

Clinton/Gore Administration Accomplishments

Background:

The Food Safety and Inspection Service (FSIS) has proposed and implemented a number of food safety initiatives since the Clinton/Gore administration took office in January 1993. Although the U.S. food supply is already among the safest in the world, this Administration has made further reductions in foodborne illness a national priority. The Administration has put in place improved safety standards for meat, poultry, and egg products and has frequently communicated these actions to the public through media addresses. Research, education, and surveillance efforts have also been greatly expanded.

Current Status:

- Here are some significant milestones in the Administration's food safety efforts.

May 2000 President Clinton, in a Saturday morning radio address, announced that USDA will propose this summer to require nutrition labels on ground or chopped meat and poultry products and for single ingredient, raw products on the package or at point-of-purchase.

May 2000 President Clinton, in a Saturday morning radio address, directed USDA and HHS to propose required systematic testing for *Listeria* at food processing plants to significantly reduce the risk of illness and death from *Listeria monocytogenes* in ready-to-eat foods.

January 2000 Final implementation of HACCP for meat and poultry establishments. All 7700-plus federal and state inspected plants now operate with pathogen reduction processes in place.

January 2000 Held a public meeting of the President's Council on Food Safety to discuss the draft strategic plan.

Dec. 1999 President Clinton, in a Saturday morning radio address, announced the Administration's Egg Safety Action Plan to reduce the number of *Salmonella* illnesses attributed to eggs and egg products.

Dec. 1999 Announced comprehensive plan by HHS and Treasury to prevent "port shopping" of unsafe imported foods. Customs and FDA will stamp rejected foods with a clear "U.S. Refused" label and step up a policy for destroying imported food that poses a serious threat to people's health.

- August 1999** Held public meeting of the President's Council on Food Safety to discuss the development of an action plan on egg safety to reduce the occurrence of *Salmonella enteritidis* in shell eggs and egg products.
- July 1999** Held public meeting on the President's Council on Food Safety Strategic Planning Task Force goals.
- July 1999** Announced grants to five land grant universities that will serve as models for very small meat and poultry plants due to implement the final phase of HACCP.
- July 1999** Proposed efforts to improve egg safety by requiring that shell eggs be stored at 45 degrees or below during transport, in warehouses, and at retail stores; and by requiring safe handling statements on egg cartons.
- July 1999** Released Interagency Working Group on Food Safety Research report, which compiles an inventory of food safety research on microbial contamination.
- July 1999** Directed the Departments of Health and Human Services and Treasury to explore additional actions they could take to protect U.S. consumers from unsafe imported foods, with reports due back to the President by late 1999.] ?
- July 1999** Directed the Strategic Planning Task Force of the President's Council on Food Safety to develop immediate recommendations concerning the regulation of eggs.
- June 1999** PulseNet expanded to include *Salmonella*, *Shigella*, and *Listeria*, as well as *E. coli* 0157:H7 bacteria fingerprinting.]
- May 1999** Published *Federal Register* notice advising meat and poultry plants to reassess their HACCP preventive control plans to ensure they are adequately addressing *Listeria monocytogenes* in ready-to-eat products, and provided guidance to industry recommending environmental and end-product testing for presence of *Listeria monocytogenes* in ready-to-eat products.
- May 1999** Implemented extensive educational efforts targeted to at-risk consumers about *Listeria monocytogenes* in ready-to-eat products.
- March 1999** FoodNet surveillance data announced by CDC that indicate important decreases in *Salmonella* and *Campylobacter* infections since 1996, including a 15 percent decrease in *Campylobacter* and a 44 percent drop in *Salmonella enteritidis* infections.

- Feb. 1999** Proposed rule on irradiation for raw meat and meat products.
- Feb. 1999** FSIS and FDA signed a Memorandum of Understanding (MOU) to facilitate the exchange of information at the field level about food establishments and operations that are subject to the jurisdiction of both agencies.
- Jan. 1999** Implemented new procedures to expedite the review of food additives that are intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against human pathogens that may be present in food.
- Jan. 1999** Implemented HACCP in almost 3,000 small meat and poultry plants. Preliminary results from the 300 largest meat and poultry plants that implemented HACCP in 1998, show significant reductions in the prevalence of pathogens on meat and poultry products.
- Jan. 1999** Announcement of new technique to detect DT104, a potentially deadly strain of *Salmonella* that resists many antibiotics.
- Nov. 1998** FoodNet expanded to include an eighth state, and now represents more than 10 percent of the U.S. population.
- Nov. 1998** Bessie Berry received an NPR "Plain Language" Award for rewriting a backgrounder on the preparation of turkey.
- Nov. 1998** Held National Conference on Food Safety Research with a goal of answering the question: "What should our food safety research be as we move forward?" Participants included Federal agency representatives as well as academics, and industry and consumer group representatives. Discussion focused on the research needs of regulatory and action agencies, and on the research needs for detection, prevention, and risk assessment.
- Aug. 1998** Finalized a regulation that requires eggs to be stored and transported at 45 degrees Fahrenheit or less. By law this regulation became effective in August 28, 1999.
- Aug. 1998** Created the President's Council on Food Safety, which is charged with developing a comprehensive strategic plan for Federal food safety activities and with ensuring that all Federal agencies involved in food safety work together to develop coordinated food safety budgets each year.
- July 1998** Announced new warning labels that would be required on packaged fresh fruit and vegetable juices not processed to kill harmful bacteria.

- July 1998** Vice President Gore appeared at 4th of July BBQ on the Mall as part of the Fight BAC campaign encouraging the use of thermometers when grilling.
- July 1998** Announced the Joint Institute of Food Safety Research, which will develop a strategic plan for conducting and coordinating all Federal food safety research activities, including with the private sector and academia.
- May 1998** Formed a national computer network of public health laboratories--called PulseNet--to help rapidly identify and stop episodes of foodborne illness. The new system enables epidemiologists to respond up to five times faster than before in identifying serious and widespread food contamination problems by performing DNA "fingerprinting" on foodborne pathogens.
- April 1998** Implemented a pilot HACCP program for the retail sector of the food industry, including restaurants, grocery stores, institutional food service and vending operations.
- Feb. 1998** Announced Administration's proposed food safety budget, which requested an approximate \$101 million increase for food safety initiatives.
- Jan. 1998** Implemented new, science-based HACCP system for 300 of the largest meat and poultry plants.
- Dec. 1997** Approved irradiation for red meat as a food additive.
- Oct. 1997** Established the Partnership for Food Safety Education, an ambitious Federal-private partnership to reduce the incidence of foodborne illness by educating Americans about safe food handling practices. The Partnership launched a multi-year, broad-based public education campaign Fight BAC! -- to teach Americans about safe food-handling practices. Federal partners include the U.S. Department of Agriculture, U.S. Department of Education, and U.S. Department of Health and Human Services.
- June 1997** First Lady Hillary Clinton was the keynote speaker at the Consumer Education Conference for food safety educators -- "Changing Strategies, Changing Behavior."
- May 1997** Reported to the President a comprehensive new plan to improve the safety of nation's food supply "Food Safety from Farm-to-Table"--

detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

- Jan. 1997** Unveiled National Food Safety Initiative, a five-point plan to strengthen and improve food safety. Working with consumers, producers, industry, states, universities, and the public, the Administration recommended actions to reduce foodborne illness.
- Jan. 1997** Announced new early warning system, the Foodborne Outbreak Response Coordinating Group (FORCG), a partnership of Federal and State agencies established to develop a comprehensive, coordinated national foodborne illness outbreak response system to increase coordination and communication among Federal, State, and local agencies; guide efficient use of resources and expertise during an outbreak; and prepare for new and emerging threats to the U.S. food supply.
- July 1996** President announced new HACCP regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent *E. coli* bacteria contamination in meat.
- Jan. 1996** Began collecting data through the Foodborne Diseases Active Surveillance Network (FoodNet), a collaborative effort among FSIS, FDA, and CDC along with state health departments and local investigators around the country to better track the incidence of foodborne illness and monitor the effectiveness of food safety programs in reducing foodborne illness.
- Oct. 1995** Declared *E. coli* O157:H7 an adulterant in raw ground beef.
- Spring 1994** Issued new rule requiring the application of safe handling instructions on labels on raw meat and poultry products.
- 1994** Embarked on strategic CDC program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, making significant progress toward this goal in each successive year.
- 1994** Reorganized USDA to establish the Office of the Under Secretary for Food Safety as a means of increasing the visibility of food safety within USDA and separating food safety functions from marketing functions carried out by other parts of USDA. Reorganization also created a new Office of Public Health and Science within FSIS to improve the scientific base needed to make good regulatory decisions that are based on public health.

1993

Vice President's National Performance Review issued report recommending that government and industry move toward a system of preventive controls for food safety.



**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

STATUS OF THE FOOD SAFETY AND INSPECTION SERVICE REINVENTION GOALS

Updated May 2000

The Food Safety and Inspection Service (FSIS) provides service to consumers by regulating the meat, poultry, and egg product industries to ensure that products in interstate commerce are safe, wholesome, and accurately labeled, including the inspection marks. The FSIS strategic goal is to enhance the public health by minimizing foodborne illness from meat, poultry, and egg products. The outcome of this goal is a 25% reduction in the number of foodborne illnesses associated with meat, poultry, and egg products by the end of year 2000. Salmonella, E. coli O157:H7, Campylobacter, and Listeria monocytogenes are significant food safety hazards associated with meat and poultry products. In 1996, FSIS estimated that the contamination of meat and poultry products with these bacteria results annually in as many as 4,000 deaths and 5,000,000 illnesses. The Centers for Disease Control and Prevention (CDC) estimates that foodborne illness from all foods may cause 76 million illnesses and 5,000 deaths in the United States every year.

1. Reduce pathogens on raw products.

- The Agency's Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems regulation for meat and poultry products requires plants to adopt this system of process controls to prevent chemical, physical, and biological food safety hazards. Specific regulatory requirements for plants for sanitation and microbiological testing are to be in place.
- By 2000, 100% of all federally inspected meat and poultry products will be produced under a HACCP system; by 1998, 80% of all federally inspected meat and poultry products will be produced under a HACCP system.
- Based on the best science available, prepare appropriate regulatory and non-regulatory options, including HACCP, for egg products.
- Develop a better understanding of E. coli O157:H7, Salmonella and other foodborne pathogens by developing baseline data and by collaborating on research and other regulatory and non-regulatory approaches.
- By 1998, more than 95% of plants slaughtering cattle, swine, chicken, and turkeys will be tested routinely for Salmonella incidence.

Status:

- FSIS reached a major milestone in its food safety strategy on January 25, 2000, with the third and final phase of HACCP implementation. On this date, 3,159 Federal and approximately 2,300 State-inspected very small plants--those with fewer than 10 employees or less than \$2.5 million in sales--were required to implement HACCP and meet performance standards for Salmonella. FSIS achieved its goal of having all domestic meat and poultry establishments operating under HACCP.
- CDC has performed active surveillance for a number of foodborne pathogens since 1996. Preliminary surveillance data for 1999 compared with data from 1996 through 1998 suggest the

following:

- The incidence of E. coli O157 declined 22%
- The incidence of Campylobacter declined 26%
- The incidence of Shigella declined on average by 44%
- The incidence of Salmonella enteritidis declined 48%
- The incidence of parasitic diseases caused by Cyclospora infections decreased 70%

CDC has stated that the declines (from 1996 through 1998) in Salmonellosis and Campylobacteriosis may reflect changes in meat and poultry processing plants in the U.S. mandated by the PR/HACCP rule of the USDA. The largest producers in the food industry implemented HACCP in January 1998. The decline from 1996 to 1998 in the incidence of Salmonellosis parallels the reported decline in the percentage of meat and poultry products testing positive for Salmonella at large, federally inspected processing plants. Reasons for the decline in Salmonella enteritidis isolates remain under investigation. This decline also might in part be explained by the decrease in the percentage of poultry products testing positive for Salmonella in large processing plants.

- As of January 2000, 100% of cattle, swine, and chicken are subject to testing for Salmonella incidence at the slaughter plant. Data from a year of testing in small plants show a decline in the prevalence of Salmonella from the pre-HACCP baseline studies. Of broiler carcasses, 20% tested positive for Salmonella before HACCP implementation, compared to 16.3% since implementation; a decline of 18.5% to date. In ground beef, 7.5% of the national baseline samples tested positive for Salmonella prior to HACCP implementation versus 4.3% since HACCP implementation; a 42.6% decline. Of cow and bull carcasses, 2.7% tested positive before HACCP implementation while 2.3% tested positive after HACCP implementation; a 15% decline.
- FSIS has prepared a white paper on E. coli:O157:H7 that was a major topic at the May 2000 meeting of the National Advisory Committee on Meat and Poultry Inspection. In the next few months, FSIS will publish notices in the Federal Register calling for all establishments that process beef to reassess their HACCP plans for control of E. coli O157:H7. The Agency will also announce that copies of the risk assessment for O157:H7 will be available.
- President Clinton, in his May 6th radio address, said that the Administration's goal is to cut the number of illnesses caused by Listeria in half by the year 2005. FSIS held a public meeting in May 2000 to discuss the issue. The Agency has also advised manufacturers of ready-to-eat meat and poultry products to reassess their HACCP plans to ensure that they adequately address this pathogen. In November 1999, FSIS released a refined laboratory methodology that reduces the analytical time required for detecting and identifying potentially contaminated products by at least two days. FSIS has made significant progress in implementing action items in a plan issued last year.
- In 1998, FSIS and the Food and Drug Administration (FDA) jointly developed a risk assessment model for shell eggs and egg products to address the risks of foodborne illness caused by Salmonella enteritidis.
- In December 1999, the President's Council on Food Safety released the Egg Safety Action Plan. It was based on the results of the joint risk assessment mentioned above. Under the Plan, FSIS will develop HACCP-based standards for shell egg packers and egg products processors, as well as be responsible for providing inspection and enforcement for both. FSIS is also developing a rule in conjunction with the Egg Safety Action Plan. This rule, expected to be published in late 2000, will establish HACCP-based systems for shell eggs as well as for processed egg products. The rule will include components such as basic facility sanitation, biosecurity, and Sanitation Standard Operating Procedures (SSOPs).

