114.htm.
[30] *See* USDA, FSIS Directive 10,240.2, *Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System* (Aug. 6, 1998).

expeditiously. For this reason, it is a useful interim step for the agency to take while it develops or finalizes a rule.

In 1999, the agency announced a number of short-term steps to control Listeria contamination. First, it published a notice advising manufacturers of ready-to-eat meat and poultry products to reassess their HACCP plans to make sure that they were adequately addressing Listeria.[31] Second, FSIS recommended that those plants conduct environmental and food-contact surface testing as well as final-product testing.[32]

At the same time, FSIS announced four longer-term initiatives relating to Listeria: 1) drafting a research protocol; 2) developing a verification protocol to assess HACCP plans for ready-to-eat products; 3) developing regulations implementing food-safety standards for ready-to-eat products; and 4) determining the relative risk to public health from Listeria among a range of ready-to-eat foods through a joint risk assessment with FDA.[33]

In January 2000, the federal government released "Healthy People 2010,"[34] a comprehensive, nationwide health promotion and disease prevention agenda, which included as one of its goals reducing by half the number of Listeria infections by the year 2010. That same month, *the Washington Post Sunday Magazine* featured a critical account of the Clinton Administration's response to the Bil Mar outbreak.[35] Stung by the articles' negative assessment of their performance and persistent criticism by consumer advocates, relevant White House and USDA staff moved Listeria -control efforts to a higher priority**.** Four months later, President Clinton announced that he was shortening the timetable for reaching a 50-percent reduction in Listeria infections from 2010 to 2005, and directed the Secretaries of DHHS and USDA to take steps to achieve that goal.[36]

A second major Listeria food-poisoning outbreak hit more than ten states between May and December 2000. It prompted the largest recall of meat and poultry products up to that time. The CDC eventually linked a single strain of Listeria to 29 illnesses--8 prenatal and 21 non-prenatal --resulting in 4 deaths and 3 miscarriages or stillbirths. FSIS traced the source of the Listeria -- deli turkey meat -- to Cargill Turkey Processors, Inc., a Texas poultry firm.[37]

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[31] 64 Fed. Reg. 28351 (1999). The HACCP regulations require every establishment to reassess the adequacy of its HACCP plan at least annually, and when any change occurs that could affect the underlying hazard analysis (such as, in this case, an increase in listeriosis cases and additional information about the prevalence and persistence of Listeria). *See* 9 C.F.R. §417.4(a)(3). As a result of a reassessment, the establishment might be required to modify its HACCP plan.

[32] *See* FSIS, Press Release, *FSIS Announces Strategy to Control Listeria Monocytogenes In Ready-to-Eat Meat and Poultry Products* (May 25, 1999), available at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OA/news/1999/lm_haccp.htm.

[33] *Id.*

[34] *See* Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, *Healthy People 2010* available at http://www.healthypeople.gov.

[35] *See* Peter Perl, *Poisoned Package*, Washington Post Magazine (Jan.16, 2000).

[36] S*ee* The White House, Press Release, *President Clinton Announces Aggressive Food Safety Strategy to Combat Listeria in Hot Dogs and Other Ready-to-Eat Foods* (May 6, 2000) available at http://www.foodsafety.gov/~dms/fs-wh20.html

[37] S Hurd et al, *Multistate Outbreak of Listeriosis --- United States, 2000*, 49 MMWR Weekly 1129 (2000) available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4950al.htm.

A. Listeria Action Plan

DHHS and USDA responded to President Clinton's directive with an eight-point "action plan" for combating Listeria.[38] The plan, the risk assessment, and the proposed rule were subject to the usual lengthy review processes, both within USDA and in the Office of Management and Budget. As a result, the materials were not given final sign-off until mid-January 2001. The Listeria proposed rule went to the Federal Register in the final days of the Clinton Administration, but publication was held up until February 2001. The regulations called for new enforcement strategies and the promulgation of new regulations, which would, among other things, require companies producing ready-to-eat meat and poultry products to test food-contact surfaces, the plant environment and, in some cases, final products for Listeria contamination.[39]

Consumer groups again criticized the timeline for action. Given the high mortality rate from Listeria poisoning, the Center for Science in the Public Interest (CSPI) argued that the lengthy phase-in of Listeria measures proposed by the Clinton Administration was unwarranted, and faulted the government for not giving priority to steps that would have the most immediate and significant public-health benefits. CSPI urged FSIS to require mandatory environmental testing for Listeria by plant employees, as well as final-product testing, and called for mandatory labeling of certain ready-to-eat products.[40]

B. The FDA/FSIS Risk Assessment

Along with the Listeria Action Plan, FDA and FSIS released the preliminary draft of their risk assessment for Listeria.[41] The risk assessment evaluated the relative risks of serious illness and death from Listeria food-poisoning that may be associated with consumption of different types of ready-to-eat foods.

It showed that the risk of Listeria food-poisoning on both a per-serving and per-annum basis varies greatly among products, and established risk-ranking categories. Two food categories were designated as presenting a "Very High" risk: deli meats and unheated frankfurters. This designation reflected the fact that these product categories have: 1) relatively high rates of contamination; 2) support the relatively rapid growth of Listeria even when refrigerated; 3) are stored for extended periods of time; and 4) are consumed extensively. These two products also had been directly linked to outbreaks of Listeria food-poisoning.

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[38] *See* USDA, News Release, *HHS and USDA Release Listeria Risk Assessment and Listeria Action Plan* (Jan. 18 2001) available at http://usda.gov/news/releases/2001/01/0020.htm.

[39] The action plan included a range of measures including consumer, health-care provider, and industry education; redirection of enforcement strategies, including increased microbial sampling; enhanced disease surveillance; and coordinated research activities.

[40] *See* CSPI, Comments on the FDA/FSIS Risk Assessment and Risk Management Action Plan (May 11, 2001).

[41] *See* FDA/USDA, Interpretive Summary, *Draft Assessment of the Relative Risk to Public Health From Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods* (Jan. 2001) available at http://vm.cfsan.fda.gov/~acrobat/Listeriarisksu.pdf.

The draft risk assessment emphasized that it was necessary to act immediately to control Listeria in very high-risk and high-risk products if the nation was to meet the national goal of cutting illness and death from Listeria poisoning in half by 2005.

V. Meat and Poultry Industry Influence over the Bush Administration

USDA's approach to controlling foodborne pathogens, including Listeria, changed substantially during President George W. Bush's first term**.** Before examining the specific**s** of that shift, it is useful to examine political factors that may have influenced it.

While campaign contributions and other support have always influenced policy, the 2000 presidential campaign is notable because: 1) the amount and distribution of agribusiness and meat industry-related campaign contributions so strongly favored one political party; 2) there is a close tie between the President and a meat company linked to a major outbreak of Listeria poisoning; and 3) a substantial number of meat industry veterans joined USDA.

It is not news that business interests contribute to political campaigns, or that contributions influence political appointments, assure access to decision makers, and sometimes drive changes in policy. In the case of the Listeria rulemaking, the changes amounted to a wholesale rejection of the proposed rule and consumer positions in favor of industry positions. USDA's change in attitude and regulatory stance coincided with a substantial increase in the rate of Listeria illnesses reported by CDC in 2003.

A. Campaign Contributions

An examination of campaign contributions to the Bush/Cheney campaigns in both 2000 and 2004 -- from agribusiness in general, from meat and poultry related companies, and from individual employees of meat and poultry companies – reveals a clear preference for the Republican ticket.

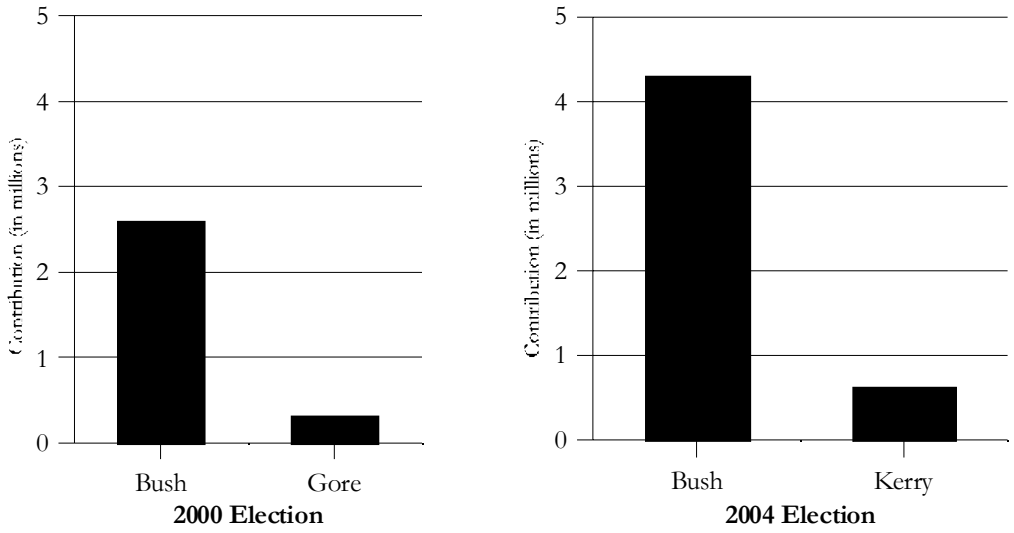
Total Agribusiness Contributions. According to the Center for Responsive Politics, agribusiness firms contributed a total of $59,431,422 to political candidates in 2000. Of this total, 74 percent of the money went to Republicans and 26 percent to Democrats. According to reports filed for the 2004 elections, as of November 2004, Republican candidates had received $30.7million (71%) from agribusiness firms, while Democrats had gathered $12.6 million (29%).[42]

Over the past dozen years, Republicans have consistently received a larger share of the total agribusiness contributions than Democrats have. With each Presidential election cycle, the gap continues to widen. In 1992, Republicans received $7.5 million more than the Democrats. In 1996, the difference was $24.4 million in the Republican's favor. The 2000 election saw the Republicans pulling in $28.2 million more than the Democrats. All

[42] All of the figures for campaign contributions included in this report were obtained from the website of the Center for Responsive Politics, http://www.opensecrets.org.

indications point to an even larger difference in 2004 once all the fundraising dollars have been counted.[43]

Total Agribusiness Contributions to Presidential Campaigns



Agribusiness Contributions to Presidential Candidates. In the 2000 presidential campaign, agribusiness companies gave $2.6 million to George W. Bush and $309,000 to Al Gore.[44] In the 2004 campaign, after four years of Bush Administration policies, agribusiness has almost doubled their contributions, with $4.6 million going to Mr. Bush and $672,656 to John Kerry.[45] In fact, agribusiness firms contributed more than 3.3 times as much to the President as to all of the Democratic presidential candidates combined: Bush received $4,632,287, while the other candidates, combined, received only $1,375,098.[46]

Contributions from Meat and Poultry Companies and Trade Associations. Companies and trade associations connected to the meat and poultry sector have been especially generous to Republican candidates in general and to President Bush in particular. An examination of campaign finance records shows that neither Al Gore nor John Kerry received any contribution from any major meat or poultry company or related trade-association political action committee (PAC). By contrast, the 2000 Bush/Cheney campaign received $10,000 from the American Meat Institute and $5,000 from the National Food Processors Association, $2,000 from the Food Marketing Institute and $1,000 each from Gold Kist and Foster Poultry Farms.[47] The trend has continued in 2004 with NFPA, Tyson Foods and Smithfield each contributing $5,000 and ConAgra $2,000 to the Bush/Cheney campaign.[48]

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[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*

CFA examined contributions made by the top 20 meat and poultry processing companies and their chief executives and the major trade associations. Of the trade associations and companies listed above, the American Meat Institute (AMI), the National Food Processors Association (NFPA), the Food Marketing Institute (FMI), the Grocery Manufacturers of America (GMA), the National Turkey Federation (NTF), The National Meat Association (NMA), and Tyson all played an active role in shaping the Listeria directive and rule.

CFA also reviewed contributions to members of the House and Senate Agriculture Committees by the top 20 meat and poultry processing companies and the major trade associations. While Congress was not directly involved in the *Listeria* rulemaking, these contributions illustrate that the same interests whose contributions assure them access and understanding within the USDA have similar access and understanding within the Congress. In 2002 and 2004, meat and poultry company PACs and trade association PACs contributed $703,630 (62%) to Republican members of the House Agriculture Committee and $430,078 (38%) to Democrats. These same company and association PACs contributed $342,980 (73%) to Republican members of the Senate Agriculture Committee in 2002 and 2004; they contributed $128,106 (27%) to Democrats.[49] The fact that the weakened Listeria rule has not been challenged by Congress demonstrates the impact of campaign contributions on the policymaking process.

Individual Contributions from Company and Trade Association Employees. The impact of industry contributions is multiplied by gifts from individual employees of companies and industry trade associations, the bulk of which went to the Bush campaign. In 2000, company and association employees gave George Bush $88,000, while Al Gore received only $2,250. In 2004, employee contributions amounted to $174,620 for Bush, but only $14,275 for John Kerry.[50]

Individual employees, especially senior-level executives, have donated generously to industry association Political Action Committees (PACs) as well as the PACs of their own companies. During the 2000 and 2004 election seasons, the National Chicken Council received $148,294 in contributions from employees of the top 20 meat processors and their own employees; FMI received $84,782; AMI received $81,557; GMA received $25,950; NFPA received $9,750; and NTF received $7,250.[51] These contributions add further weight to the industry viewpoints in Washington.

Contributions from Pilgrim's Pride. Pilgrim's Pride and its chairman, Lonnie "Bo" Pilgrim, warrant special mention in a description of Bush Administration ties to the meat industry. There is a long and special relationship between George W. Bush and Pilgrim's Pride, a Texas-based food processing company. Lonnie "Bo" Pilgrim, Chairman of the Board of Pilgrim's Pride Corporation, began supporting George W. Bush when Bush ran for governor in 1998, contributing $78,000, which put him just outside the top ten contributors

[49] *Id.*
[50] *Id.*
[51] *Id.*

to Bush's candidacy.[52] Pilgrim's Pride also made its private corporate jet available to the Governor five times during 1999.[53]

When Bush ran for President in 2000, "Bo" Pilgrim pledged to raise $100,000 for the Bush campaign. In 2004, Mr. Pilgrim has qualified as a "Pioneer," a fundraiser pledged to raise $100,000 for the campaign.[54] Pilgrim gave Bush $4,000 from his own pocket in 2004 and other Pilgrim's Pride executives have pledged as well. In the 2004 election cycle, Pilgrim's Pride employees contributed $49,150 to the 2004 Bush/Cheney campaign.[55] Employees gave no money to Democratic candidates or to Presidential candidates Al Gore in 2000 and John Kerry in 2004.

Pilgrim's Pride has also been a substantial contributor to other Republican organizations. In the 2000 campaign cycle, the company PAC gave $240,000 to the Republican National Committee, $100,000 to the National Republican Senatorial Committee, $25,000 to the National Republican Congressional Committee and $20,000 to both the 1999 and 2000 Republican Senate/House dinner. Lonnie Pilgrim contributed $2,500 to the National Republican Senatorial Committee in 2000.[56]

In the 2002 election cycle, Pilgrim's Pride contributed $190,000 to the Republican National Committee, $175,500 to the National Republican Senatorial Committee, $55,250 to the National Republican Congressional Committee, and $100,000 each to the 2001 and 2002 President's Dinner Committee. Bo Pilgrim contributed $50,000 to the National Republican Senatorial Committee as well.[57] No money was contributed to Democratic organizations.

To the extent that campaign contributions influence public policy, individual consumers, victims, public-health advocates, and the groups that represent them do not have PACs, do not make substantial campaign contributions, and, as a result, are simply not players.

B. Meat Industry Alumni Flock to USDA

In its first term, the Bush Administration has turned to its supporters in the meat and poultry industry to fill a wide range of political slots at USDA. Secretary Ann Veneman's chief of staff, Dale Moore, came to USDA directly from the National Cattlemen's Beef Association (NCBA), where he was executive director for legislative affairs. He was joined

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[52] Texans for Public Justice. Press Release (Apr. 12, 1999).
[53] Center for Responsive Politics, *supra*, note 42.
[54] Public Citizen at www.whitehouseforsale.org. Warren Staley, CEO of Cargill, achieved "Ranger" Status in 2004, which means he has raised at least $200,000 for the Bush campaign.
[55] Connie Allen, ($250); Dianne Barger, ($2000); Tommy Barger ($2000); Clifford Butler ($2000); Richard Cogdill ($2000); George Davis, ($250); Laverne Davis,($2000); Dan Emery ($2000); David Hand ($300); Tom Kilburn ($300); Larry Lyon ($250); Arbus Manns ($2000); Kim Martin ($2000); Mike Martin ($2000); James Matthews ($2000), Michael Murray ($2000), Joseph Nears ($2000); Sharon Nears ($2000); Greta Pilgrim Owens (2000) Richard Pearce ($2000); Bo Pilgrim ($2000); Lonnie A. Pilgrim ($2000); Lonnie K. Pilgrim ($2000); Patrick Pilgrim ($2000); Rodolfo Rivas ($2000); Clinton Rivers ($500); Randy Stroud ($250); Gary Tucker ($500).
[56] Center for Responsive Politics, *supra*, note 42. The Center for Responsive Politics notes that these donations may be made by individuals associated with the organization as well as by the organization itself.
[57] *Id.*

by other former NCBA alumni: Alisa Harrison, appointed as the Secretary's director of communications, served as executive director of public relations at NCBA; and Beth Johnson, special assistant to Veneman, had been associate director for food policy at NCBA. Chuck Lambert, Deputy Under Secretary for Marketing and Regulatory Programs, had served in various positions at NCBA for 15 years, most recently as chief economist. Mary Waters, assistant secretary for congressional affairs, had been director of the Washington office of ConAgra.