2. Establish effective working partnerships with other public health agencies and stakeholders to support the President's National Food Safety Initiative.

- Expand and improve interagency cooperative agreements on inspection and establish effective partnerships with States and other agencies.
- Collaborate with other food safety and public health agencies to identify and encourage research to address food safety risks.
- Collaborate with States, other Federal agencies, industry, and academia to expand existing information systems and data on foodborne illness and establish a national clearinghouse on food safety information and education.

Status:

- FSIS continues to actively participate in the Partnership for Food Safety Education, the President's Council for Food Safety, the National Partnership for Reinventing Government, and other intra- and inter-agency food safety task forces. FSIS and FDA worked together to establish the National Food Safety Information Network, part of the Food Safety Initiative, that maintains a database of educational materials. In addition, the Agency continues to produce educational materials for a wide audience.
- Under the Food Safety Initiative, FSIS contributes to the Foodborne Disease Active Surveillance Network (FoodNet) which currently contains nine sites. For 2000, FoodNet now encompasses approximately 29 million Americans, nearly 11% of the population. In addition to new data on the burden of foodborne illness in general, FoodNet found *Campylobacter* to be the leading cause of sporadic cases of foodborne illness from 1996 through 1998.
- FSIS also contributes to the PulseNet, a computerized database that matches the DNA fingerprint of foodborne diseases, and accelerates the traceback process to the source of the contamination. PulseNet is especially successful in identifying dispersed illnesses with potentially common sources of implicated product and in alerting the appropriate regulatory agencies so they can take action. Recently, Harvard University and the Ford Foundation selected the interagency PulseNet effort to receive the prestigious "Innovations in American Government Award."
- Under the Food Safety Initiative, U.S. Department of Agriculture (USDA), Health and Human Services (HHS), and the Environmental Protection Agency (EPA) created the Foodborne Outbreak Response Coordinating Group (FORCG) to bring together Federal, State and local agencies to develop a comprehensive, coordinated, national foodborne illness outbreak response system.
- During 1999, FSIS hosted the first-ever joint meeting of State Secretaries of Health and Agriculture with federal food safety officials on improving cooperation and working towards a seamless national food safety system.
- In February 1999, FSIS and FDA signed a Memorandum of Understanding to facilitate an exchange of information between the Agencies about establishments and operations that are subject to the jurisdiction of both Agencies. This exchange of information permits resources to be used more efficiently, and will improve public health protection.
- On December 23, 1999, FSIS published a final rule to streamline the approval process for food ingredients and additives by ending the requirement that they be approved separately by both FDA and FSIS. Previously, once FDA approved a food ingredient, FSIS had to conduct separate rulemaking in order for it to be approved for use in meat or poultry. The new rule became effective January 24, 2000.
- In November 1999, FSIS and the U.S. Public Health Service (PHS), Commissioned Corps, signed a Memorandum of Understanding assigning Commissioned Corps officers to FSIS to assist in reducing the incidence of foodborne illness.

3. Promote food safety from farm to table.

- Cooperate with States and producers to expand knowledge and use of public health-based on-farm

practices.

- Improve food safety during transportation and distribution.
- By 2000, communicate food safety information to 158 million people a year through partnerships between FSIS and industry, academics and educational institutions, scientists, and consumers.
- Promote the nationwide adoption of the Food Code.

Status:

- Through FSIS efforts, state veterinarians, and other officials responsible for the production of food animals are incorporating food safety responsibilities into their practices. Producers and veterinarians are becoming more aware of the impact of the HACCP rule. State partnerships to foster producer education continue to encourage small packer-producer information sharing, and efforts to strengthen relationships between and among public health and animal health officials are increasing. FSIS entered into several new state partnerships; producers from these states represent 32% of all producers. FSIS continues its leadership role by cooperatively organizing a national conference on the role of animal production in food safety. The conference is scheduled for September 6 and 7, 2000 in St. Louis, Missouri.
- FSIS continues to be actively involved in the Partnership for Food Safety Education. The "Fight BAC" campaign began in October 1997 as a unique partnership of industry, government, and consumer groups dedicated to reducing the incidence of foodborne illness. The partnership, which was originally kicked off by Vice President Gore, has grown from 10 founding members to 18 active organizations. Hundreds of grassroots organizations are now "BAC Fighters" helping to spread the consumer education messages designed to reduce foodborne illness. Tens of thousands of publications, curricula packages, and fact sheets from the Web-based Virtual Tool Box have been distributed throughout the U.S. and the Fight BAC! Web sites had 3 million hits in 1999. Additionally, Canada became the first international affiliate.
- On May 25, 2000, FSIS launched a new food safety education campaign to promote the use of food thermometers in the home. The campaign theme is: "It's Safe to Bite When The Temperature Is Right!" FSIS introduced its new messenger, Thermy™, after focus group testing confirmed consumer acceptance of the character and the message. The campaign was created as a result of USDA research that indicated that 1 out of 4 hamburgers turned brown before reaching a safe internal temperature--high enough to destroy harmful bacteria. Color can be misleading and a food thermometer is the only safe way to be sure meat, poultry, and egg dishes are safely cooked.
- USDA and FSIS support adoption of the Food Code by all jurisdictions because it promotes uniformity in the nation's laws on food safety. This uniformity in turn promotes commerce, fosters cooperation among jurisdictions on a problem that is inherently multi-jurisdictional, and enhances public health for all Americans. Senior USDA officials have shown support through numerous public remarks, direct communications to State governors and other officials, and agency support of various intergovernmental initiatives. The Secretary of Health and Human Services and the Secretary of Agriculture signed a joint letter to state governors promoting the Food Code. In good measure due to federal prompting, the Food Code has been adopted by increasing numbers of jurisdictions. As of December 1999, 27 State agencies in 19 states, and many federal, local, and tribal agencies have done so. Another 25 State agencies, and the Puerto Rican Department of Health, among others, are in some stage of the adoption process.
- To better inform consumers, FSIS recently adopted a policy to issue a press release for each recall. The policy went into effect February 2000, and serves to alert consumers of all recalls conducted. It also serves to remind consumers to always follow safe handling practices with meat, poultry, and egg products.

4. Complete the necessary cultural change to support HACCP and food safety.

- Train the workforce to carry out the redefined regulatory tasks and procedures generated by the HACCP rule.
- Clarify and emphasize industry's responsibility for food safety through regulatory reform.
- Promote new technologies to enhance food safety.
- Establish a Management Development Academy.
- Centralize the management of all policy, rulemaking, and program development activities to reform existing regulations and eliminate layering.

Status:

- FSIS completed training 100% of the meat and poultry inspectors responsible for HACCP implementation to ensure a smooth transition to HACCP. Inspection personnel were provided with resource materials and participated in work unit meetings. FSIS maintained a HACCP hotline at the FSIS Technical Services Center in Omaha for additional information as needed.
- FSIS implemented the Management Leadership Development Program (Management Academy) both in headquarters and in the field. The Agency plans to phase it in over the next few years.
- In 1997, FSIS and Texas A&M began collaborating on the Food Safety Education Program designed to educate FSIS employees in the scientific foundation for HACCP and related issues. By the end of fiscal year 2000, approximately 1,175 individuals will have graduated and received five college credits for their efforts.
- Management of all policy, rulemaking, and program development activities to reform existing regulations and to eliminate layering is now centralized under the Office of Policy, Program Development and Evaluation.
- FSIS is significantly reforming its regulations, and putting them into plain language that can be understood by plant personnel, FSIS employees, and the public. Traditionally, Agency regulations were very long, detailed, prescriptive, and not easily-understood. FSIS has been converting these command-and-control regulations to performance standards, to clarify responsibilities and allow flexibility for industry innovation. Examples of regulatory reform include: eliminating prior approval for certain types of product labels; eliminating prior approval requirements for equipment; converting highly prescriptive sanitation requirements to performance standards; harmonizing and streamlining FSIS and FDA procedures to review and approve use of food ingredients and sources of irradiation in meat and poultry products.
- On December 23, 1999, FSIS published a final rule, previously discussed in this document, to streamline the approval process for food ingredients and additives. On May 30, 2000, FSIS published a final rule removing requirements for partial quality control (PQC) programs in meat and poultry processing plants. This followed previous rulemakings that eliminated many PQC program requirements. This new rule is the latest in a series of regulatory reform initiatives published by the Agency to improve food safety. Simultaneously, FSIS is making regulations less burdensome, easier to use, and more consistent with HACCP systems.
- In FY1999, FSIS created new job descriptions defining the more science-based inspection role we will play under HACCP. Although we received OPM approval for Consumer Safety Officers (CSOs), Congress raised concerns about our plans to implement conversion to and hiring of CSOs. FSIS reported to Congress that we intend to minimize costs by advertising vacancies only in local commuting areas where there is an adequate number of qualified candidates. FSIS still hopes to hire 50 to 75 CSOs during FY 2000. In the future, we will need a mix of technical, professional, and administrative employees. However, within that mix FSIS must increase the proportion of scientific professionals in frontline occupations. The CSO, a scientific generalist, will be the journeyman FSIS employee of tomorrow.
- FSIS will soon issue the report entitled The Future of FSIS Veterinarians: Public Health Professionals For the 21st Century. To develop this report, in 1999, FSIS convened a select panel of veterinarians from inside and outside of FSIS, a variety of FSIS management personnel, and

individuals affiliated with academe, non-government organizations, and foreign governments. This task force met numerous times during 1999. In February 2000, FSIS held a public meeting and solicited comments on the draft report. Recommendations cover five major issues: Defining the role of the FSIS veterinarian; Education, training, recognition and recruitment; Development and refinement of partnerships; Information management centered around animal identification; and Veterinary contributions to international credibility. Upon receipt of the final report in the next few weeks, FSIS intends to implement most of the recommendations which will positively impact our approximately 1,200 veterinarians.

5. Promote international cooperation on food safety.

- Assure the safety of the domestic food supply through the application of appropriate domestic food safety standards to imported products.
- Participate in Codex Alimentarius to improve the Codex system and to develop and adopt international food safety standards that promote fair trade.

Status:

- All plants exporting meat and poultry products to the U.S. must now meet the new requirements of our HACCP system. To ensure the safety of imported meat and poultry products, FSIS developed and applied a process to assess the equivalency of eligible foreign inspection programs relative to the requirements of the HACCP rule. Although foreign food regulatory systems need not be identical to the U.S. system, they must employ equivalent sanitary measures that provide the same level of protection against food safety hazards as is achieved domestically.
- FSIS houses the U.S. Codex Office and maintains an active role in all Codex activities. These activities include restructuring the interagency policy steering committee to ensure focus on policy development and coordination; training of delegates; conducting foreign outreach efforts; hosting Codex sessions on food hygiene, processed fruits and vegetables, and residues of veterinary drugs in foods.
- During the 23rd session of the Codex Alimentarius Commission, FSIS Administrator, Thomas J. Billy, was elected to a two-year term as Chairperson of this United Nations Commission. His role as Chair helps to ensure that the processes used by Codex to develop food standards are based on sound science and have integrity. Under his leadership, the Codex priorities will include: 1) continuing support of science-based decision making; 2) obtaining support from WHO and FAO; 3) increasing and strengthening participation of developing countries; 4) ensuring greater participation of non-governmental organizations and addressing the need for transparency; and 5) improving efficiency and speed of the Codex process and consensus building.

For Further Information Contact:

FSIS Planning Staff
6904 East Franklin Court
Washington, DC
Tel: 202-501-7136
Fax: 202-501-7642

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**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Speeches

Office of the Under Secretary for Food Safety
U.S. Department of Agriculture

Food Safety: An International Perspective

Remarks prepared for delivery by Dr. Catherine Woteki, Under Secretary for Food Safety, before the Association of Food and Drug Officials, Burlington, Vermont, June 19, 2000.

Good afternoon. Last year when I presented the USDA keynote address at your meeting in San Antonio, I discussed the progress we had made in establishing a framework to make significant food safety improvements. This framework was first presented in 1997, as the President's Food Safety Initiative, and it now is being continued by the President's Council on Food Safety, which is in the final stages of developing a strategic plan for federal food safety activities. I'd like to recognize the important role that AFDO has played and continues to play in developing the strategic plan.

Last year, I also addressed the need to work toward the integration of federal, state, and local government activities and resources, and I'll talk more about that in a few moments. This is a major theme of the strategic plan that carries through all three of the plan's major goals.

At this year's conference, AFDO has chosen a global focus, and that certainly is relevant to our food safety activities and to the theme of working together to achieve food safety goals. Not only should we aspire to a unified food safety approach domestically, but internationally as well. There are many similarities between our domestic food safety goals and those that are implemented at the international level. Of utmost importance is that they be rule-based and utilize the best science available. Thus, as we improve our domestic program, we must ensure that science guides international food safety policies as well. This is particularly important as food safety is appearing frequently on the agendas of international leaders. And it has become central to negotiations with respect to trade over the last decade.

Let me provide you with some background on what is happening at the international level. Last year, President Clinton and the leaders of the G-8 countries during their annual Summit meeting held a discussion and issued a communiqué on food safety.

As you know, the heads of state or government of the major industrial democracies meet each year to deal with major economic and political issues facing their own countries and the international community as a whole. The communiqué issued by the G-8 leaders requested that the Organization for Economic Cooperation and Development --OECD-- prepare background papers for their discussion this summer that would focus on biotechnology and other aspects of food safety. To respond to this request, the Ad Hoc Group on Food Safety was established, and five papers have been prepared for this year's Economic Summit, which will be held in July in Okinawa, Japan.

The first paper is a report of the scientific forum held in Edinburgh, Scotland, in February to examine the safety of food produced through biotechnology. A second paper describes the roles of our national and international food safety organizations. Papers three and four review how environmental and food

safety determinations are performed for foods produced through biotechnology. And the fifth paper is a report of the consultations that OECD has conducted with non-governmental organizations on these topics.

At next month's G8 meeting, we can expect discussions to occur about the need to strengthen international efforts to address these food safety and environmental questions. The United States will emphasize that for food safety such a mechanism already exists through Codex, and that Codex has a proven track record in developing international food safety standards. You will have to stay tuned until July to hear the results.

EU Precautionary Principle

One international issue that will also occupy the G-8 leaders, has been the subject of recent meetings, and has generated much discussion in Codex and other international organizations is the EU's Precautionary Principle. The EU has been attempting to introduce its Precautionary Principle into various international forums and agreements for more than a decade. And in an effort to provide more cohesion among its member states and to enhance the credibility of the principle, the EU issued a paper in February entitled *Communication from the Commission on the Precautionary Principle*.

If you've missed the full-page newspaper ads and the heated rhetoric, let me try to describe the debate. The European Commission proposes that politicians should be able to invoke the Precautionary Principle when making risk management decisions in which there is poor, limited, or contradictory scientific evidence as to safety. The risk management decisions could be in any area of the environment or public health. The European Commission communiqué also goes on to say that the precautionary principle cannot be defined, but that it can be inferred from international law and court decisions.

The U.S. has argued in these international discussions that precaution is built into the decision making activities of Codex and that precaution is also inherent in our own food safety laws and regulations. Therefore, there is no need for an ill-defined Precautionary Principle.

However, there are some sections of the EU's communication with which we agree. For example, we agree with the EU that decision-making procedures should be transparent and should involve all interested parties. In addition, we agree that precaution can be an integral component of risk management and that decisions usually need to be made in the face of uncertainty and in the absence of complete knowledge. And we welcome the commission's insistence that the precautionary principle can, under no circumstances, be used to justify the adoption of arbitrary decisions regarding trade.

But on the other hand, we have some concerns that the EU's Precautionary Principle is vaguely defined. At the same time there are numerous sections in the EU's communication about which we have questions and concerns. We are continuing this discussion of the use of precaution in food safety decisions in the Codex Committee on General Principles, which we believe is the appropriate venue.

Working with interested federal agencies, the U.S. Codex office is now preparing comments on the principles of risk analysis, which will be submitted to the Codex by July 1. The United States will hold a public meeting on Thursday this week to discuss the issue with interested parties. I urge AFDO to keep involved in Codex, because these international decisions may affect our domestic policies.

Domestic Issues With International Implications

It is important to recognize the converse - that U.S. domestic issues potentially have international

implications. Permitting the interstate shipment of state-inspected product is a good example. USDA's legislative proposal has been introduced by Senators Daschle and Hatch and is currently pending before the Senate Agriculture Committee. We do not anticipate that the bill as written will interfere with international trade, but because state-inspected products would be eligible for export, the issue has international implications. AFDO has been active in discussions of this bill and the Senate may move it this session, so, I encourage you to contact your Senators to express your views on the bill.

Another example of a domestic issue with international implications is the USDA's Pathogen Reduction and HACCP rule for meat and poultry products. As you know, the rule has been implemented in all plants, and FSIS has completed its equivalency determinations to ensure that countries eligible to export to the United States have equivalent systems in place. In his talk tomorrow on the "Globalization of HACCP," Dr. John Prucha will provide you with an update on FSIS work in this area. USDA is a leader in applying the concept of equivalence, and FSIS continues to audit and inspect to remain confident that exporting countries have implemented equivalence systems.

Federal-State-Local Cooperation

As we pursue our food safety initiatives in both the domestic and international sectors, it is a major priority of USDA to work more closely with our state and local counterparts. I believe there are many good examples of our commitment to strong partnerships.

Interstate shipment is one prime example. Our legislative proposal is designed to encourage the creation and continuation of state programs. We believe the state programs have many strengths--one of these being regulating smaller plants.

The implementation of HACCP is another example of how committed USDA is to working closely with the states. Throughout the implementation of HACCP, FSIS worked very closely with state HACCP contacts and coordinators to ensure that the small and very small plants had the resources available to them to successfully implement HACCP.

Our project to ensure the continued safety of the meat, poultry and egg products while in distribution channels is another project where we are working very closely with the states. FSIS recently held a public meeting on food safety during in-distribution, and I am pleased that AFDO was represented at the meeting. This project illustrates the type of cooperative working relationship to improve food safety that we believe is possible among the various levels of government. In fact, FSIS is now working with Minnesota to develop a model appropriate for that particular state, and we look forward to working with other states as well.

USDA is very aware of concerns that this project will lead to an overlap of activities at the retail level. I want to assure you that we want to avoid this as well. We certainly don't want a retail store to be visited by a series of retail inspectors--that does not serve anyone's interests.

We recognize that States have the primary jurisdiction for food safety at the retail level. However, FSIS has a role in ensuring that the integrity of the mark of inspection is maintained on Federal products, and the Agency has the authority to set performance standards for the handling of federally inspected products in retail. Our focus is not on facilities, but on the product, and we are interested in exploring with the states how we can both meet our food safety responsibilities without overlap. This project is an enhancement of what states are currently doing.

I also want to emphasize that this project is exploratory in nature. At the public meeting, we emphasized

that we have no one model to present. Our ultimate strategy for in-distribution will be based on what we learn. Information collection will be a big part of the project. We believe that models may look different in different states, depending on the extent of the program already in place. Minnesota has given us a clear message that if a State is carrying out an effective program at the retail level, it should take the lead. We intend to evaluate that as part of the project. It is possible that some states may not need Federal inspectors in-distribution.

We welcome your comments as we proceed with this project. In fact, we expect there to be issues raised that will require your involvement. For example, a hypothetical situation was raised by a consumer group representative regarding a supermarket that receives a chub of irradiated ground beef and then mixes it with non-irradiated trimmings, and how that would affect labeling requirements. We hope AFDO will help in ensuring that situations such as these are appropriately handled.

Closing

In closing, the need to address food safety issues simultaneously at the state and local, Federal, and international levels will require us to continue to improve our working relationships. With initiatives such as interstate shipment, HACCP, and in-distribution food safety, I believe USDA has illustrated its commitment to strengthening state programs and providing assistance to the states as much as possible.

For the future, we must further our goal of a unified approach to food safety domestically, and to use that unified front to ensure that science guides international food safety policies as well. This is indeed a challenge, and one I look forward to working with AFDO to achieve.

For Further Information:

FSIS Congressional and Public Affairs Staff

Phone: (202) 720-3897

Fax: (202) 720-5704

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**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Speeches

Office of the Under Secretary for Food Safety
U.S. Department of Agriculture

Antimicrobial Resistance—The USDA Perspective

Remarks prepared for delivery by Dr. Catherine Woteki, Under Secretary for Food Safety, before the conference on Antimicrobial Resistance sponsored by the Royal Society of Medicine Foundation, the Royal Society of Medicine, and the Tufts University School of Medicine, May 4, 2000, Washington, DC.

It's a pleasure to be here today to talk about antimicrobial resistance from the perspective of the U.S. Department of Agriculture (USDA). With the tremendous growth in international trade of agricultural commodities we have seen in recent decades, food safety issues must be addressed on a global level. Antibiotic resistance is no exception, so I am pleased to see this issue being addressed in an international forum. Antimicrobial resistance is a growing public health threat that has been identified as a major priority in the United States by a number of expert groups, including the Institute of Medicine, the American Society for Microbiology, and the Congressional Office of Technology Assessment. It also is a concern for our agricultural producers who are striving to produce safe, high-quality products.

A Complex Problem

Antibiotic resistance is a complex problem—one that requires attention by many diverse interests, including agriculture experts, public health experts, and regulatory agencies. The list of speakers at this conference certainly reflects the diversity of involvement needed to contain the problem of antimicrobial resistance. Here in the United States, the Department of Health and Human Services is leading the development of a coordinated public health action plan to address antimicrobial resistance, and I expect the action plan to be released shortly. USDA has participated in this effort through the Antimicrobial Resistance Working Group, which has membership from six USDA agencies.

The complexity of the antimicrobial resistance issue stems from the fact that two previously parallel stories are now converging. First is the story of how the inappropriate use of antibiotics in human medicine has contributed to the growing human health problem of antimicrobial resistance. The second story is the use of antibiotics in animal agriculture, and the growing recognition that this practice contributes to antimicrobial resistance in both animal and human pathogens.

We have long recognized that the health of food-producing animals is intrinsically linked to human health. But in the past, agriculturists resisted the idea that the use of antibiotics in animals could relate to resistant pathogens in humans. It's time to move beyond that, because there are now cases that provide evidence of such a link. For example, a May 1999 article in the *New England Journal of Medicine* showed a genetic association between resistant *Campylobacter* strains from chicken products produced and consumed in Minnesota and resistant *Campylobacter* strains causing infections in Minnesota residents.

In addition, a report published by the Institute of Medicine in July 1998 acknowledged that there is a link between the use of antibiotics in food animals and the development of bacterial resistance to these

drugs.

I want to acknowledge from the outset the multifactorial nature of drug resistant human infections. As Under Secretary for Food Safety for USDA, I am here to focus on those infections that may be acquired through the food supply. It is well known, however, that resistant human infections are acquired in other ways, such as through the use or abuse of antimicrobials in human medicine.

It is not possible to quantify the contribution of antibiotic use in the agricultural setting to the broader problem of drug resistance in humans, nor do I believe that this exercise would be particularly helpful. I believe it is more helpful to acknowledge that antibiotic use in animals contributes to the problem and that prudent antibiotic use should be encouraged in all sectors. The agricultural community must accept part of the responsibility.

Both of these pathways to antimicrobial resistance—human and animal—must be *managed*. The emphasis is on the word *managed*, because, a totally risk-free system of food production is an unreasonable and unattainable goal. At least so far, microbes always develop resistance to antimicrobials used against them. But we can intelligently manage the use of antimicrobials so we can prolong their usefulness for both humans and animals.

Risk Assessment

The need to take action now to address the problem of antimicrobial resistance in our animal populations does not mean we have all of the answers to our questions. Many data gaps remain. For example, we do not know what degree of resistance is transferred for various organisms. In many cases, we do not even know exactly how resistance is transferred. We also do not know which practices related to antibiotic use present the greatest risks.

But having to make food safety decisions and take action based on incomplete data is nothing new to risk managers. We must make the best possible public health decisions based on the information available today, and build our knowledge base so that we can make more informed decisions in the future.

Sound science is the key in making these decisions. In January 1999, the Food and Drug Administration published a discussion paper—commonly referred to as the "Framework document," that presents a risk-based process for evaluating the microbial safety of antimicrobial drugs used in food producing animals. FDA Commissioner Dr. Jane Henney will be here tomorrow to provide more detail on this document and the risk assessment models FDA is developing to account for the transfer of resistance from bacteria in food producing animals to bacteria in humans via food. The United States firmly believes that such a scientifically sound, risk-based approach is key to the decisionmaking process for the use of antimicrobials in food producing animals—both here and abroad.

USDA's Current Role in Managing Antimicrobial Resistance

Because I am here to address the agricultural sector, let me provide a very brief overview of the role of veterinary drugs in food animal production and then discuss what USDA is currently doing to address the problem of antimicrobial resistance.

Veterinary drugs are a critical component of food animal production and contribute to the exceptionally high level of health we find in food animals today. They also provide other benefits related to animal welfare and economic return for the industry. Since the benefits of antibiotics in enhancing growth and

feed efficiency in animals were observed almost half a century ago, the number and use of these products has increased.

U.S. controls regarding the use of veterinary drugs emphasize sound science and risk assessment. And in addition to activities that generally address the proper use of these drugs, Federal agencies also have in place programs to learn more about, track, and reduce antimicrobial resistance in animals. Many of these activities are joint activities among several Federal agencies and are supported by the agricultural industries.

First is surveillance. In 1996, HHS and USDA established the National Antimicrobial Resistance Monitoring System for Enteric Bacteria—NARMS-EB. The goal of the system is to obtain a spectrum of, and monitor trends in, antimicrobial resistance in foodborne pathogens. NARMS collects and analyzes *Salmonella*, *Campylobacter*, *E. coli* and *enterococcus* isolates from animals and humans. USDA supports the project through three of its agencies. The Food Safety and Inspection Service (FSIS) contributes isolates from its regulatory program for *Salmonella* and isolates of *Campylobacter* from its microbiological baseline data collection surveys. The Animal and Plant Health Inspection Service (APHIS) contributes isolates from clinically ill animals and isolates from healthy animals on farms. And the Agricultural Research Service (ARS) conducts all testing and analysis of data.

APHIS also carries out farm surveys through the National Animal Health Monitoring System (NAHMS), which provide information on the spectrum of antimicrobial resistance and the relative contribution of various management practices to the development of resistance.

In addition to surveillance, USDA carries out research on antimicrobial resistance. Research has a vital role in delaying and controlling the emergence of resistance in pathogens associated with food products because our progress is hampered by data gaps. We need basic as well as applied research on antimicrobial resistance. More research is needed to assess which agricultural practices can reduce antimicrobial use, to identify what types of antimicrobial use present a high risk of resistance, and to better understand how resistance is transferred by means other than food.

For example, the Institute of Medicine, in its 1998 report, indicated that farm workers could be at greater risk for clinical antimicrobial resistance, so environmental factors may also play a role in this transfer. A recent article in the April 27th *New England Journal of Medicine* provides further evidence of an environmental link. The authors concluded that a boy's infection by *Salmonella enterica* serotype typhimurium resistant to ceftriaxone—a widely used pediatric antibiotic—came from cattle on his farm.

USDA's Agricultural Research Service recently established an Antimicrobial Resistance research unit in Athens, GA. Researchers there are determining how both pathogens and nonpathogens acquire and transfer antibiotic resistance and whether the presence of resistance alters virulence in pathogens. A major accomplishment has been the development of a rapid gene probe for *Salmonella typhimurium* DT-104—a multi-drug resistant pathogen that is difficult and time-consuming to identify.

In addition, USDA's Cooperative State Research, Education and Extension Service (CSREES) last year awarded three grants through a new program within the National Research Initiative that specifically address antimicrobial resistance. These studies seek to understand the processes involved in the rapid spread of multiple drug resistance in poultry and to identify management practices that may help to address the problem of antimicrobial resistance in cattle.

Prevention and control is a third area of emphasis within USDA. This is closely related to the research area, because as scientists determine what on-farm interventions can help to reduce antimicrobial

resistance in animals, these management practices can be encouraged. For example, the use of vaccines to eliminate pathogenic bacteria from the food chain is a relatively unexplored area. And competitive exclusion cultures are providing alternatives to antimicrobial use in animals.