Veterans of another trade association, the National Pork Producers' Council, filled other top posts: Dr. Eric Hentges, who was appointed director of USDA's Center for Nutrition Policy and Promotion, which is responsible for all of the Department's important nutrition education initiatives; and 2) Steven Cohen, who was brought in to serve as FSIS spokesman. In addition, Deputy Secretary of Agriculture James Moseley was a former partner in Infinity Pork LLC.[58]

In filling the position of Under Secretary for Food Safety, the Bush Administration did not choose directly from a regulated company or related trade association but, instead, appointed Elsa Murano, a professor who had worked at both Texas A&M University and Iowa State University. Much of Murano's work at both universities involved research on the use of irradiation to improve food safety.[59] Murano was known to the industry and they were comfortable with her. Eric Schlosser, author of *Fast Food Nation*, recounts a 2003 meeting with Murano:

> She seems like a sincere person. But her views are much more consistent with those of a top meatpacking executive than what you'd expect from the government's foremost advocate of safe meat . . . Murano thinks USDA doesn't need the authority to order recalls, or to fine meat companies that deliberately break the rules. She thinks most outbreaks of food-borne illness could be avoided if consumers just cooked their food properly.[60]

From the outset, the Bush Administration signaled that food safety would not be exempt from politics at USDA: it converted the position of FSIS Administrator from career civil service to a political position.[61] Given all of these personnel changes, it is not surprising

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[58] By contrast, recent Democratic presidents have tended to view supporting consumer positions on meat and poultry safety issues as good politics, and their appointments at USDA reflected that attitude. Both Presidents Carter and Clinton chose former members of Congress to run USDA and filled most subcabinet positions with former congressional staff, and environmental and consumer advocates. Those appointments with some food industry experience did not work for meat or poultry interests. For example, Clinton's Deputy Secretary Richard Rominger, a California farmer, did not raise cattle, and Deputy Under Secretary for Food Safety Caren Wilcox had previously worked for Hershey Foods, a company with no meat or poultry businesses. One exception to this rule is Scott Shearer, an aide to USDA Secretary Dan Glickman, who had previously worked for the American Meat Institute.

[59] A number of news reports characterized Murano as an irradiation "advocate" and "ally." Public Citizen highlighted the fact that her program at Texas A&M had signed a 10-year research and development deal with Titan Corporation, a leading player in food irradiation. Philip Mattera, *USDA. Inc.: How Agribusiness has Hijacked Regulatory Policy at the U.S. Department of Agriculture* 24 (2004).

[60] Eric Schlosser, *Order the Fish*, Vanity Fair, November 2004, at 246.

[61] Traditionally, the administrator of the inspection agency has been a career civil servant. For a short time in the Clinton Administration, it was converted to a non-career position but, when Congress created the position

that critics charge USDA and FSIS with being disposed to create regulations and policies that overwhelmingly benefit industry over public health.[62]

The new Administration did not waste any time putting its mark on USDA policies. In April 2001, the Department moved to end the zero-tolerance standards for *Salmonella* and *E. coli* O157:H7 contamination in meat served in the school lunch program. Meat suppliers vociferously opposed these standards, which had been established in 2000. When the new policy made the front pages of the *Washington Post* and *New York Times*, the White House ordered the zero-tolerance standards reinstated.

In addition, the Bush Administration completely reversed position on a key element of the HACCP rule, thereby undermining its effectiveness. At the urging of consumers, USDA had established performance standards to verify that meat and poultry plants HACCP plans were in fact controlling pathogen levels on end products. A plant that consistently failed to meet the Salmonella standards could be closed permanently. In December 2001, a federal appeals court ruled that USDA did not have the authority to close a plant for failing to control *Salmonella* levels in raw meat and poultry.[63] Not only did the Bush Administration choose not to appeal this decision, but it also opposed legislation that would give the Department the authority to set and enforce limits on pathogens, as well as to require companies to recall contaminated meat and poultry products.

By April 2002, the meat and poultry industry was openly praising the new regime. Rosemary Mucklow, executive director of the National Meat Association, told the *Washington Post* that, "meat producers believe that the USDA now understands their problems better and is better able to come up with workable solutions to food safety and other problems."[64] Over the past three and one-half years, USDA's actions have consistently emphasized solutions that are termed "workable" by industry but "inadequate" by consumer and public-health groups.

VI. The Proposed Rule on Listeria

A. Publication of the Proposed Rule

When FSIS issued its 1998 sampling directive, the agency's leaders made it clear that this was an interim measure aimed at controlling Listeria while the USDA/FDA risk assessment was completed and a new regulation was drafted. By the fall of 2000, FSIS had developed a proposed rule and submitted it for departmental and White House regulatory review.

Consumer advocates and food-poisoning victims shared the industry's view that an administration led by George W. Bush would be more attuned to industry interests and less

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of Under Secretary for Food Safety, which was a presidential appointee, the Clinton administration changed the administrator job back to a career position.

[62] *See, e.g., Philip* Mattera, *supra* note 59.

[63] *See* Supreme Beef v. U.S. Department of Agriculture, 5th Cir. (Dec. 17 2001).

[64] Marc Kaufman, *Food Safety Report Ignites Angry Debate***,** Apr.19, 2002, available online at washingtonpost.com.

likely to pursue a vigorous regulatory attack on Listeria. The consumer and public-health organizations pushed hard to get the proposed Listeria rule published before. They failed.

The viewing stands for the Inaugural Parade had not yet been removed when the new administration issued a sweeping memorandum on January 24, 2001, halting all proposed and final regulations from the Clinton Administration that had not yet been published in the Federal Register.[65] This included USDA's proposed Listeria rule.

Distressed that publication of the proposal had been stopped, consumer advocates sought to get it back on track. Center for Science in the Public Interest wrote to Secretary Veneman urging action. Food- poisoning victims organized a trip to Washington to publicly protest the delay. They asked an intermediary to contact the new Secretary of Agriculture, Ann Veneman, directly and urge her to push the White House to free the proposed rule from the holding action and publish it for comment. Veneman, who had developed good relations with consumer groups during her tenure as California Secretary of Food and Agriculture, responded positively to the overture and contacted OMB. She also promised the victims and consumer groups that she would both push hard to get the proposed rule out within a few weeks and keep them informed on progress and timing..

Secretary Veneman made good on the commitment. On February 27, 2001, the Bush Administration published the proposed Listeria rule,[66] without making any substantive changes to the proposal drafted by the Clinton Administration.

B. Key Elements of the Proposal

In the proposed rule, USDA proposed establishing pathogen-reduction "performance standards" for all ready-to-eat products and, under some circumstances, requiring final-product testing for Listeria to ensure that the standards were being met. A performance standard generally limits the amount of a particular pathogen in the final product, and is monitored at the CCPs that are identified in an establishment's HACCP plan. Establishments are required to verify that they are consistently, and over time, in compliance with any applicable FSIS performance standards. The performance standard for Listeria in a finished product is zero.[67]

The proposed rule spelled out in detail the Clinton Administration's view that performance standards were vital to protecting the public from Listeria in processed meat and poultry products. The document noted that voluntary compliance mechanisms had not been successful in combating Listeria contamination and maintained that not establishing performance standards for ready-to-eat meat and poultry products "would result in a significant inconsistency in the Agency's public health policy:"[68]

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[65] *See* Executive Office of the President, Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7701 (2001).
[66] 66 Fed. Reg. 12590 (2001).
[67] *See supra* page 7 for a discussion of performance standards.
[68] 66 Fed. Reg. at 12633.