There are some management practices that producers can take now to prevent and control resistance. They include improved nutrition for farm animals, biosecurity measures to minimize the introduction of infections on the farm, and, of course, the prudent use of antimicrobials. All of these steps are supported by USDA.

These activities—surveillance, research, and prevention and control—are part of a multi-hurdle approach within USDA. Each by itself will not solve the problem, but together, they provide cumulative protection against antimicrobial resistance. Through the action plan now being developed by Federal agencies, these public health protections will become even stronger.

Another way USDA is helping to reduce antimicrobial resistance is through its successful strategy to reduce pathogen loads on meat and poultry products. Through mandatory HACCP and *Salmonella* performance standards for meat and poultry products, USDA has seen significant reductions in *Salmonella* levels in most types of products. Reduced levels of *Salmonella* are not a solution to the problem or a substitute for other efforts, but any action USDA takes to reduce pathogen loads on meat and poultry will help to reduce the transfer of resistant pathogens to humans.

Future Directions--Public Health Action Plan

For the future, as I mentioned, the U.S. agencies with a role in managing the problem of antimicrobial resistance, including USDA, are developing a public health action plan through an interagency Task Force on Antimicrobial Resistance that was created in 1999. The task force is co-chaired by the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health. It also includes the Agency for Health Care Research and Quality, the Department of Defense, the Department of Veterans Affairs, the Environmental Protection Agency, the Health Care Financing Administration, and the Health Resources and Services Administration. This extensive list reflects the fact that antimicrobial resistance is a multifaceted problem, and combating it successfully will require creative solutions on many fronts.

The plan reflects a broad-based consensus of Federal agencies on actions needed to address antimicrobial resistance. It is being developed through a public process, and a public meeting was held last July in Atlanta. The purpose of the meeting was to solicit ideas from a variety of constituents about possible ways that Federal agencies might address antimicrobial issues. We have received input from state and local government agencies, universities, professional societies, pharmaceutical companies, health care delivery organizations, agricultural producers, consumer groups, and other members of the public. Ideas discussed at the July public meeting have been incorporated into the action plan. When it is ready, the action plan will be made available to the public through the *Federal Register*, with opportunity for additional public input.

I can't provide details at this time, but I can tell you that the plan will have four areas of focus—surveillance, prevention and control, research, and product development. Under the proposed action plan, many of the activities already underway to address antimicrobial resistance will be expanded, and new activities will be initiated. All four areas will be important to containing the problem of antimicrobial resistance, and it will take involvement from all of the constituents I mentioned to implement the action plan.

Closing

In closing, I believe that the next few years hold much promise in terms of addressing the growing issue of antimicrobial resistance. The development of a multi-agency, coordinated action plan in the United States is a major step forward. The United States looks forward to a continuing dialog on antimicrobial resistance not only domestically, but internationally as well.

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For Further Information:

FSIS Congressional and Public Affairs Staff

Phone: (202) 720-3897

Fax: (202) 720-5704

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**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Speeches

Food Safety and Inspection Service
U.S. Department of Agriculture

The U.S. Food Safety System The Uses of Precaution

Remarks prepared for delivery by Caren A. Wilcox, Deputy Under Secretary for Food Safety, United States Department of Agriculture, at the 9th Annual European Food Law Conference, Swissotel, Brussels, June 20, 2000

Good afternoon everyone. It's certainly a privilege to be with you all this afternoon at this important conference on Food Safety in the European Union. We have already spent a good deal of time talking about the plans that the Commission has proposed to enhance food safety throughout the whole union, although we know that member states have had a long tradition of food safety – albeit under different laws or systems of law, regulations and customs.

Exchanges like this can only lead to more understanding among the member states and the Commission, the media, industry and consumers, as well as information and understanding for me and for others from other parts of the world attending the conference.

I especially appreciated learning more about the EU White Paper and Dr. Belveze's discussion of the EU's paper on the "Precautionary Principle."

The White Paper states that the establishment of the new Authority will "help restore and maintain consumer confidence." Certainly maintaining consumer confidence is something everyone in government and in the entire world food system – from farm to table – has to place at the top of their daily agendas.

We believe that your discussions here of this Authority and necessary laws and organizing theories within the EU are important steps as you work to ensure consumer confidence.

I am not going to spend my time with you today critiquing the White Paper or the "Precautionary Principle" paper, we feel that these discussions are your internal business. Both papers contain some worthy objectives and concepts. However, it is well known that the U.S. government has asked many questions relative to uncertainty of definitions, and is seeking clarification regarding both these papers.

I am going to comment on the difficulties of defining and transferring any "general principle" into a legal framework that is already extant. As you will hear in my remarks today, we in the United States have an almost one hundred year history of food safety law, regulation and judicial interpretation. It has been created and reviewed within our constitutional framework and our national traditions of law – including its absorption of much of the history of English Common Law. We recognize that the Commission is trying to find such common frameworks for its own laws and regulations, and we recognize that this cannot be an easy process since it is working with member states that have a tradition

of the Napoleonic Code on the one hand and English Common Law on the other hand – with many other legal and regulatory traditions in between.

Therefore, we should not be surprised that there could be difficulties finding the vocabulary to discuss "principles" in an international context outside the Commission and the European Union.

This is why we believe this is an important project for the Commission and the member states to work out among yourselves, and why we in the United States and many other countries find it difficult to address such an internal debate from afar.

Instead, today, we thought it would be helpful to concentrate on the almost one hundred year history of food law and regulation in the United States, its inherent use of precaution and risk analysis, risk management and risk communications, and the contributions these factors make to consumer confidence in the United States.

By describing this system, I hope to outline the strengths that have led to a long history of consumer confidence. Key elements of this system are:

- Strong, risk-based laws,
- Well thought through science based regulations,
- A transparent system of legal, regulatory and enforcement procedures;
- A public and private system for research and scientific advice,
- Effective inspection and strong enforcement actions, and,
- A focus on transparency and direct communication with consumers and the affected industry.

A BRIEF HISTORY

Since 1906, the United States has had a national food safety system based on risk and codified in law. Many of our states preceded the federal government in enacting strict food safety laws, and indeed there were some federal rules before that time. Both the Meat Inspection Act and the Pure Food and Drug Act were enacted in response to the current events of their time. From their inception, these laws focused on different parts of the food supply and they took different legislative approaches to ensure food safety – based on the contemporary congressional understanding of risk.

The Meat Inspection Act of 1906 acknowledged the significant risk of and link between some animal diseases and human diseases. Prior to its enactment, U.S. food safety policy had not kept pace with the changing needs of a society that was becoming more urban and less agrarian. Many problems had been exposed in U.S. meat packing plants and consumer confidence was eroding.

In response, the Meat Inspection Act created an inspection force within USDA and required continuous inspection of red meat (including ante-mortem and post mortem inspection), to identify animal diseases, maintain more sanitary slaughter and processing environments, and thus prevent contaminated meat from reaching the market.

The Act required USDA to stop any adulterated products from reaching the marketplace as well as to prevent consumer deception in labeling or other practices. It recognized that most meat reached the consumer raw – without an intervening step to control disease-causing agents. And to address consumer confidence, it required placing the inspection mark on all marketed product demonstrated through inspection not to be adulterated.

The Pure Food and Drug Act – also passed in 1906 – was born out of a debate surrounding the use of impure additives like borax, and substitute foods such as margarine. The Pure Food and Drug Act originally gave USDA jurisdiction over domestic and imported foods (not covered by the Meat Inspection Act) that are marketed in interstate commerce. The Act forbade adulteration and misbranding of foods with the government having enforcement capabilities to find and remove such products from the marketplace. In the 1940's, during the War, the Food and Drug Administration was moved from USDA to a security agency and then to what is now the Department of Health and Human Services (DHHS) when that department's predecessor agency was created.

Passage of the Poultry Products Inspection Act in 1957, and the Egg Products Inspection Act in 1970 broadened the United States Department of Agriculture's (USDA) oversight and inspection authority to include poultry and egg products. Several other statutes such as the Public Health Service Act and the Food Quality Protection Act (FQPA) contribute to food safety as well.

For many years the Food Safety and Inspection Service (FSIS) reported to an area of USDA that oversaw both marketing and regulatory programs. However, in 1994, Congress decided to create a new separate mission area, the Office of the Under Secretary for Food Safety within USDA – so the U.S. has recently been involved in reorganizing its food safety system too. Moreover, we continue to look at more ways to build a national seamless food safety system including the deliberations of the President's Council on Food Safety that I will describe more fully later.

Today, primary responsibility for enforcement of the U.S. food safety system is vested in USDA's Food Safety and Inspection Service (FSIS), which is required to inspect meat, poultry and egg products, and in the Health and Human Services' Food and Drug Administration (FDA), which has primary jurisdiction over the other food products in the system. The FDA's Center for Veterinary Medicine (CVM) oversees animal drugs and animal feeds, and their potential impact on human health.

The Environmental Protection Agency (EPA) establishes tolerances for pesticide residues on food and in animal feed.

All these agencies operate with the philosophy that food safety is truly a farm to table concern. Toward this goal, USDA, DHHS, and EPA regularly enter partnerships with states, local government, grower organizations and public interest groups. Together, these teams work to:

- Analyze risks through surveillance of hazards,
- Utilize risk assessments to develop effective interventions and management
- Develop policies and risk management methods for reducing hazards
- Implement risk management procedures within statutory authorities
- Assure compliance with food safety laws and regulations
- Communicate effectively with the public, and segments of the food system about risk management from farm to table – including: developing good agricultural practices to minimize pesticide residues and microbial risks.

THE FEDERAL SYSTEM

The U.S. Department of Agriculture (USDA), Department of Health and Human Services (DHHS), and the Environmental Protection Agency (EPA), are part of the executive branch of the U.S. government, which is responsible for the implementation of food safety laws. This is achieved through the development of and implementation of regulations, which the U.S. publishes in the *Federal Register* and posts on the web. The other two branches of government – legislative and judicial – also play key roles

in our food safety system. Under the legislative branch, Congress enacts statutes designed to ensure the safety of the food supply and establish the nation's level of protection.

Food safety statutes enacted by Congress provide USDA, DHHS, and EPA with broad authority but also set limits on regulatory actions. The statutes are drafted to achieve specific objectives. The agencies then develop regulations that give specific direction and establish specific measures. When new technologies, products, or health risks must be addressed, agencies have the flexibility to revise or amend regulations generally without need for new legislation.

Agencies are able to maintain their state-of-the-art scientific methods and analyses because changes of this type can be made at the administrative/technical level.

The judicial branch of government adjudicates disagreements over implementation or interpretation of food safety laws. If a person or organization wishes to challenge an agency decision, the complainant may take the agency to court. The judiciary plays a critical role in the regulatory process in that it reviews an agency's action in light of the substantive law and procedural requirements. An independent judge or panel examines the whole agency record of activity detailing what the agency did and why. If the court finds that the agency did not follow its statutory mandates, fulfill the procedural requirements, or have a rational basis for its action, the judicial system can overturn the agency's action.

Under the U.S. legal system, producers of food products have a legal obligation to put safe food on the market. If food laws and regulations are violated agencies have varying enforcement authorities. The judicial system serves as a forum for such consumer complaints and agency-initiated enforcement actions. Consumers who feel they have been harmed by an individual product can bring suit against the company that they believe produced the food as well. These judicial actions can provide an important safeguard in our system.

State and local governments also have jurisdiction over many food safety issues. State and local health departments conduct inspections of restaurants and at the retail level. And though the laws differ somewhat from state to state, an increasing number of them are adopting the U.S. Food Code, a model law developed by the FDA and FSIS.

U.S. consumers have the opportunity to influence food safety policy in all three branches of the federal government, and in state and local government as well. At the legislative level, consumers regularly communicate with lawmakers through face-to-face meetings, written submissions, and testimony at hearings. During the rulemaking process, regulatory agencies – including FSIS, FDA and EPA – invite consumers to submit written comments and suggestions, as well as to participate in public meetings. FSIS alone has held 138 public meetings in the last five years. And, if consumers are still unsatisfied they have the option to challenge regulations and laws through the judicial system.

AN OPEN AND TRANSPARENT SYSTEM

The opportunity for citizen participation in the U.S. regulatory system is much more extensive than the examples I've just listed. In fact, there are a number of laws, which outline – in very specific terms – the obligations of U.S. agencies to keep citizens informed of all proposals and relevant decisions.

To further ensure an open and transparent regulatory system, all U.S. regulatory agencies are subject to several procedural statutes, including, the Administrative Procedures Act (APA), the Federal Advisory Committee Act (FACA), and the Freedom Of Information Act (FOIA). The APA specifies the requirements for rulemaking (i.e., the process by which federal agencies formulate, amend, or repeal a

regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation.) Substantive regulations promulgated by an agency under the APA have the force and effect of law.

FACA requires that certain kinds of groups whose advice is relied upon by the government be chartered as advisory committees, that they be constituted to provide balance, to avoid a conflict of interest, and to hold committee meetings in public with an opportunity for comment from those outside the committee. Currently, USDA has over 50 such committees, including The National Advisory Committee on Meat and Poultry Inspection and the National Advisory Committee on Microbiological Criteria for Foods, and the Secretary recently created his Advisory Committee on Biotechnology.

The FOIA provides the public and the media with a statutory right to access federal agency information, records of discussions and other data. "Pre-decisional" information used for policy development need not be revealed.

The U.S. regulatory process is conducted in an open and transparent manner. Regulations are developed and revised in a public process that not only allows, but also encourages, participation by consumers, the regulated industry, and other stakeholders. In developing new regulations and revising existing ones, agencies often provide the public a preliminary discussion and opportunity for comment by publishing an Advance Notice of Proposed Rulemaking (ANPR). This notice lays out the issues, presents the agency's suggested resolution, and solicits alternative solutions. The information received from the public is used by the agency to decide whether and how to pursue rulemaking further. All public comments must be addressed in the proposed regulation either by being reflected in the rule or via an explanation of their omission.

The next steps are publication of a proposed regulation and publication of a final regulation, which is enforceable, with opportunities for public comment. It may interest regulators here to know that while a regulation development process is underway what our law calls "ex parte" communication regarding the rule is not permitted. Thus all parties who may be impacted by the rule are given the same chance for information and input about it as well as to influence it.

When confronted by a particularly complex issue where advice is needed from experts, who are not part of the agency, the regulatory agency may choose to hold a public meeting or convene an advisory committee meeting. Open, public meetings, announced in advance, and structured according to the agency's needs, bring together experts and stakeholders via an informal process. These meetings are used to receive the public's input on a specific subject area or on the agency's future programs.

An advisory committee meeting is structured more formally under requirements of a specific law. Public meetings and advisory committee meetings are announced in the *Federal Register* and the meetings are held in public unless an exempt issue, such as trade secrets, confidential commercial information, or personal medical information, is being discussed.

INSPECTION & ENFORCEMENT

Now that you have a sense of the framework of our system, I would like to get into the specifics of our inspection and enforcement activity. Since I am Deputy Under Secretary for USDA, my remarks will focus mainly on the activities under my mission area, food safety. But first, let me give you a brief overview of FDA's system.

All food and food products not under FSIS' authority are subject to oversight of FDA. They review the

safety of food and color additives before marketing, establish good food manufacturing practices and other production standards including criteria for HACCP programs, and, with the states, inspect food production establishments and food warehouses. The agency also reviews animal drugs for safety to humans who eat food produced from the animals and monitors the safety of animal feeds used in food producing animals.

FDA implements and oversees the U.S. nutrition labeling law as it applies to FDA inspected products. Under this law, all products with the exception of certain raw single ingredient foods – such as fruits and vegetables– are required to display a detailed label outlining everything from calories and saturated fat to the vitamins contained in the product.

When FSIS instituted nutrition labeling the Agency first chose to focus its requirements on multi-ingredient foods that vary in composition by manufacturer and brand such as frozen dinners, canned soup, and sausage. Labeling of raw, single ingredient products, like chicken breasts, hamburger, and steak was adopted on a voluntary basis with the caveat that if participation by the industry did not reach 60%, the Agency would initiate a mandatory program.

Nutrition labeling has been extremely popular with U.S. consumers, and has contributed to their overall confidence in our system. Even so, many consumer groups argued that the labeling laws did not go far enough, and that they should be extended to raw, single ingredient meat and poultry products, particularly ground beef. FSIS surveys showed that the voluntary labeling program had, indeed, not reached 60%. Therefore, the Agency initiated rulemaking to make nutrition labeling of raw, single ingredient meat and poultry mandatory.

FSIS maintains jurisdiction over the regulation and continuous inspection of all meat, poultry, and egg products, overseeing both domestic production and imports. The agency employs approximately 7,500 Federal inspectors who carry out continuous inspection in approximately 6,000 federal plants across the country. This involves nearly 8 billion poultry carcasses and 135 million livestock carcasses annually. In addition, it oversees 25 state programs for meat and poultry inspection that are equal to the federal system. Nevertheless, products from those state plants may not move into interstate commerce.

It is also important to note that both FDA and FSIS are subject to strict ethics laws – the FSIS law is the most stringent in the federal system and under it an inspector, administrator or even the Under Secretary and Deputy Under Secretary are forbidden to accept anything of value – including a cup of coffee from a regulated industry.

HACCP

As we all know there are numerous possibilities of foodborne illness or conditions being caused by pathogens, zoonotic diseases, chemical contamination or physical hazards. Following an analysis of the known causes of foodborne illness it was determined that an attempt should be made to apply scientific principles and HACCP systems to reduce the incidence of pathogens in the U.S. food supply.

Toward that goal, FSIS recently completed implementation of the Pathogen Reduction and Hazard Analysis and Critical Control Point (PR/HACCP) rule. Implementation of the rule was a three-year process with large plants coming on first, followed by small, and then very small operations. Before the rule became final, FSIS held over twenty public meetings including technical conferences and issue focus groups. At these meetings, consumers and industry representatives shared their concerns and gave suggestions for changes to the rule. These meetings were given top priority by both FSIS and USDA. Senior FSIS officials were present at every meeting, and Agriculture Secretary Glickman participated in

many as well.

FSIS recognized that implementation of the HACCP rule would affect all countries that export meat and poultry to the U.S. Therefore, when the rule was still a proposal, the agency held public meetings for the 37 affected countries. At those meetings, USDA officials informed the export countries of the rule and invited them to take part in the comment process.

In keeping with the SPS agreement, FSIS formally notified affected countries of the HACCP rule through the WTO. After the rule was made final, the agency held another public meeting at which the final rule was explained, copies were handed out, and questions were answered. In addition, FSIS contacted all affected countries before each of the public meetings and invited them to respond in writing if they would not be able to attend the meeting in person.

Under the HACCP system, plant owners must identify any and all food safety hazards reasonably likely to occur in their processes and products. For each specified hazard, the point at which the hazard can be controlled, reduced, or eliminated must be identified. Next, a determination must be made how to control the hazard, what limits are placed on that control, how plant personnel will monitor those limits, and what the plant personnel will do if there is a mistake or problem. Of course the plans are all very specific to the type of product produced by the plant.

FSIS inspectors review the HACCP plans in action. And if a plan fails in any way, FSIS inspectors can stop production if necessary while the plant evaluates the problem and their system.

As part of this rule the Agency had to predict the actual impact on foodborne illness and then provide evidence of success or failure. Under the Government Performance and Results Act, FSIS predicted a 25% reduction in foodborne illness in four years. It supported a plan to measure progress. It did so with the help of Congress and Health and Human Services' Centers for Disease Control and Prevention (CDC) by working with them to fund a monitoring network. More on that later.

Adoption of the HACCP system marks a critical development in the FSIS approach to inspection from one of command-and-control to a performance-based system of preventative controls. And it reflects FSIS' commitment to a science-based food safety system. The HACCP system includes a performance standard for *Salmonella*. HACCP has reduced the prevalence of *Salmonella* on raw meat and poultry by up to 50% in large and small plants. In addition, DHHS' Centers for Disease Control and Prevention (CDC) reported a decline in human illness caused by *Salmonella* and *Campylobacter*, and they have attributed that decline in part to meat and poultry HACCP implementation.

FSIS also enforces a zero tolerance policy for *Listeria monocytogenes* in ready-to-eat products. In 1987, the agency established an Lm monitoring program, which today analyzes some 3,500 samples annually from a variety of product categories. Last year, approximately 2.5% of these tests came back positive for the pathogen. When a positive sample is found, the manufacturer recalls any product in commerce, and FSIS conducts follow-up testing of all at-risk products produced by that plant. The agency also requires slaughter plants to conduct regular product testing for generic *E. coli*.

When any product in commerce is deemed adulterated, the company is asked to issue a recall. Should a company refuse, the agency has the authority to detain and to seek judicial seizure of the product. We have sought authority to order recalls – something that has not been granted yet.

In an effort to ensure adulterated product is not consumed, FSIS issues a press release on all recalls regardless of whether they are for 2 pounds of product or for 2 million pounds of product. In addition,

FSIS's enforcement actions are made public through its web page.

PRESIDENT'S FOOD SAFETY INITIATIVE

Recognizing the need to improve food safety coordination, in 1998 President Clinton created the President's Council on Food Safety. Co-chaired by USDA Secretary Dan Glickman, Assistant to the President for Science and Technology Policy Neil Lane, and DHHS Secretary Donna Shalala, the Council began work on a strategic plan and coordinated budget designed to fill existing gaps, improve coordination, and raise the visibility and importance of food safety issues. Prior to that, in January of 1997, the President announced his National Food Safety Initiative, which provided multiple years of targeted funding for coordinated food safety, surveillance, detection, research, education, and inspections.

These efforts were extended to state agencies through activities such as the expansion of FoodNet and PulseNet. Unique to the U.S., these systems represent cutting edge technologies designed to make the best uses of scarce resources. This is accomplished through the exchange of data from state health departments to the CDC, which uses it to track trends, identify outbreaks, and trace down the sources of specific foodborne outbreaks.

Formed in 1995, FoodNet is a collaborative project of the CDC, nine states, USDA and FDA. The project conducts active surveillance for foodborne diseases and related epidemiological studies. FoodNet provides a network for responding to new and emerging foodborne diseases, monitoring the burden of foodborne disease, and identifying the sources of specific foodborne diseases. With the help of the President's initiative, the surveillance area under the project has grown each year. Today, FoodNet covers about 25 million U.S. citizens. It is this system to which I referred earlier as the basis to measure progress on our goal of a 25% reduction in foodborne illness, and we are well on the way.

Also formed in 1995, PulseNet is a national network of public health laboratories that perform DNA "fingerprinting" on bacteria that may be foodborne. This data enables public health authorities to recognize when cases of foodborne illness may be related even if the outbreaks occur in different geographic regions. Matching patterns can indicate possible nationwide outbreaks and lead to public health actions such as epidemiological investigations and product recalls.

PulseNet has already aided FSIS to identify several outbreaks, and stem them before contaminated product could continue to be manufactured and distributed.

U.S. consumers have played an active role in the development of the Initiative and the Council's strategic plan and coordinated budget. Many consumer organizations have participated in large public meetings on the initiative and the strategic planning task force has periodically called meetings of all affected constituencies to gauge reaction to the plan.

THE COMING STRATEGIC PLAN FOR FOOD SAFETY - RISK ASSESSMENT, RISK MANAGEMENT, RISK COMMUNICATION

The President's Food Safety Initiative recognized the important role of risk in managing a successful food safety system. First it was recognized that more risk analysis was necessary to establish priorities and appropriate levels of regulation. Under the initiative, USDA and DHHS have completed a risk assessment on *Salmonella* Enteritidis in eggs and egg products, which included the first farm-to-table quantitative microbial risk assessment. This plan was used to develop an Egg Safety Action Plan to be implemented by FSIS and FDA. DHHS, with help from USDA has recently completed work on a risk

assessment for *Listeria monocytogenes* in a variety of ready-to-eat foods. In addition, USDA is also conducting a risk analysis for *E. coli* 0157:H7 in ground beef and has entered into a cooperative agreement with Harvard University's School of Public Health for a risk analysis of any possible unexpected pathways for Bovine Spongiform Encephalopathy to enter the United States.

These are some specific examples of the use of risk assessment leading to risk management programs in our system.

The Strategic Plan is envisioned to be fashioned around Risk Analysis, Surveillance and Risk Assessment; Risk Management; and Risk Communication. We expect it to be sent to the President this summer.

I would now like to take a moment to talk about our use of risk management and precaution in a more general sense.

Highly qualified regulatory authorities with the sole objective to provide high levels of protection to the U.S. consumer exercise risk management. Management of risk is necessary when much, some, little, or no data are available, thus requiring knowledgeable experienced experts capable of making scientifically defensible decisions in the interest of public health. Risk management principles are set by law or by the risk manager's expert judgment to reduce risk to the lowest practical, or achievable, level.

Certainly we all recognize that emergencies can arise, and we have several structures in place to deal with them. As part of the President's Initiative a Memorandum of Understanding was signed among several departments and agencies to create the Foodborne Outbreak Response Coordinating Group (FORC G). It is co-chaired by the Under Secretary for Food Safety and the Surgeon General and Assistant Secretary of Health and Human Services. It is intended as a coordinating mechanism in the event of a regional or national outbreak that would require the utilization of all governmental tools to manage it.

When there is a need for emergency risk communication, alerts are conveyed through national and regional media to make citizens aware of the risk. If appropriate, international organizations (World Health Organization, Food & Agriculture Organization, Office of International Epizootics and the World Trade Organization, if appropriate), as well as to the EU and its member states, and other individual countries would be informed immediately.

Risk communication is critical throughout the risk assessment and management stages. The U.S. is committed to openness and transparency of its work to protect the public from food-related health risks. For example, regulatory agencies provide public notification of recalls of food products. Information about meat and poultry recalls is also provided on FSIS' website, as are frequent reports of regulatory and enforcement actions taken against regulated food establishments. EPA's pesticides website contains the full risk analysis for specific pesticides, and risk analyses procedures have been made available to the public for comment. Where appropriate, risk analyses processes have been modified in response to these comments. Food Safety education campaigns and televised public service announcements are used to communicate and there are many programs for school children and food service workers as well as general consumer messages.

The genesis of many health, safety, and environmental laws is associated with the prevention of undesirable events and the protection of public health and the environment. Specific prevention and protection measures reflect differing provisions of law, regulation, and circumstances. However, they all are risk-based.

ROLE OF PRECAUTION

There are, of course, times when decisions need to be made when complete scientific evidence is insufficient. For this reason, precaution is built into every aspect of the U.S. decision-making process and has been part of our food safety system for almost 100 years. As I stated earlier, the Federal Meat Inspection Act and Poultry Products Inspection Act were written in a manner, which allows the regulators to react quickly to emerging threats. This is an example of how precaution is used in the execution of our laws.

Another example of the use of precaution is the control system for ingredients in food and feed, such as the feeding prohibition of certain animal proteins to ruminants to prevent the introduction of BSE in the U.S. The use of precaution is also apparent in the U.S. pre-market approval requirements for food additives, animal drugs, and pesticides. The products are not allowed on the market unless, and until, they are shown by producers to be safe to the satisfaction of the regulatory authorities. When the petition is reviewed, data are evaluated to determine exposure to the additive, including exposure to all likely impurities in the additive. The degree of testing considered necessary depends on the class of chemical and expected exposures, including exposures to vulnerable parts of the population such as children. The data or the lack of data drives a decision. The evaluation of all is documented.

As I come to a close, I must clarify and use as an illustration, a misunderstanding of the supposed need to use precaution in the U.S. last year. Some have tried to characterize the actions taken by the United States in response to the dioxin problem in feed and animals in Belgium last year as an example of an application of the "Precautionary Principle." However, this was simply an example of the strong laws in place in the United States. When it was learned that meat products had been accidentally or deliberately contaminated with a substance that, if added to a product, is considered an adulterant in the United States, there was no question of invoking a separate principle of precaution. These products were simply considered adulterated under our statutes, and thus could not be admitted to the United States.

CLOSING

As you can see, the United States system is both comprehensive and flexible, thus allowing our regulations to protect the American people while keeping up with modern science and reacting to current issues. Our system is also extremely transparent and is designed to allow consumer participation at every level. As a result, the U.S. system enjoys a high level of consumer confidence. This is because our citizens have the opportunity to influence the types of laws that are passed and the means by which they are implemented. And if all else fails, U.S. consumers can freely challenge our regulations in a court of law.