Anticipating industry opposition, the proposed rule laid out the case for performance standards:

> [S]ome members of the meat and poultry industry believe that regulatory performance standards are unnecessary or redundant…FSIS believes, however, that developing HACCP systems around verifiable, objective performance standards is the most effective way for establishments to consistently produce safe, unadulterated meat and poultry products…[W]ithout some regulatory requirements addressing Listeria, many establishments will continue not to regard Listeria as a post-lethality hazard reasonably likely to occur and not take steps through Sanitation SOPs or HACCP to ensure the safety of their products. FSIS tentatively concludes that without defining required actions in either the Sanitation SOPs or HACCP, product will continue to test positive for Listeria and outbreaks will continue to occur.[69]

Under the proposal, establishments producing ready-to-eat meat and poultry products also would be required to test food-contact surfaces for *Listeria spp.*[70] to verify that they are controlling Listeria within the entire processing environment. If an establishment were to find one of its food-contact surfaces positive for *Listeria spp.,* then it would have to take corrective action to demonstrate that its product was not adulterated with Listeria. In addition, an establishment would be required to implement procedures for determining which product lots were affected, and to hold and test products as well as dispose of them, if necessary.

This proposal was based on FSIS's tentative determination that Listeria was a "hazard reasonably likely to occur" in the production of ready-to-eat meat and poultry products.[71] For this reason, the agency proposed requiring that Listeria controls be incorporated into establishments' HACCP plans. The proposed rule provided that, if an establishment had already incorporated Listeria-control measures into its HACCP plan, it would be exempt from the testing requirements. Otherwise, a ready-to-eat meat and poultry plant would be required to test food-contact surfaces for *Listeria spp.* after a "lethality treatment"[72] had been applied to the product but before it was placed in its final packaging.

Because no appropriate antimicrobial technologies were available, the proposed rule rejected mandating that establishments implement antimicrobial controls, in lieu of testing of food-contact surfaces for Listeria.[73] The agency also tentatively decided to base the frequency of required testing on plant size.[74]

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[69] *Id.*

[70] If *Listeria spp.,* a non-pathogenic form of the bacteria, is found in a plant environment, it can indicate serious sanitation problems in a plant, and possible Listeria contamination in product.

[71] *Id.* at 12603.

[72] A "lethality treatment" is any process, application or action that eliminates a particular pathogen from a meat product (e.g., steam pasteurization, irradiation, or an antimicrobial treatment).

[73] *Id.* at 12634.

[74] FSIS acknowledged that it had no data to support the efficacy of this position, and specifically asked for comments on this issue.

VII. The Bush Administration's Response to Listeria

From the very start, Elsa Murano, who was sworn in as the new Under Secretary for Food Safety in October 2001, signaled the Department's more industry-friendly approach to food safety in general and Listeria specifically. In one of her first speeches, given in November 2001, Murano asked members of the National Food Processors Association to give her their views on the proposed Listeria rule, the existing Listeria directive, and other options for controlling Listeria contamination in ready-to-eat products.[75] Charged with assuring the American people a safe meat supply, Murano delivered a five-point action program that put consumer education first and industry regulation last.

Murano pointedly distanced herself from the proposed regulation; indicating that "we have several options in terms of a final rule. The end result will depend greatly on the scientific information we have available to us, including that supplied by the industry**."**

Murano directly sought industry input on the Listeria rule and assured her industry audiences that she was committed to protecting consumers in a way that was "based on science." She stated that she wanted input from all stakeholders. However, during the period the rule was under consideration, Murano's speeches were almost exclusively to industry-oriented groups. She did not seek meetings with consumer groups.

A. The FSIS Risk Assessment

In November 2002, FSIS announced its plans to conduct its own risk assessment relating to Listeria. While FDA and FSIS had previously described their joint risk assessment as "comprehensive," soon after it was released Murano and others at USDA began recasting it as a "retail-focused" risk assessment, and then as a "risk ranking."[76] Murano and other staff claimed that their new risk assessment was initiated in response to comments on the proposed rule.[77] Unlike the first risk assessment, this one was not done in conjunction with FDA, so FSIS was freed from having to consider the input of FDA scientists. Conducting a second risk assessment also allowed FSIS to further delay finalizing the Listeria rule.

CSPI vigorously criticized this decision and the delay in finalizing the rule that it prompted. Caroline Smith DeWaal of CSPI pointed to Murano's pledge that she would rely on the counsel she received from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) regarding risk assessments.[78] The NACMCF had indicated that, when a serious pathogen was involved, time was "of the essence": "[w]hile the committee believes health-based performance standards, based on a complete quantitative risk assessment would be the best approach to reducing foodborne illness, not all situations

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[75] Remarks by Under Secretary Elsa Murano before the National Food Processors Association (Nov. 28, 2001) available at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main =http://www.fsis.usda.gov/oa/speeches/2001/em_nfpa.htm.

[76] *See, e.g.,* Food Chemical News (Nov. 25, 2002).

[77] FSIS, Press Release, *USDA Issues Directive to Reduce Listeria Monocytogenes in Ready-to-Eat Meat and Poultry Products at Scientific Summit* (Nov. 18, 2002).

[78] *See* Remarks of Charlotte Christin, Senior Food Safety Attorney, on the Draft FSIS Risk Assessment on *Listeria* in RTE Meat and Poultry Products (Feb. 26, 2003).

require an in-depth risk assessment…*particularly if it would unnecessarily delay timely protection of human health*."[79] Listeria was just such a pathogen.

B. Listeria Outbreaks in 2002

1. Recalls by Pilgrim's Pride and Jack Lambersky

In June 2002, CDC began to receive reports of Listeria poisoning that ultimately spread to eight states.[80] By November, the CDC reported that a total of 131 people had been infected with Listeria.[81] Most were hospitalized, seven people died and three pregnant women suffered miscarriages or stillbirths.

CDC identified a ready-to-eat product -- turkey deli meat -- as the likely source of most of the illnesses. Meat from two companies was implicated: Jack Lambersky Poultry Company, doing business as J.L. Foods Company, Inc. and Wampler Foods, of Franconia, Pennsylvania, a subsidiary of Pilgrim's Pride Corporation. Lambersky recalled 4.2 million pounds of fresh and frozen, ready-to-eat poultry products in November 2002;[82] and Pilgrim's Pride eventually recalled close to 28 million pounds of chicken and turkey products.[83] Some of the implicated product sold by Pilgrim's Pride had been distributed through the National School Lunch Program. Both companies suspended operations for a limited period.

2. Agency Response

On October 17, 2002, when announcing the second, expanded Pilgrim's Pride recall, USDA Secretary Veneman stated that she had asked FSIS to develop a plan to revise its Listeria testing protocol. The new protocol, she said, would focus on establishments that produce the vast majority of products, increasing the number of samples taken and the volume of testing conducted at each establishment. Veneman indicated that this regime would include testing of final product as well as plant environment. As part of this process, Veneman also stated that plants producing ready-to-eat products would, once again, be required to reassess their HACCP plans.[84]

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[79] National Advisory Committee on Microbiological Criteria for Foods, *Response to the Questions Posed by FSIS Regarding Performance Standards With Particular Reference to Ground Beef Products (Final Report)* (Oct. 8, 2002) at 4 (emphasis added).

[80] Those states included Connecticut, Delaware, Maryland, Massachusetts, Michigan, New Jersey, New York and Pennsylvania.

[81] Ultimately, the CDC determined that 50 of those cases were caused by the same strain of Listeria found in the ready-to-eat product; the additional 81 people stricken with Listeria food-poisoning in the same region during the same period were infected with a strain of Listeria that did not match the fingerprint of the strain linked to the widespread outbreak.

[82] Lambersky initially recalled 200,000 pounds of product on November 2, 2002, but the voluntary recall was expanded on November 21st to approximately 4.2 million pounds.

[83] Initially, on October 2, 2002, Pilgrim's Pride recalled 295,000 pounds of turkey and chicken. On October 14th, the company recalled an additional 27.4 million pounds of chicken and turkey products.

[84] *See* USDA Press Release, *USDA Provides Update on Listeria Recall* (Oct. 17, 2002) available at http://www.usda.gov/news/releases/2002/10/0445.htm.

The following week, the new FSIS Administrator Dr. Gary McKee traveled to the annual convention of the American Meat Institute to deliver a tough message. McKee told the group that the agency would not tolerate plants throwing together minimalist HACCP plans and then ignoring them, and that plants should expect tougher enforcement. He repeated the Secretary's comments about the new Listeria control program, that the agency would focus on big producers and that they would be subject to increased government testing.[85]

A few weeks later, in mid-November 2002, FSIS issued a draft revised directive to USDA inspectors, outlining additional steps they should take to ensure that establishments producing ready-to-eat products were taking the necessary steps to prevent Listeria contamination.[86] It gave interested parties until December 2nd to file comments on the directive, which would become effective December 9th.