Time was too short today to outline the millions of dollars of food safety research projects currently underway in our department and at DHHS and coordinated by the Joint Institute for Food Safety Research.

Let me recommend to you a web site that will connect you to almost all activities on food safety in the U.S. It is: www.foodsafety.gov.

In closing, I would like to reiterate my support for exchanges such as this one. Senior level meetings have already occurred between DG Sanco and U.S. government officials as well as meetings with member state leaderships. These meetings are an important step toward increased understanding of our respective systems and improved relations. All of us share a concern for food safety and for the public health of all of our citizens. The U.S. government supports the continuation of such dialogue. I am

personally looking forward to hearing more from my colleagues as this meeting progresses.

Thank you.

For Further Information:

FSIS Congressional and Public Affairs Staff

Phone: (202) 720-3897

Fax: (202) 720-5704

[Speeches Menu](#) | [FSIS Home Page](#) | [USDA Home Page](#)

Remarks

As Prepared for Delivery
by

Secretary of Agriculture Dan Glickman
Memorial Service For Jean Hillery, Tom Quadros And Bill Shaline
June 30, 2000 Oakland, California

"Before I say a few words, I want to share a message from someone who couldn't be here today.

Secretary Glickman reads statement from President Clinton

"On behalf of the entire U.S. Department of Agriculture, I want to offer my condolences to the families, friends and colleagues of Jean Hillery, Tom Quadros and Bill Shaline. USDA and the California Department of Food and Agriculture are better off for the time that they gave to us.

"Many people have come up to me and expressed their sadness at this loss. Just the other day, I received a letter from the members of the Safe Food Coalition asking that I pass along their condolences as well.

"Food safety compliance officers perform one of the most important functions in public service, protecting the American people where they are largely powerless to protect themselves. Jean Hillery, Tom Quadros and Bill Shaline did the people's work. And over this holiday weekend, as we grill our steaks, chicken and burgers, I hope we'll all remember that it's the efforts of these three people and the thousands of others like them that ensures the safety of the food we serve to our families.

"And while their work is absolutely critical, rarely do we think of it as dangerous and life-threatening. Which makes last week's tragedy all the more shocking and unsettling. It's cruelly ironic that, in the process of protecting the lives of the American people, their own lives were taken from them violently and needlessly.

"All of them led lives of purpose and dedication, not just at their jobs but within their families and their communities. Whether it was Jean Hillery going to college and beginning a new career after raising three daughters, or Tom Quadros' work with the Special Olympics, it's clear that these were more than distinguished public servants...they were extraordinary people as well.

"Yesterday, back at USDA headquarters, I gave a speech about civil rights at our Department. And although I talked some about programs and procedures, the message I really tried to convey was that civil rights and human rights begin with people simply treating each other with respect and common courtesy. This tragedy is not about race or civil rights in any way, but I think it can still teach a lesson about civility and decency, about open communication and the importance of resolving disputes peacefully and sensibly. Jean Hillery, Tom Quadros and Bill Shaline lived those values, but they died because some people still do not.

"I want to close with a message to their children. Last December, I lost both of my parents, within just a few weeks of each other. They were old, and they were sick. But I'm immensely grateful that they lived into their 80's and that I was able to enjoy them for 55 years of my life. I can't

imagine the pain you must feel at losing parents in the prime of their lives..
But I hope that you measure their time in terms of quality rather than
quantity...always remembering that their lives, though short, were ones of
both accomplishment and integrity.

"Thank you".

#



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

AUG 1 2000

MEMORANDUM

TO: Tom Billy
Administrator, Food Safety and Inspection Service

FROM: Catherine Woteki *CSWoteki*
Under Secretary, Office of Food Safety

SUBJECT: Recalls

It has now been six months since we instituted the policy of issuing press releases on all recalls. At that time we committed to review the policy in July and make any needed adjustments. As a first-step in this review process, I would like to discuss the Agency's findings at an upcoming Wednesday staff meeting.

In addition, there are some specific questions and concerns that I have regarding recalls and our recall policy in general. I would also like to address these issues at the same Wednesday meeting.

Specifically, the increasing number of recalls has meant the recall committee (OPHS), Field Operations staffs, and CPA staff have had to work on a number of weekends/holidays and evenings. In addition, CPA staff have had to be essentially "on call" for an entire weekend, wearing a beeper and being prepared to stop whatever they are doing if a recall occurs in order to put out press releases and answer questions. I am sure that compliance staff is similarly impacted.

The odd hour at which many of these recalls have occurred has meant that FSIS press releases have received little or no media attention. As a result, the Agency has essentially been unable to accomplish its public health goal of informing the public. This situation has opened the Agency to questions and criticisms from the media.

I understand that recalls are not something that can be predicted, and it is unlikely that late night and weekend recalls can be eliminated. But I do believe that we can reduce the percentage of recalls occurring during "non-business" hours. It is important to do so for many reasons – not the least of which is to better inform consumers of possible health risks, and to maintain the well deserved reputation of the agency in many other areas of transparent practices.

I have several specific questions about our recall procedures and would like a briefing on the following issues:

- Does FSIS have written recall procedures outlining who needs to be contacted and when? If so, does FSIS document recalls as to the time that each office was notified? For instance, on Friday evening, July 7, ERD notified the CPA staff of a recall at 7 p.m. It would be helpful to know when ERD was notified, when the lab knew the final results of the tests and notified ERD, etc.
- The labs have regular hours and a schedule that they adhere to. Therefore, would it be possible for the labs to give a "latest possible time" that a positive would come back? This would at least allow the staff to go home or turn a beeper off after certain hours on the weekend. I understand that staff stay in the office on a Saturday or Sunday awaiting a call that only comes late in the day.
- There is also concern emerging about the timing of laboratory tests, orders for follow up and the subsequent schedule that seemingly ends up in recalls on Saturday evenings. Would it be possible to schedule tests in such a manner so that fewer results would come back on Friday afternoons, without delays that run into the following week? How are confirmatory tests treated in the priority of testing? Is this a problem of capacity or scheduling or both?

In addition, I would appreciate receiving a tabulation of data on recalls such as day and date of recall, time of recall, type of recall etc., for the past eight months.

On a related note, questions are now arising on possible disparities between large and small plants and their recalls/market withdrawals. I would also like more information about market withdrawal. Specifically, I would like a report of all the market withdrawals over the past eight months with a breakdown by plant size – with as much specificity as possible.

I have attached a copy of a press story from the Associated Press today. It makes clear that the press is watching the timing of these actions by the agency and the industry, which should be expected.

Attachment

Cc: Caren Wilcox
Margaret Glavin

WI Delayed Meat Warning, 0288
Meatpacker waits four days for tests before telling public of

recall
With BC-WI--Bacteria Illness
phqdrflsjdh

SOUDERTON, Pa. (AP) A meatpacker waited four days while tests were run before notifying the public that it was recalling nearly 350,000 pounds of ground beef because of E. coli concerns.

"We told distributors immediately that they should consider recalling the meat," Moyer Packing Co. spokeswoman Ella Roush said. "We didn't tell consumers until the weekend because we weren't even sure it was ours."

Federal food inspectors notified the company on July 24 that preliminary tests showed that beef sent to New York state had the bacteria. Customers were warned on Saturday, after further tests confirmed that the meat was from Moyer Packing Co., also known as Mopac.

The recalled Mopac packages have the plant establishment number 1311 and are dated 07/11/00. They were distributed in five- and 10-pound packages to wholesalers in Connecticut, Delaware, Louisiana, Massachusetts, Maryland, Michigan, New Jersey, New York, Virginia, Pennsylvania and Wisconsin.

Roush would not identify the distributors or the retailers that carry the products.

"That's not what's important," Roush said. "We need to make things right with our distributors to make sure none of that meat is in the market right now."

U.S. Department of Agriculture spokeswoman Carol Blake said no cases of illness linked to the Mopac meat have been reported.

But Milwaukee health officials have said they are checking to see whether the meat might be related to an E. coli outbreak there.

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(SRC:AP; ST:WI;)
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AUG 17 2000

The Honorable Richard G. Lugar
Chairman
Committee on Agriculture,
Nutrition, and Forestry
United States Senate
328-A Russell Senate Office Building
Washington, D.C. 20510-6000

Dear Mr. Chairman:

Thank you for your February 8, 2000, letter about the coordination of Federal research activities related to foodborne pathogens.

We believe that in order to protect consumers from foodborne illness, we have to strengthen the Nation's capacity to predict and prevent foodborne hazards and to monitor and rapidly react to outbreaks of foodborne illnesses. Federal agencies are working together to attain those goals by sharing information and scientific data, coordinating research efforts, and cooperating in activities intended to protect the public from foodborne illness. For example, the Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS), and the Centers for Disease Control and Prevention (CDC) collaborated with one another, as well as with State and local public health and food control agencies, industry, academia, and consumers, to update the Food Code in 1999. FDA and FSIS are conducting a joint risk ranking on *Listeria monocytogenes*. The Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) recently had the opportunity to participate with the Soldier and Biological and Chemical Command in a simulation of a major foodborne outbreak. Through participation in the exercise, we used our mutual responsibilities and authorities to respond to naturally occurring, as well as terrorist-initiated, disease outbreaks. The Department of Defense (DOD) is represented on the Foodborne Outbreak Response Coordination Group.

We have made progress through the President's Food Safety Initiative, which was announced in 1997, as a means of providing funds for food safety. This initiative set in motion a number of activities that have contributed greatly to reducing foodborne illness, including surveillance and outbreak response, new food safety research, and development in the science of risk assessment. For example, the initiative called for all Federal agencies with food safety risk management responsibilities to establish the Interagency Risk Assessment Consortium, which was charged with advancing the science of microbial risk assessment by encouraging research to develop predictive models and other tools that can be used to conduct risk assessments. It also has established a clearinghouse that will collect and catalogue resources on risk assessment offered by various sources.

The Honorable Richard G. Lugar

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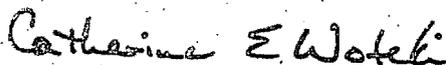
The President's Council on Food Safety is building on the achievements of the Food Safety Initiative. The Council, jointly chaired by HHS Secretary Shalala, Neal Lane, the President's science advisor and Director of the White House Office of Science and Technology Policy (OSTP), and me, was established in August 1998 to strengthen and focus our efforts to coordinate food safety policy and resources. The Council was directed to: (1) develop a comprehensive strategic Federal food safety plan; (2) advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the Office of Management and Budget (OMB); and (3) ensure that the Joint Institute for Food Safety Research (JIFSR) establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. By prioritizing research needs and coordinating our efforts across the Federal government through JIFSR, we can ensure that our research dollars are well spent.

The Joint Institute for Food Safety Research (JIFSR) was formed by the cooperative action of the Departments of Agriculture and Health and Human Services in response to the President's Food Safety Initiative. The Institute will identify critical gaps in our knowledge that can be researched and thereby help resolve conflicts between trading partners, segments in the food production system, and shareholders (private and governmental) with responsibility to produce safe food. The Institute will foster development of joint program announcements involving multiple Federal research programs and multi-center trails to demonstrate the cost effectiveness of prevention strategies and technologies and improve cost-efficiency of research initiatives. By improving communication between agencies and private shareholders, the Institute will increase the transparency of Federal food safety research efforts and move toward eliminating redundancy in private and Federal research endeavors. Finally, as a result of all of these efforts, the overall quality of the scientific research in the area of food safety will improve and be more focused on issues critical to preventing foodborne illnesses.

We appreciate your constituents' interest in food safety and hope that this information is helpful. Your constituents may be interested in visiting the FSIS web site at <http://www.fsis.usda.gov>, which carries the latest information on our programs and also has links to other relevant government web sites. In addition, at <http://www.FoodSafety.gov>, a Gateway to Government Information, is a web site established by the President's Food Safety Initiative. It is designed to help web site users more easily find government information on food safety.

If you have questions or if we can be of further assistance, please let us know.

Sincerely,



CATHERINE WOTEKI, Ph.D., R.D.
Under Secretary

The Honorable Richard G. Lugar

Page 3

FSIS:FSEMCS:KathyBrown:03/22/00:720-8973:lugstudy.wpd:EH:4/03/2000:08/16/00;
35-4146747

Information: markey letter/35/4117998

Std lang on Pres Council on Food Safety

Speeches: T Billy/11/15/99/Using Science to Avoid Chaos

C Wilcox/03/09/00/USDA Policy Perspective

Clearances

Initial/Date

K.Wachsmuth,Dep.Adm.,OPHS

P.Derfler,Dep.Adm.,OPPDE

L.Swacina,Dir.,CPAS

M.Glavin,Assoc.Adm



October 19, 2000

MEMORANDUM FOR SEE DISTRIBUTION BELOW:

FROM: NEIL F. OMANSKY *NO*
Congressional and Public Affairs

SUBJECT: FY2001 Agriculture Appropriations Conference Report

On October 18, the Senate passed the Conference Report (106-948) accompanying the FY01 Agriculture Appropriations Act (H.R. 4461) by a vote of 86-8. On October 11, the House passed the Report by a vote of 340-75. President Clinton has indicated that he will sign it into law. The following is a brief description of the FSIS related bill and report language with attachments:

	FY00	President's Request	House Mark	Senate Mark	Conference Mark	Change From FY00	Change From Pres.
OFS	\$446,000	\$560,000	\$446,000	\$460,000	\$460,000	+\$14,000	-\$100,000
FSIS	\$649.119M	\$688.204M	\$673.79M	\$678.011M	\$696.704M	+\$47.5M	+\$8.5M

FSIS:

- No less than \$591,258,000 shall be available for Federal food inspection; (attachments 1 and 2)
- \$1,000,000 may be credited to this account from fees collected for the cost of lab accreditation;
- Not more than \$2,500,000 for mandatory ratite and squab inspection (section 752); (attachment 1)
- The conference agreement includes \$6,000,000 to be used to the extent approved by the Director of OMB to liquidate obligations incurred in previous years that violated the Antideficiency Act. According to the House and Senate Agriculture Appropriations Subcommittees, old report language prohibiting FY01 money from being used to address these obligations was accidentally left in the Conference Report. FSIS is reviewing the issue with OGC to determine if the statutory language overrides report language or if a correction will be needed; (attachments 1 and 2)
- No money is specifically appropriated for delays in implementing HIMP. House and Senate Agriculture Appropriations Subcommittee staff have orally indicated that if money is needed, the issue should be addressed in a supplemental appropriation;
- The perennial prohibition on using FSIS funds for shell egg surveillance under the EPIA has been lifted; (attachment 2)
- The conferees note that the conference agreement provides for all mandatory pay cost increases and the full amount requested for the FSIS portion of the Food Safety Initiative; (attachment 2)
- The conference agreement includes \$2,039,000 for activities related to Codex. The conference agreement provides for up to \$50,000 for representational expenses associated with Codex activities; (attachment 2)