The meat and poultry industry was not shy about voicing its objections to the Secretary's approach to Listeria in general and the draft directive in particular. During this period, a steady stream of industry lobbyists filed into the glass enclosure that houses the Secretary's office to meet with Veneman, Dale Moore, her chief of staff, and Murano. These included representatives of Kraft (owner of Oscar Meyer Meat Company), ConAgra, the National Food Processors Association (NFPA), the American Meat Institute, the National Chicken Council, the National Turkey Federation and the National Cattlemen's Beef Association.[87]

NFPA wrote its members in early November, informing them of industry efforts to stop Veneman's new Listeria program from going into effect. It claimed that "consumer advocacy group criticism" had "compelled" Veneman to propose changes in the Listeria program. It characterized the directive as "very onerous," requiring "untrained" inspectors to undertake "extensive" product testing.[88]

According to the NFPA, it was working "furiously" with other trade associations to persuade the Secretary to delay releasing the directive. "Through industry efforts made at the White House level, the USDA decision to take additional action on Listeria . . . has been

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[85] Dr. Garry McKee, Remarks Prepared for Delivery to the American Meat Institute Annual Convention, New Orleans, LA (Oct. 25, 2002). McKee was the first FSIS administrator to come from the public health community, having served as director of the Wyoming Department of Public Health. After only 19 months in the post, he left FSIS to become Science Advisor for the Technical Service Center in Omaha, Nebraska, a position he had sought, according to the agency press release, in order to be geographically closer to his family. FSIS, Press Release*, McKee Selected as Science Advisor for FSIS Technical Service Center* (Feb. 26, 2004) available at http://www.usda.gov/ Newsroom/0086.04.html.

[86] *See* USDA, *USDA Issues Directive to Reduce Listeria Monocytogenes in Ready-to-Eat Meat and Poultry Products at Scientific Summit* (Nov. 18, 2002) available at http://www.usda.gov/documents/NewsReleases/2002/11/ 0478.doc

[87] CFA has been able to track Moore's meetings because, in response to a FOIA request, he made his public calendar available. By contrast, we have been unable to determine with whom and how often the under secretary and FSIS administrator met with industry lobbyists about Listeria because USDA refuses to release those calendars.

[88] NFPA Newsletter, Vol. 6, No. ii (Nov. 11, 2002).

averted," boasted an NFPA newsletter article. The newsletter also stated that, "we believe that a number of key Agency personnel have bought into much of the industry proposal."[89]

TIME Magazine reported that the White House denied any role in the final directive. Although Under Secretary Murano acknowledged consulting with both the White House and the industry during the period when the directive was being finalized, she insisted that the directive was "fine-tuned" solely to advance public health.[90]

On December 9, 2002, FSIS issued its revised directive on Listeria testing,[91] which had been changed substantially from the approach advocated by the Secretary and the Administrator, and from the draft released in November. The final directive more closely mirrored the industry position.

C. The Interim Final Rule on Listeria

The draft of the second risk assessment, initiated in early 2001, was not completed until February 2003 – two years after publication of the Listeria proposed rule. CSPI faulted the agency for limiting the new assessment to deli meats only (and ignoring hot dogs and other high-risk meat and poultry products), and for failing to include sampling of non-food contact surfaces in the risk model. The risk assessment also excluded consideration of whether the risk would be reduced if, in addition to other steps, final product testing was required. Moreover, CSPI took issue with FSIS's reliance on unpublished industry data (which found Listeria prevalence in ready-to-eat meat products at 0.9%) instead of data from an FDA study (which found a 2.7% prevalence).[92]

The final version of FSIS's risk assessment, released in May 2003, found that the minimal testing frequency in the proposed Listeria rule would result in a small reduction in Listeria levels; and, that a combination of interventions (sanitation and testing of food-contact surfaces, lethality interventions, and growth inhibitors) appeared to be more effective than any single intervention.[93]

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[89] *Id.*

[90] Michael Weisskopf, *Can Cold Cuts Kill? The USDA may be dragging its feet on inspections and favoring the industry*, Time Magazine, Mar. 3, 2003.

[91] *See* USDA, FSIS Directive 10,240.3, *Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program* (Dec. 9, 2002) available at http://www.fsis.usda.gov/Frame/ FrameRedirect.asp?main=/ oppde/rdad/fsisdirectives/10240.3.pdf. The directive was revised again, after release of the interim final rule. *See* USDA, FSIS Directive 10,240.4, V*erification Procedures for the Listeria Monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program* (Oct. 2, 2003) available at http://www.fsis.usda.gov/OPPDE/rdad/ FSISDirectives/10240-4.pdf.

[92] *See* Remarks of Charlotte Christin, *supra* note 78.

[93] FSIS, *FSIS Risk Assessment for Listeria Monocytogenes in Deli Meats* (May 2003) available at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F/ListeriaReport.pdf.

A final version of the Joint FDA/FSIS risk assessment was released in September 2003. It included a number of revisions to and refinements of the draft assessment, but still classified both deli meats and unheated frankfurters as "Very High Risk." *See* FSIS/FDA, *Quantitative Assessment of the Relative Risk to Public Health From Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods* (Sept. 2003) available at http://www.foodsafety.gov/~dms/Listeriar2-toc.html.

Finally, one month later, in June 2003, five years after the Bil Mar outbreak, FSIS issued an "interim" final rule on Listeria and ready-to-eat products[94] During the two and one-half years since publication of the proposed rule, hundreds more people were sickened and hospitalized and more than 30 million pounds of potentially Listeria-contaminated ready-to-eat product had been recalled.

From the first sentence, it was clear that the interim final rule was markedly different from the original proposal. Pathogen-reduction performance standards -- a core element of the proposed rule and the object of vociferous industry opposition -- had disappeared. The agency eliminated them, based on its determination that there was "insufficient scientific information" on which to base such standards.[95]

By examining two of the key issues addressed in the Listeria rule – mandatory testing and the characterization of Listeria controls – it becomes abundantly clear that FSIS adopted the views expressed by the industry in their comments on the proposed rule, and ignored the positions taken by consumer and public health groups.

1. *Testing*

FSIS had tentatively decided in the proposed rule to require establishments producing ready-to-eat meat and poultry products to test food-contact surfaces for *Listeria spp.* and, if the non-pathogenic form was found, to test products for *Listeria monocytogenes.*

a. Industry Position

Usefulness of Environmental Testing. Many industry members portrayed environmental testing as simply useless, arguing that, since Listeria is "ubiquitous" in the environment, positive test results from food-contact surfaces were meaningless in relation to possible contamination of the final product.[96]

Mandatory Testing. Industry groups resoundingly criticized FSIS's proposal to require mandatory testing of food-contact surfaces. Historically, the meat and poultry industry has uniformly opposed any type of mandatory testing requirement, maintaining that a voluntary system would foster greater compliance. Many commenters echoed this view in their comments on the proposed rule.[97]

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[94] 68 Fed. Reg. 34207 (2003). The word "interim" was used to describe the final rule to make clear that agency was going to accept comments on the rule for 18 months after publication for the purpose of reviewing and evaluating the effectiveness of the alternative approaches set out in the rule.

[95] *Id.* at 34215.

[96] *See* Grocery Manufacturers of American Comments at 2; *See also* American Frozen Food Institute Comments at 8 (a positive environmental sampling result did not "necessarily indicate that products produced in such an establishment are or may be contaminated).

[97] The National Turkey Federation (NTF) "strongly opposed" the mandatory testing of food contact surfaces, arguing that a risk analysis did not support the agency's position. NTF Comments at 4. The American Meat Institute (AMI) flatly rejected the agency's proposal, arguing that it was no different than the former command-and-control approach to meat and poultry safety. AMI Comments at 8; s*ee also* National Meat Association Comments at 3. ConAgra asserted that an environmental testing requirement at this time would be premature, essentially arguing that such a requirement should be delayed until the agency was more familiar with environmental testing programs. ConAgra Comments at 8. *See also* National Food Processor Association

Testing Frequency. Across the board, industry assailed FSIS for its faulty logic in basing testing frequency on plant size rather than the amount of product produced.[98] They argued that the establishment, not FSIS, should determine testing frequency.[99]

Response to a Single, Positive Test Result. Additionally, FSIS's proposed rule required establishments to take corrective actions after an establishment finds that one of its food contact surfaces tests positive for *Listeria spp*. The agency had proposed that such corrective actions include product testing and other actions that would demonstrate that the affected lot or lots of product were not adulterated with Listeria. Industry comments objected resoundingly to this aspect of the proposal, calling it a "waste of resources," and urging the agency to require actions in response to several positive findings.[100] One company argued that treating a single positive as a "regulatory event" would "inevitably discourage companies from acting aggressively to control *Listeria*, undermining rather than enhancing food safety."[101]

b. Consumer-Group Position

Members of the Safe Food Coalition (SFC)[102] filed joint comments, in which they strongly supported mandatory Listeria testing. In fact, the group urged the agency to go even further than the proposed rule and implement a more widespread testing program, including testing of the plant environment -- both food-contact and non-food-contact surfaces, as well as final products.[103] They urged the agency to increase the sampling frequencies and specify the testing intervals.

c. FSIS Decision

In the interim final rule, FSIS reversed its original position regarding mandatory testing frequencies, indicating that it did not want to "discourage" plants from performing measures beyond what it had recommended. It opted for a more "flexible" approach to Listeria control,[104] giving establishments complete control over the choice of testing methods and frequencies for verifying the effectiveness of their Listeria-control measures.[105]

This "greater flexibility" was translated into three alternative approaches that plants could follow to reduce the likelihood of Listeria contamination:

Comments at 20 (suggesting that FSIS's proposal include an alternative to mandatory testing); Cargill Comments at 4. (advocating for effective process controls instead of environmental testing)

[98] *See*, e.g., AFFI Comments at 4.

[99] *See, e.g.,* Farmland Comments at 1.

[100] *See, e.g.,* NTF Comments at 9.

[101] *See* Kraft Comments at 3.

[102] The Safe Food Coalition is comprised of consumer, victims' rights, public health, whistle blower and labor organizations.

[103] SFC Comments at 17.

[104] 68 Fed. Reg. at 34214.

[105] *Id.* at 34227.

- Alternative One -- allows an establishment to control Listeria by using both a post-lethality treatment and an antimicrobial agent or process on products to suppress or limit pathogen growth. This approach would treat the post-lethality treatment as a "CCP" in the plant's HACCP plan. However, under this approach, a plant could choose whether to treat an antimicrobial agent or process as a CCP or as part of the plant's prerequisite program.[106]

- Alternative Two – allows an establishment to use either a post-lethality treatment or an antimicrobial agent/process Again, the post-lethality treatment had to appear in the plant's HACCP plan while the antimicrobial agent/process could be included in either its prerequisite program or HACCP plan. If the plant uses only the antimicrobial agent/process, then FSIS requires that it test food contact surfaces, but at a frequency and sample size to be determined by the establishment. FSIS did indicate that if the plant uses only a post-lethality treatment, it would likely be subject to more frequent verification testing than if it adopts the first alternative.[107]

- Alternative Three -- allows establishments to control Listeria in the post-lethality-processing environment by using only sanitation procedures. FSIS mandates testing of food-contact surfaces under this approach, but allows the establishment to determine the frequency of testing and the size and location of samples. Plants would also be required to develop hold-and-test procedures under this alternative. While FSIS stated that selection of this alternative would likely subject plants to a higher testing frequency by FSIS than the other two alternatives,[108] this option provides industry with the maximum degree of freedom to establish its own requirements for controlling Listeria contamination.

FSIS indicated that Alternative One was "likely to be among the most effective means of reducing the risk of Listeria contamination and hence listeriosis mortality among vulnerable populations."[109] Nevertheless, the agency proceeded to provide industry with two additional options. Each alternative involves progressively fewer demands on the industry.

In addition to changing its view of mandatory environmental testing, FSIS capitulated to the industry by dropping its proposed requirement that a single positive result on a food-contact surface would trigger mandatory product testing.

These FSIS reversals seriously weakened the interim final rule. While the rule requires establishments to verify the effectiveness of their Listeria control program through

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[106] A "prerequisite program" is defined by FSIS as a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. Sanitary Standard Operating Procedures are one type of prerequisite program. The term ``prerequisite'' refers to the fact that these programs are prerequisites to a HACCP plan.

A further concession under Alternative One allows a plant to skip an additional treatment if it uses the antimicrobial agent/process as part of its initial lethality treatment, and the effect of that treatment lasts through processing and distribution. 68 Fed. Reg. at 34218.

[107] *Id.* at 34219.

[108] *Id.*

[109] *Id.* at 34219.

testing, they have no obligation to conduct such testing at any particular frequency, even if they produce high-risk products such as deli meats and hot dogs. Without mandatory minimum testing frequencies, plants simply cannot be assured that their controls are working effectively on a day-to-day basis to control Listeria.

Moreover, even though the rule requires establishments to make their own testing results available to FSIS inspection personnel upon request, nothing in the interim final rule imposes on establishments an affirmative obligation to disclose test results, particularly positive results, to FSIS at the time the results are obtained. It should not matter whether a positive is found in response to government sampling or whether it is discovered by the establishment itself. Without immediate access to this data when a problem is first identified, inspection personnel may be unaware that there is a sanitation problem at a facility, that interventions are not working properly, or that those problems may be persistent and uncorrected.

FSIS's continued failure to require establishments to report their positive test results or other evidence of ongoing sanitation problems is inconsistent with Secretary Veneman's statements immediately after the Pilgrim's Pride recall, when she declared USDA's commitment to "ensure that [FSIS] programs are strong and effective to best protect the public health."[110]

2. *Government Oversight of Listeria Controls*

FSIS initially proposed to require plants to include Listeria controls within their HACCP plans, based on its determination that Listeria contamination is "reasonably likely to occur" in the production of all ready-to-eat meat and poultry products. As a result, plants would be required to address Listeria contamination at the CCPs that plants had identified in their plans.

a. Industry Position

Industry commenters overwhelmingly opposed the proposal to treat Listeria controls as "CCPs" in a plant's HACCP plan.[111] Instead, they strongly favored handling Listeria contamination through their prerequisite programs or Sanitation SOPs. Some industry groups argued that characterizing Listeria controls as "CCPs" would actually be a "detriment to human health and food safety;"[112] others argued that since there was no technology that a plant could employ as a CCP to eliminate Listeria "with 100% certainty," it was more appropriate to include these controls in prerequisite programs.[113]

The industry's clear preference for this approach to Listeria contamination is most likely based on the fact that treating Listeria controls as SOPs or as part of a plant's prerequisite program results in less government oversight and enforcement than what would occur if they were included as part of a HACCP plan.

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[110] See *supra* note 84.
[111] *See* NMA Comment at 3.
[112] *Id.*
[113] *See* NTF Comments at 8; *See also* ConAgra Comments at 6; Kraft Comments at 6.

b. Consumer-Group Position

SFC members supported FSIS's original proposal to have plants include Listeria controls within their HACCP plans because this approach would give USDA the greatest ability to assure that plants were meeting their obligation to control Listeria contamination.

c. FSIS Decision

In the interim final rule, FSIS once again reversed itself. The agency determined that plants were not required to incorporate CCPs for Listeria into their HACCP plans, but rather, could address Listeria controls in their prerequisite programs.[114] As noted above, this approach limits FSIS authority over plant's Listeria-control measures, demoting those measures to little more than guidelines for sanitation.

D. Safety/Information Labeling for Ready-to-Eat Products

One issue of particular importance to consumer and public -health groups is safety labeling on ready-to-eat meat and poultry products. In a January 2000 petition to FSIS, CSPI and members of the Safe Food Coalition requested that the agency require safety labeling for all ready-to-eat meat and poultry products that had not been produced at a plant that had incorporated microbial testing into its HACCP verification program. CSPI argued that the labels would alert consumers to the fact that the product may be contaminated and should not be eaten by at-risk consumers without first reheating it.[115]

Consumer advocates point to the fact that the labels of ready-to-eat products are particularly problematic because they say, "cooked, "ready-to-eat" and "USDA inspected," messages that all indicate that it is safe to eat the products directly from the package. In addition, most ready-to-eat products have "best if used by" dates, again suggesting that the product is safe if consumed before that date. For so many consumers, however, these products are not safe to be eaten without further reheating, something that people rarely, if ever, do.

Advocates recommended that USDA require the labels of ready-to-eat product packages to include the same language used by both FDA and USDA in their consumer education materials. "If you are pregnant or immune suppressed, thoroughly reheat this product before using." Putting this message on the label would make the information immediately available at the time of purchase and consumption, reminding susceptible individuals that the product is not "ready-to-eat."