- The House and Senate report language that is not changed by the conference is approved by the committee of conference. The statement of the managers, while repeating some report language for emphasis, does not intend to negate the language referred to above unless expressly provided herein. In cases in which the House or the Senate have directed the submission of a report, such report is to be submitted to both the House and Senate Committees on Appropriations. (attachment 3) and
- School food authorities in Ohio participating in a domestic food assistance program administered by the Secretary and preparing meals for use by other schools and institutions also participating in a domestic food assistance program, shall, with regard to such meals, not be subject to additional requirements under section 301(c) of the FMIA or section 5(c) of the PPIA. (attachment 4)

Directives and Reports (from Conference Report): (attachment 2)

- The conferees direct the Agency to continue to provide the Quarterly Report on Budget Execution and Staffing to the Committees on Appropriations.
- The conferees direct a report by March 1, 2001 on meat and poultry inspection regulations in place prior to publication of the HACCP Rule.
- The conferees direct that as part of HHS' and USDA's ongoing rechartering of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the Secretaries of Agriculture and Health and Human Services shall: (1) appoint a number of members consistent with scientific advisory committees utilized by agencies such as the FDA and the EPA; (2) adhere strictly to applicable Federal conflict-of-interest requirements for Federal advisory committee membership; (3) report to the Senate Committees on Appropriations and Agriculture, Nutrition, and Forestry, the House Committees on Appropriations and Agriculture, and the Secretaries of Agriculture and Health and Human Services on any conflicts of interest of NACMCF members involved in making recommendations to Federal agencies, whether waived under applicable Federal law or not, and what those conflicts are.
- The conferees direct the Agency to provide \$500,000 to the National Research Council for an evaluation, at the earliest date practicable, by the National Research Council of the role of scientifically determined criteria, including microbiological criteria, in the production and regulation of meat and poultry products.
- The conferees direct the Agency to prepare a report, including recommendations to the Secretary, to be prepared by the NACMCF, no later than March 1, 2001, regarding microbiological performance standards, including the role of such standards as a means of assuring meat and poultry product safety, as well as such other considerations as the Committee deems appropriate. These activities should in no way delay the implementation of the HACCP inspection system or other food safety activities.

Directives and Reports (from House Report): (attachment 5)

- The Committee expects all appropriate senior personnel of the Agency, specifically senior personnel in FO, OPHS and OPPDE, to become HACCP certified and to observe operations in the range of establishments inspected by the agency at least annually. The Agency is directed to provide the Committee a report no later than March 1, 2001 listing these senior personnel (GS 14 and above), the date on which they have become HACCP certified and the date and type of establishment in which they have observed operations.

- The Committee expects the Agency to make full use of its authority to ensure that inspection resources are rationally dedicated to address relative food safety risks and to avoid the disruptive effect of continued inspector shortages. To further these objectives, the Agency is expected to evaluate greater flexibility in requirements for frequency of unscheduled inspection and other possible means of enhancing the efficiency of inspection in processing establishments. FSIS should report its findings to the Committee by January 31, 2001.
- The Inspector General is directed to undertake an investigation of the adequacy of FSIS financial management and project management, as well as the adequacy of management controls in those areas. The Committee directs the Inspector General to provide a preliminary report no later than March 1, 2001. The investigation should ascertain what deficiencies resulted in recent inspector shortages and why Anti-Deficiency Act violations occurred over the last two years.

Directives and Reports (from Senate Report): (attachment 6)

- The Committee expects the Agency to make full use of its authority to ensure that inspection resources are rationally dedicated to address relative food safety risks and to avoid the disruptive effect of continued inspector shortages. To further these objectives, the Agency should evaluate greater flexibility in requirements for frequency of unscheduled inspection and other possible means of enhancing the efficiency of inspection in processing establishments. FSIS should report its findings to the Committee by January 31, 2001.
- The Committee believes that agency managers should have an understanding of the establishments the agency regulates, which necessarily requires the occasional observation of operations in an inspected establishment. The Committee expects senior policy development personnel of FO, OPHS, and OPPDE to become HACCP certified and to observe operations in the range of establishments inspected by the agency at least semi-annually. The Agency is directed to provide the Committee a report, no later than March 1, 2001, listing the senior personnel (GS 14 and above), the date on which they become HACCP certified, and the date and type of establishment in which they have observed operations.

General Provisions: (attachment 7)

- **Sec. 705.** New obligational authority provided for FSIS' field automation and information management project shall remain available until expended;
- **Sec. 713.** FSIS may use cooperative agreements to reflect a relationship between FSIS and a State or cooperator to carry out special studies to improve the safety of the nation's food supply;
- **Sec. 716.** Not more than \$1,800,000 shall be used to cover necessary expenses of activities related to all advisory committees, panels, commissions, and task forces of the USDA, except for panels used to comply with negotiated rule makings and panels used to evaluate competitively awarded grants;
- **Sec. 717.** None of the funds appropriated by this Act may be used to carry out section 410 of the FMIA or section 30 of the PPLA (Safe Meat and Poultry Inspection Panel);
- **Sec. 718.** No employee of the USDA may be detailed or assigned from an agency or office funded by this Act to any other agency or office of the Department for more than 30 days unless the individual's employing agency or office is fully reimbursed by the receiving agency or office for the salary and expenses of the employee for the period of assignment;
- **Sec. 719.** None of the funds appropriated or otherwise made available to the USDA shall be used to transmit or otherwise make available to any non-USDA employee questions or responses to questions that are a result of information requested for the appropriations hearing process;

- **Sec. 720.** None of the funds made available to the USDA by this Act may be used to acquire new information technology systems or significant upgrades, as determined by the Office of the Chief Information Officer (OCIO), without the approval of the CIO and the concurrence of the Executive Information Technology Investment Review Board;
- **Sec. 721.** (a) None of the funds provided by this Act, or provided by previous Appropriations Acts to the agencies funded by this Act that remain available for obligation or expenditure in FY01 shall be available for obligation or expenditure through a reprogramming of funds which: (1) creates new programs; (2) eliminates a program, project, or activity; (3) increases funds or personnel by any means for any project or activity for which funds have been denied or restricted; (4) relocates an office or employees; (5) reorganizes offices, programs, or activities; or (6) contracts out or privatizes any functions or activities presently performed by Federal employees; unless the Committees on Appropriations of both Houses of Congress are notified 15 days in advance of such reprogramming of funds. (b) None of the funds provided by this Act, or provided by previous Appropriations Acts to the agencies funded by this Act that remain available for obligation or expenditure in FY01 shall be available for obligation or expenditure for activities, programs, or projects through a reprogramming of funds in excess of \$500,000 or 10 percent, whichever is less, that: (1) augments existing programs, projects, or activities; (2) reduces by 10 percent funding for any existing program, project, or activity, or numbers of personnel by 10 percent as approved by Congress; or (3) results from any general savings from a reduction in personnel which would result in a change in existing programs, activities, or projects as approved by Congress; unless the Committees on Appropriations of both Houses of Congress are notified 15 days in advance of such reprogramming of funds. (c) The Secretary of Agriculture shall notify the Committees on Appropriations of both Houses of Congress before implementing a program or activity not carried out during the previous fiscal year unless the program or activity is funded by this Act or specifically funded by any other Act;
- **Sec. 729.** None of the funds appropriated by this Act or any other Act may be used (by AMS) to: (1) carry out the proviso under 7 U.S.C. 1622(f) (increasing consumer education); or (2) carry out 7 U.S.C. 1622(h) (Inspection and certification of products in interstate commerce; credit and future availability of funds; investment; certificates as evidence; penalties) unless the Secretary of Agriculture inspects and certifies agricultural processing equipment, and imposes a fee for the inspection and certification, in a manner that is similar to the inspection and certification of agricultural products under that section, as determined by the Secretary: Provided, That this provision shall not affect the authority of the Secretary to carry out the FMIA, the PPIA, or the EPIA;
- **Sec. 730.** None of the funds appropriated by this Act or any other Act shall be used to pay the salaries and expenses of personnel who prepare or submit appropriations language as part of the President's Budget submission to Congress for programs under the jurisdiction of the Appropriations Subcommittees on Agriculture, Rural Development, and Related Agencies that assumes revenues or reflects a reduction from the previous year due to user fees proposals that have not been enacted into law prior to the submission of the Budget;
- **Sec. 752.** Effective 180 days after the date of the enactment of this Act and continuing for the remainder of fiscal year 2001 and each subsequent fiscal year, ratite and squab slaughter and processing for distribution in commerce as human food shall be subject to the ante mortem and post mortem inspection, reinspection, and sanitation requirements of the PPIA rather than the voluntary poultry inspection program of the USDA under section 203 of the Agricultural Marketing Act of 1946;

- **Sec. 753.** In developing a rule concerning on-farm standards for prevention of *Salmonella* Enteritidis in shell eggs pursuant to any plan to eliminate SE illnesses due to eggs, the FDA shall – (a) consider one environmental test per laying cycle for each layer house for verification of the producer’s SE reduction plan; (b) consider when it is appropriate to require diversion of shell eggs to treatment, such as pasteurization, and base any requirement for testing that would necessitate diversion, which may include the receipt of a positive egg test result, on sound science; (c) conduct or support research to develop cost-effective and improved tests for determination of SE; and (d) solicit comments on appropriate options for implementing a SE reduction plan in shell eggs, including comments on conducting and funding testing, through State and Federal programs; and

Other: (attachment 8)

- The conferees expect FDA to make final the regulations regarding labeling of irradiated foods by March 1, 2002, and report to the House and Senate Committees on Appropriations on the status by November 15, 2000. This agreement changes the dates proposed for final regulations by the House of September 30, 2001, and by the Senate of October 30, 2001.

Distribution:

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TITLE I

AGRICULTURAL PROGRAMS

PRODUCTION, PROCESSING, AND MARKETING

OFFICE OF THE UNDER SECRETARY FOR FOOD SAFETY

For necessary salaries and expenses of the Office of the Under Secretary for Food Safety to administer the laws enacted by the Congress for the Food Safety and Inspection Service, \$460,000.

FOOD SAFETY AND INSPECTION SERVICE

For necessary expenses to carry out services authorized by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, including not to exceed \$50,000 for representation allowances and for expenses pursuant to section 8 of the Act approved August 3, 1956 (7 U.S.C. 1766), \$696,704,000, of which no less than \$591,258,000 shall be available for Federal food inspection; and in addition, \$1,000,000 may be credited to this account from fees collected for the cost of laboratory accreditation as authorized by section 1017 of Public Law 102 237: Provided, That not more than \$2,500,000 of this appropriation may be used to implement section 752 of title VII of this Act: Provided further, That this appropriation shall be available for field employment pursuant to the second sentence of section 706(a) of the Organic Act of 1944 (7 U.S.C. 2225), and not to exceed \$75,000 shall be available for employment under 5 U.S.C. 3109: Provided further, That this appropriation shall be available pursuant to law (7 U.S.C. 2250) for the alteration and repair of buildings and improvements, but the cost of altering any one building during the fiscal year shall not exceed 10 percent of the current replacement value of the building: Provided further, That from amounts appropriated under this heading not needed for federal food inspection, up to \$6,000,000 may be used to liquidate obligations incurred in previous years, to the extent approved by the Director of the Office of Management and Budget based on documentation provided by the Secretary of Agriculture.

TITLE I--AGRICULTURAL PROGRAMS

PRODUCTION, PROCESSING, AND MARKETING

OFFICE OF THE UNDER SECRETARY FOR FOOD SAFETY

The conference agreement provides \$460,000 for the Office of the Under Secretary for Food Safety as proposed by the Senate instead of \$446,000 as proposed by the House.

FOOD SAFETY AND INSPECTION SERVICE

The conference agreement provides \$696,704,000 for the Food Safety and Inspection Service instead of \$673,790,000 as proposed by the House and \$678,011,000 as proposed by the Senate.

The conference agreement includes \$591,258,000 for federal food inspection.

The conference agreement includes \$6,000,000 to be used to the extent approved by the Director of the Office of Management and Budget to liquidate obligations incurred in previous years that violated the Antideficiency Act. The conferees expect the agency to take appropriate action to avoid violations of the Antideficiency Act from occurring again.

The conference agreement does not adopt Senate bill language providing that the appropriation shall not be available for shell egg surveillance under the Egg Products Inspection Act.

The conferees direct the agency to provide \$500,000 to the National Research Council for an evaluation, at the earliest date practicable, by the National Research Council of the role of scientifically determined criteria, including microbiological criteria, in the production and regulation of meat and poultry products and a report, including recommendations to the Secretary, to be prepared by the National Advisory Committee on Microbiological Criteria for Foods, no later than March 1, 2001, regarding microbiological performance standards, including the role of such standards as a means of assuring meat and poultry product safety, as well as such other considerations as the Committee deems appropriate. These activities should in no way delay the implementation of the HACCP inspection system or other food safety activities.

The conferees direct the agency to continue to provide the Quarterly Report on Budget Execution and Staffing to the Committees on Appropriations.

The conference agreement does not include language under this heading which permits FSIS to expend funds appropriated for FY 2001 to liquidate overobligations and overexpenditures incurred in previous fiscal years as proposed by the House.

The conferees note that the conference agreement provides for all mandatory pay cost increases and the full amount requested for the FSIS portion of the Food Safety Initiative.

The conference agreement includes full funding for inspection costs and activities and \$2,039,000 for activities related to the Codex Alimentarius. The conferees note increased responsibilities for the agency regarding participation in the Codex Alimentarius. The conference

agreement provides for not to exceed \$50,000 for representational expenses associated with Codex activities.