CSPI envisioned such a labeling requirement as "an interim measure," pending adoption of a final rule requiring microbial testing in all processing plants.[116] The group

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[114] 68 Fed. Reg. at 34218.
[115] *See* Center for Science in the Public Interest et al., Petition for Regulatory Action to Require Microbial Testing By Industry for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Products (Jan. 13, 2000) at 3, available at http://www.cspinet.org/foodsafety/listeria.html.
[116] *Id.* at 14.

indicated that it was amenable to FSIS granting an exemption from any labeling requirement to any plants that voluntarily conducted microbial testing that "proved effective at substantially lowering contamination rates."[117]

In its proposed rule on Listeria, FSIS mentioned CSPI's request for what the agency described as "warning" labels and indicated that it would "respond…fully in any final action stemming from this proposed rule."[118] In the proposed rule, the only proposed labeling requirement discussed was the use of the statement "Refrigerate After Opening," where applicable.[119]

In addition, FSIS indicated that it had considered, but decided against, proposing that certain ready-to-eat products include a "use-by" date in their labeling. In its proposal, the agency acknowledged that such labeling "may provide further reductions in the risk of listeriosis if the labeling increases the likelihood that high-risk ready-to-eat products would be consumed before very low levels of Listeria undetectable at the establishment, could grow to dangerous levels."[120]

But the agency declined to propose "use-by" labeling, determining "further information regarding the potential effects of use-by date labeling is needed," including information on consumer understanding of the use-by date labeling.[121] FSIS delayed any further deliberation on this issue by referring it to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) for its consideration, but not before noting that the agency will consider modifying its consumer message to vulnerable populations about avoiding ready-to-eat products or fully recooking them first.[122]

Most industry and trade association comments were silent on the labeling issue. A few groups, however, did address it. NFPA signaled its agreement with FSIS' determination that further information on use-by date labeling was necessary before any action should be taken. NFPA then spoke directly to FSIS's regulatory approach to Listeria for ready-to-eat products and concluded that use-by dates could be useful in a regulatory policy that allowed products on the market that contained low levels of Listeria during their shelf life. This type of policy, NFPA said, "would benefit public health."[123]

Cargill tied its comments on the labeling issue to the suggested revisions it offered on the proposed rule and determined that if those modifications were made, "a warning label will not be necessary."[124] This conclusion was based on Cargill's assumption that its suggestions for process controls would render ready-to-eat foods "essentially Listeria-

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[117] *Id.*
[118] 66 Fed. Reg. at 12604.
[119] *Id.* at 12605.
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] NFPA comments at 12.
[124] Cargill comments at 5.

free."[125] Further, it saw shelf-life dates as useful "only for those ready-to-eat foods whose safety is assured by a short shelf life (less than 10 days)."[126]

Kraft stated flatly that establishing "use by" dates would "not enhance food safety" and agreed that FSIS should postpone consideration of "use by" date labeling until NACMCF had reviewed the issue. Kraft also opined that "open date labeling is provided to help consumers judge quality but date labeling never was intended to control product safety."[127] Kraft further determined that "the development of a science-based, meaningful food safety expiration date is not feasible."[128]

In its interim final rule, FSIS noted that the NACMCF was still in the process of considering "safety-based, use-by dates" and that the agency would consider those findings before undertaking further rulemaking on the issue.[129] Regarding other possible Listeria-related labeling, the interim proposed rule contained no discussion of FSIS's original proposal for refrigeration labeling. Instead, the agency announced a voluntary provision for what it called "incentive labeling", labeling on ready-to-eat products that would indicate that the products were processed in a manner to eliminate, reduce or limit the growth of Listeria, provided that the claim is validated.[130]

The agency further clarified that such a label statement should identify the presence of ingredients and their purposes, but not make claims that the particular product was "safer than" untreated products.[131] FSIS emphasized that this was not a mandatory requirement, but was "intended to encourage the industry to implement effective Listeria controls and to provide useful information to consumers, especially vulnerable subpopulations."[132]

Some consumer groups believe that use of such claims would further compound the misleading nature of these labels. They argue that allowing companies to provide information about technologies, without also including safe-handling instructions, may create further potential to mislead consumers -- particularly susceptible sub-populations -- into a false sense of safety and lead to improper handling.

Six years after the Bil-Mar outbreak, consumers have no additional label information that might alert a vulnerable individual or group to the risk of Listeria food poisoning.

E. OIG Audit Reports and FSIS Response

The major, multi-state outbreak of Listeria food-poisoning in 2002, linked to ready-to-eat poultry products from Pilgrim's Pride's Wampler facility and the Jack Lambersky plant, prompted the biggest recall of meat or poultry products in history. Serious questions

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[125] Id. at 5.
[126] Id. at 6.
[127] Kraft comments at 13.
[128] *Id.* at 14.
[129] 68 Fed. Reg. at 34217.
[130] *Id.* at 34228.
[131] *Id.* at 34220.
[132] *Id.* at 34228.

exist as to whether everything was done to prevent the outbreak, and whether all of the necessary steps were followed in carrying out the recall.[133]

Other divisions within USDA have raised many of these questions. In June 2004, the Department's Office of the Inspector General (OIG) released a report of its audit of the Lambersky recall, which addressed both the effectiveness of the inspection services at the Lambersky plant, as well as FSIS's oversight of the recall.[134]

Regarding the performance of the federal inspection staff at Lambersky, the OIG found that, prior to the recall, FSIS inspection personnel had failed to identify material instances of noncompliance at the Lambersky plant. It concluded that this failure occurred because federal inspection personnel did not follow governing regulations and the personnel were not adequately supervised. Furthermore, the OIG concluded that both plant employees and federal inspectors failed to identify the Lambersky plant as one that should have instituted a Listeria testing program. The OIG determined that, even after the product recall had begun, FSIS's inspection services at this plant did not improve.

Regarding FSIS's oversight of the Lambersky recall, the audit found serious deficiencies in FSIS's performance. The OIG also determined that the agency could not have accurately assessed the effectiveness of the recall because it failed to adequately review critical information. The OIG noted that FSIS did make several revisions to its directive on recall verification procedures[135] that reflected some of the recommendations made by the OIG. The directive, however, did not address many others. In particular, OIG faulted FSIS for failing to address, in the revised directive, the OIG's recommendations on how to improve accountability over recalled product distributed to schools and institutions that serve vulnerable populations.

A second OIG Audit report, also released in June 2004, addressed only FSIS's oversight of the Pilgrim's Pride recall.[136] FSIS claimed in July 2003 that the Pilgrim's Pride recall was "successful," but the OIG disagreed, finding an "overwhelming number of significant discrepancies" on the agency's effectiveness check forms related to this recall that call into question the claim of success.[137]

In the Pilgrim's Pride report, the OIG found that some FSIS compliance officers failed to obtain pertinent data regarding the recall, while others did not fully analyze and act on the information they collected. The discrepancies the OIG uncovered in the recall

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[133] These questions are not limited to Listeria-related recalls, but apply to recalls involving other pathogens as well. *See, e.g.,* USDA Office of Inspector General, Great Plains Region Audit Report: *Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)* Report No. 24601-2-KC (September 2003) available at http://www.usda.gov/oig/webdocs/24601-2-KC%20conagra%20091603.pdf.

[134] USDA Office of Inspector General, Northeast Region, Audit Report: *Food Safety and Inspection Service Oversight of the Listeria Outbreak in the Northeastern United States*, Report No. 24601-02-Hy (June 2004), available at http://www.usda.gov/oig/webdocs/24601-02-HY.pdf.

[135] *See* FSIS, FSIS Directive 8080.1, Rev. 4, *Recall of Meat and Poultry Products* (May 24, 2004) available at http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf.

[136] As noted *supra* note 9 and accompanying text, the OIG did not examine the performance of FSIS inspection staff at the Pilgrim's Pride plant because this issue is the subject of a criminal investigation. As of October 2004, this investigation has yet to be concluded.

[137] *Id.* at i.

effectiveness check forms included: failure to reconcile the amount of product purchased with the amount recorded on Pilgrim's Pride distribution list; a lack of evidence of follow-up to ensure that customers had located and controlled recalled product; failure to perform compliance checks in a timely manner; and failure to develop a selection methodology for selecting customers for the effectiveness checks. Finally, OIG criticized FSIS for relying on undocumented information.

To further strengthen the existing recall process, OIG recommended that FSIS document the factors that should be considered in evaluating a recall, as well as the methodology used to determine its effectiveness. It also noted the need for FSIS to ensure that it conducts effectiveness checks in a timely manner and that the checks include the appropriate customers.

Rather than working with the government to improve the existing recall process, the meat and poultry industry and their trade associations have focused their energies on defeating any attempts to provide FSIS with the authority to mandate a recall. Echoing this view, USDA has indicated time and again that it does not need mandatory recall authority.[138]

VIII. Conclusion

This report has traced the course of USDA's policy regarding Listeria contamination in ready-to-eat meat and poultry products. While consumer and public-health advocates were sometimes critical of the deliberate pace of the Clinton Administration's initial response to Listeria, that administration's proposals were aimed at holding companies responsible for producing safe products and at requiring them to demonstrate that their products met applicable standards. By contrast, in its first four years in office, the Bush Administration has shifted focus from protecting public health to preserving industry's autonomy.

USDA released a proposed regulation on Listeria in February 2001 that promised real progress toward significantly reducing contamination in ready-to-eat meat and poultry products. Since that time, however, the Department has:

- Disregarded a joint risk assessment undertaken with FDA and embraced its own assessment based on limited assumptions, limited products, and limited data (supplied by industry).

- Responded inadequately to a major Listeria outbreak in 2002, which prompted the largest ever recall of potentially tainted meat and poultry products, some of which were served in the school lunch program. Even USDA's own watchdog strongly criticized FSIS for its faulty monitoring of the HACCP plans at the implicated plants and its inadequate oversight of the product recalls.

[138] *See. e.g., Modern Meat* (PBS television broadcast, Apr. 21, 2002)(Interview with Under Secretary Murano).

- Delayed completion of a final Listeria rule until two and one-half years after it had published the proposed rule and five years after the major Bil-Mar Listeria outbreak was linked to ready-to-eat meat and poultry products. On every single issue of importance to the regulated industry, the Department reversed its position from what it had initially proposed.

- Effectively rejected labeling that would alert susceptible individuals and their caregivers that deli meats marked "cooked, ready-to-eat" may be contaminated with the pathogen.

While the regulatory process grinds slowly and secretly, USDA is quick to tout any information that might demonstrate the success of their approach to Listeria. However, there is often a disconnect between the rhetoric and the facts. For example, in a speech before the NFPA in May 2004, Under Secretary Murano bragged that the Department's Listeria rule was responsible for a 25-percent drop, in 2003, in the percentage of regulatory samples tested by the agency and found to be positive for Listeria contamination.[139]

In that speech, Murano claimed that there was a direct relationship between the drop in the number of positive samples found in the agency's regulatory sampling program and the nationwide prevalence of Listeria in meat and poultry products. She failed to disclose, however, the fact that FSIS has stated that it is inappropriate to correlate the results of a regulatory sampling program and data on nationwide disease prevalence.[140]

More significantly, the under secretary couched her NFPA remarks to suggest that the Listeria rule was related to reductions in foodborne illness that had been announced a few weeks earlier by the CDC. While bragging about the success of the Listeria rule and reductions in *E. coli* O157:H7 infections in 2003, Murano failed to note that the CDC data showed that the incidence of Listeria food poisoning had *reversed* in 2003, from a four-year decline -- down to .27 cases per 100,000 people in 2002 -- back up to a rate of .33 cases per 100,000.[141] This change represents a 22% *increase* in the incidence of this deadly illness in a single year, the first year in which the Bush Administration directive and rule were in effect.

In spite of the CDC data showing an increase in Listeria food-poisoning cases, FSIS released a report on December 1, 2004, which touted the success of its interim final rule on Listeria. The agency claims that the overall safety of ready-to-eat meat and poultry products has improved since the rule went into effect because establishments have "strengthened their control procedures, increased testing, and taken additional steps to eliminate the pathogen."[142] The 64-page report, compiled by a 28-person team of FSIS staff, is long on rhetoric and short on specifics: it fails to provide details on the number of plants following each of the three alternative Listeria-control approaches set out in the interim final rule; it

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[139] Under Secretary Elsa Murano, Address at the National Food Processors Association Annual Conference (May 20, 2004).

[140] *See, e.g.,* FSIS, Electronic Reading Room: Microbiological Testing Program, *Microbiological Testing Program for Ready-to-Eat (RTE) Meat and Poultry Products*, available at http:/www.fsis.usda.gov/ophs/rtetest/.

[141] Vugia et al., *supra* note 3.

[142] FSIS, News Release, *Report Finds Listeria Rule Sparks Major Industry Changes* (Dec. 1, 2004) available at http://www.fsis.usda.gov/News_&_Events/NR_120104_01/index.asp

includes no summary of test results, and contains no discussion of the types of additional steps taken by plants to control Listeria contamination.[143]

The meat and poultry industry seems pleased with the way that USDA policy has shifted over the past four years, and would like to continue on this course. As noted above, by the end of August 2004, agribusiness companies had doubled the contributions made to Bush in 2000, from $2.3 million to $4.6 million.[144] For the first time in history, the NCBA this year formally endorsed a presidential candidate (President Bush).[145] Two months before the 2004 Presidential election, the National Pork Producers' Council presented George W. Bush with their "Friend of the U.S. Pork Producer" award, because his "tireless work protecting the nation's livestock herd has made him a true friend to the industry."[146]

In September, the chief executives of eight industry trade associations, appearing at a conference, pledged their support for the President's re-election. Perhaps, most telling, was the comment made by J. Patrick Boyle, president of the American Meat Institute, when sharing his views on the need to control the regulatory process: "Do you think (a Kerry Administration) would brief industry on regulatory changes? No, they'd bring in the consumer advocates."[147]

Boyle and his colleagues feel well served by the Bush Administration's USDA. The public, however, has been less well served. It is unlikely that the goal of reducing the rate of Listeria food poisoning by half (down to .25 cases per 100,000) will be met by 2005.[148] In fact, the Bush Administration has clearly abandoned the accelerated schedule established by President Clinton and has reverted back to the old target date of 2010.[149] This report details some of the reasons for this change in policy. The report demonstrates that, in the arena of food-safety policymaking, when the regulated industry wins – by exerting its influence by making strategic campaign contributions and placing friends in high policy-making positions – public health loses.

While reading a report like this one, it is easy to get mired in the statistics and technical terminology of food-safety regulation and the speeches of self-serving industry and public officials who can find a way to spin a success story from the most dismal

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[143] The report does mention the higher, 2003 FoodNet incidence rate for Listeria food-poisoning but makes no meaningful comments about it; the report merely states that FoodNet "may provide a more precise measure for monitoring trends in listeriosis." FSIS, *Assessing the Effectiveness of the "Listeria monocytogenes" Interim Final Rule,* Summary Report at 8, available at http://www.fsis.usda.gov/Oppde/rdad/frpubs/97-013F /LM_Assessment_Report_2004.pdf.

[144] *See supra* notes 44-45 and accompanying text.

[145] *See Beltway Notebook*, Food Chemical News (Vol. 46, No. 28).

[146] National Pork Producers' Counsel, Press Release, *NPPC AWARDS PRESIDENT BUSH FRIEND OF THE U.S. PORK PRODUCER* (Aug. 27, 2004) available at http://www.nppc.org/ news/ releases/ 2004/ 040827_Friend_of_NPPC.html.

[147] Sally Schuff, *Inside Washington,* Feedstuffs, Sept. 27, 2004

[148] *See supra* note 36 and accompanying text.

[149] *See*, *e.g.*, FSIS Press Release, *supra* note 142 ("Under the *Listeria* rule, ready-to-eat meat and poultry products are safer and public health is being better protected," Agriculture Under Secretary for Food Safety Dr. Elsa Murano said. "If progress continues at the current rate, we should achieve the Healthy People 2010 goal of lowering the incidence of listeriosis to 0.25 cases per 100,000 people.")

performance. But it is critical to remember that the statistics of deaths and illnesses represent real people -- some of them very young -- who are the real losers here.

One of those was tiny Matthew Wysocki, born several weeks premature by emergency cesarean, due to Listeria food-poisoning. He laid in intensive care for six days, attached to every imaginable piece of neonatal lifesaving equipment. When the infection began attacking his brain, his parents decided to remove him from life support. His father held his tiny body, and Matthew opened his eyes and struggled to breathe on his own. Then he died."[150]

Why did Matthew, have to suffer this way? Because the meat and poultry industry and USDA too often forget their responsibility to the people they serve, and because his pregnant mother ate "ready-to-eat" cold cuts that were <u>not</u> ready or safe to eat.

[150] Kathryn Wallace, *A Plateful of Trouble*, Readers Digest, Aug. 2004, at 111.