The conferees direct a report by March 1, 2001 on meat and poultry inspection regulations in place prior to publication of the Pathogen Reduction HACCP Rule.

Furthermore, the conferees, in supporting food safety regulations based upon the best available science, recognize the importance of the National Advisory Committee for Microbiological Criteria for Foods' (NACMCF) chartered mission of providing impartial, scientific advice to Federal agencies on food safety matters. The conferees, therefore, direct that as part of Department of Health and Human Services and Department of Agriculture's ongoing rechartering of the NACMCF, the Secretary of Agriculture and Secretary of Health and Human Services shall: (1) appoint a number of members consistent with scientific advisory committees utilized by agencies such as the Food and Drug Administration and the U.S. Environmental Protection Agency; (2) adhere strictly to applicable Federal conflict-of-interest requirements for Federal advisory committee membership; (3) report to the Committee on Appropriations and Committee on Agriculture, Nutrition, and Forestry of the U.S. Senate, the Committee on Appropriations and Committee on Agriculture in the U.S. House of Representatives, and the Secretaries of Agriculture and Health and Human Services on any conflicts of interest of NACMF members involved in making recommendations to federal agencies, whether waived under applicable Federal law or not, and what those conflicts are.

Congressional Directives

The statement of the managers remains silent on provisions that were in both the House and Senate bills that remain unchanged by this conference agreement, except as noted in this statement of the managers.

The conferees agree that executive branch wishes cannot substitute for Congress' own statements as to the best evidence of congressional intentions--that is, the official reports of the Congress. The conferees further point out that funds in this Act must be used for the purposes for which appropriated, as required by section 1301 of title 31 of the United States Code, which provides: "Appropriations shall be applied only to the objects for which the appropriations were made except as otherwise provided by law."

The House and Senate report language that is not changed by the conference is approved by the committee of conference. The statement of the managers, while repeating some report language for emphasis, does not intend to negate the language referred to above unless expressly provided herein.

In cases in which the House or the Senate have directed the submission of a report, such report is to be submitted to both the House and Senate Committees on Appropriations.

TITLE IV DOMESTIC FOOD PROGRAMS

FOOD AND NUTRITION SERVICE
Child Nutrition Programs
(including transfers of funds)

For necessary expenses to carry out the National School Lunch Act (42 U.S.C. 1751 et seq.), except section 21, and the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.), except sections 17 and 21; \$9,541,539,000, to remain available through September 30, 2002, of which \$4,413,960,000 is hereby appropriated and \$5,127,579,000 shall be derived by transfer from funds available under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c): Provided, That except as specifically provided under this heading, none of the funds made available under this heading shall be used for studies and evaluations: Provided further, That of the funds made available under this heading, up to \$6,000,000 shall be for school breakfast pilot projects, including the evaluation required under section 18(e) of the National School Lunch Act: Provided further, That of the funds made available under this heading, \$500,000 shall be for a School Breakfast Program startup grant pilot program for the State of Wisconsin: **Provided further, That school food authorities in Ohio participating in a domestic food assistance program administered by the Secretary and preparing meals for use by other schools and institutions also participating in a domestic food assistance program, shall, with regard to such meals, not be subject to additional requirements under section 301(c) of the Federal Meat Inspection Act or section 5(c) of the Poultry Products Inspection Act:** Provided further, That up to \$4,511,000 shall be available for independent verification of school food service claims.

House Directives and Language

The Committee believes that agency managers must have an understanding of the establishments that the agency regulates, which necessarily requires the occasional observation of operations in an inspected establishment. The Committee expects all appropriate senior personnel of the agency, specifically senior personnel in the Field Operations, the Public Health and Science and the Policy and Program Development and Evaluation offices, to become HACCP certified and to observe operations in the range of establishments inspected by the agency at least annually. The agency is directed to provide the Committee a report no later than March 1, 2001 listing these senior personnel (GS 14 and above), the date on which they have become HACCP certified and the date and type of establishment in which they have observed operations.

FSIS has a plan to better utilize available inspection personnel through implementation of daily, unscheduled inspection in processing establishments. The Committee expects the Agency to make full use of its authority to ensure that inspection resources are rationally dedicated to address relative food safety risks and to avoid the disruptive effect of continued inspector shortages. To further these objectives, the Agency is expected to evaluate greater flexibility in requirements for frequency of unscheduled inspection and other possible means of enhancing the efficiency of inspection in processing establishments. FSIS should report its findings to the Committee by January 31, 2001.

The Committee remains concerned that the Food Safety and Inspection Service has not finished removing or revising those meat and poultry inspection regulations inconsistent with the HACCP-based inspection system. The agency has missed self-imposed deadlines for completing this project, and the Committee believes the accomplishments in this area, as cited in testimony and correspondence, are not as extensive as they should be. Accordingly, the Committee directs FSIS to prepare by March 1, 2001, a report listing every meat and poultry inspection regulation in place prior to publication of the Pathogen Reduction/HACCP rule, the agency's determination of whether each regulation should be revised or removed in the wake of HACCP implementation and the agency's proposed date for completing that revision or removal.

The Inspector General is directed to undertake an investigation of the adequacy of Food Safety and Inspection Service financial management and project management, as well as the adequacy of management controls in those areas. The Committee directs the Inspector General to provide a preliminary report no later than March 1, 2001. The investigation should ascertain what deficiencies resulted in recent inspector shortages and why Anti-Deficiency Act violations occurred over the last two years.

Senate Directives and Language

The Committee remains concerned that FSIS has not finished removing or revising those meat and poultry inspection regulations inconsistent with the Hazard Analysis Critical Control Point (HACCP) based inspection system. The agency has missed self imposed deadlines for completing this project, and the Committee believes the accomplishments in this area are not as extensive as they should be. Accordingly, the Committee directs FSIS to prepare by November 1, 2000, a report listing every meat and poultry inspection regulation in place prior to publication of the Pathogen Reduction/HACCP rule, the agency's determination of whether each regulation should be revised or removed in the wake of HACCP implementation, and the agency's proposed date for completing that revision or removal.

The amount provided assumes savings proposed in the budget of \$4,000,000 upon implementation of daily, unscheduled processing inspection. This proposal will allow FSIS to better utilize available inspection personnel. The Committee expects the Agency to make full use of its authority to ensure that inspection resources are rationally dedicated to address relative food safety risks and to avoid the disruptive effect of continued inspector shortages. To further these objectives, the Agency should evaluate greater flexibility in requirements for frequency of unscheduled inspection and other possible means of enhancing the efficiency of inspection in processing establishments. FSIS should report its findings to the Committee by January 31, 2001.

The Committee believes that agency managers should have an understanding of the establishments the agency regulates, which necessarily requires the occasional observation of operations in an inspected establishment. The Committee expects senior policy development personnel of the Field Operations and Policy, the Public Health and Science and the Program Development and Evaluation offices to become HACCP certified and to observe operations in the range of establishments inspected by the agency at least semi-annually. The agency is directed to provide the Committee a report, no later than March 1, 2001, listing the senior personnel (GS 14 and above), the date on which they become HACCP certified, and the date and type of establishment in which they have observed operations.

TITLE VII--GENERAL PROVISIONS

Sec. 705. New obligational authority provided for the following appropriation items in this Act shall remain available until expended: Animal and Plant Health Inspection Service, the contingency fund to meet emergency conditions, fruit fly program, integrated systems acquisition project, boll weevil program, up to 25 percent of the screwworm program, and up to \$2,000,000 for costs associated with collocating regional offices; **Food Safety and Inspection Service, field automation and information management project;** funds appropriated for rental payments; Cooperative State Research, Education, and Extension Service, funds for competitive research grants (7 U.S.C. 450i(b)), funds for the Research, Education and Economics Information System (REEIS), and funds for the Native American Institutions Endowment Fund; Farm Service Agency, salaries and expenses funds made available to county committees; Foreign Agricultural Service, middle-income country training program and up to \$2,000,000 of the Foreign Agricultural Service appropriation solely for the purpose of offsetting fluctuations in international currency exchange rates, subject to documentation by the Foreign Agricultural Service.

Sec. 713. Notwithstanding chapter 63 of title 31, United States Code, marketing services of the Agricultural Marketing Service; the Grain Inspection, Packers and Stockyards Administration; the Animal and Plant Health Inspection Service; and the **food safety activities of the Food Safety and Inspection Service may use cooperative agreements to reflect a relationship between the** Agricultural Marketing Service; the Grain Inspection, Packers and Stockyards Administration; the Animal and Plant Health Inspection Service; or the **Food Safety and Inspection Service and a state or cooperator to carry out** agricultural marketing programs, to carry out programs to protect the nation's animal and plant resources, or to carry out **educational programs or special studies to improve the safety of the nation's food supply.**

Sec. 716. Of the funds made available by this Act, not more than \$1,800,000 shall be used to cover necessary expenses of activities related to all advisory committees, panels, commissions, and task forces of the Department of Agriculture, except for panels used to comply with negotiated rule makings and panels used to evaluate competitively awarded grants.

Sec. 717. None of the funds appropriated by this Act may be used to carry out section 410 of the Federal Meat Inspection Act (21 U.S.C. 679a) or section 30 of the Poultry Products Inspection Act (21 U.S.C. 471).

Sec. 718. No employee of the Department of Agriculture may be detailed or assigned from an agency or office funded by this Act to any other agency or office of the Department for more than 30 days unless the individual's employing agency or office is fully reimbursed by the receiving agency or office for the salary and expenses of the employee for the period of assignment.

Sec. 719. None of the funds appropriated or otherwise made available to the Department of Agriculture shall be used to transmit or otherwise make available to any non-Department of Agriculture employee questions or responses to questions that are a result of information requested for the appropriations hearing process.

Sec. 720. None of the funds made available to the Department of Agriculture by this Act may be used to acquire new information technology systems or significant upgrades, as determined by the Office of the Chief Information Officer, without the approval of the Chief Information Officer and the concurrence of the Executive Information Technology Investment Review Board: Provided, That notwithstanding any other provision of law, none of the funds appropriated or otherwise made available by this Act may be transferred to the Office of the Chief Information Officer without the prior approval of the Committees on Appropriations of both Houses of Congress.

Sec. 721. (a) None of the funds provided by this Act, or provided by previous Appropriations Acts to the agencies funded by this Act that remain available for obligation or expenditure in fiscal year 2001, or provided from any accounts in the Treasury of the United States derived by the collection of fees available to the agencies funded by this Act, shall be available for obligation or expenditure through a reprogramming of funds which: (1) creates new programs; (2) eliminates a program, project, or activity; (3) increases funds or personnel by any means for any project or activity for which funds have been denied or restricted; (4) relocates an office or employees; (5) reorganizes offices, programs, or activities; or (6) contracts out or privatizes any functions or activities presently performed by Federal employees; unless the Committees on Appropriations of both Houses of Congress are notified 15 days in advance of such reprogramming of funds. (b) None of the funds provided by this Act, or provided by previous Appropriations Acts to the agencies funded by this Act that remain available for obligation or expenditure in fiscal year 2001, or provided from any accounts in the Treasury of the United States derived by the collection of fees available to the agencies funded by this Act, shall be available for obligation or expenditure for activities, programs, or projects through a reprogramming of funds in excess of \$500,000 or 10 percent, whichever is less, that: (1) augments existing programs, projects, or activities; (2) reduces by 10 percent funding for any existing program, project, or activity, or numbers of personnel by 10 percent as approved by Congress; or (3) results from any general savings from a reduction in personnel which would result in a change in existing programs, activities, or projects as approved by Congress; unless the Committees on Appropriations of both Houses of Congress are notified 15 days in advance of such reprogramming of funds. (c) The Secretary of Agriculture shall notify the Committees on Appropriations of both Houses of Congress before implementing a program or activity not carried out during the previous fiscal year unless the program or activity is funded by this Act or specifically funded by any other Act.

Sec. 729. Hereafter, none of the funds appropriated by this Act or any other Act may be used to: (1) carry out the proviso under 7 U.S.C. 1622(f); or (2) carry out 7 U.S.C. 1622(h) unless the Secretary of Agriculture inspects and certifies agricultural processing equipment, and imposes a fee for the inspection and certification, in a manner that is similar to the inspection and certification of agricultural products under that section, as determined by the Secretary: **Provided, That this provision shall not affect the authority of the Secretary to carry out the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).**

Sec. 752. Effective 180 days after the date of the enactment of this Act and continuing for the remainder of fiscal year 2001 and each subsequent fiscal year, establishments in the United States that slaughter or process birds of the order Ratitae, such as ostriches, emus and rheas, and squab, for distribution in commerce as human food shall be subject to the ante mortem and post mortem inspection, reinspection, and sanitation requirements of the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) rather than the voluntary poultry inspection program of the Department of Agriculture under section 203 of the Agricultural Marketing Act of 1946 (7 U.S.C. 1622).

Sec. 753. In developing a rule concerning on-farm standards for prevention of Salmonella Enteritidis in shell eggs pursuant to any plan to eliminate Salmonella Enteritidis illnesses due to eggs, the Food and Drug Administration shall-- (a) consider one environmental test per laying cycle for each layer house for verification of the producer's Salmonella Enteritidis reduction plan; (b) consider when it is appropriate to require diversion of shell eggs to treatment, such as pasteurization, and base any requirement for testing that would necessitate diversion, which may include the receipt of a positive egg test result, on sound science; (c) conduct or support research to develop cost-effective and improved tests for determination of Salmonella Enteritidis ; and (d) solicit comments on appropriate options for implementing a Salmonella Enteritidis reduction plan in shell eggs, including comments on conducting and funding testing, through state and federal programs.

TITLE VI--RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Salaries and Expenses

The conferees expect FDA to make final the regulations regarding labeling of irradiated foods by March 1, 2002, and report to the House and Senate Committees on Appropriations on the status by November 15, 2000. This agreement changes the dates proposed for final regulations by the House of September 30, 2001, and by the Senate of October 30, 2001.

Status of FY2001 FSIS Congressional Reports

Name and Description of Report/Assigning Bill	Date Assigned/ Author	Other Agencies Involved	Date Due to Congress	Clearance Due Dates/ Current Status
<p><u>1. Quarterly Updates on Budget Execution and Analysis of Staffing and Recruitment:</u> The conference report to the FY2001 appropriations bill directs the Agency to continue to provide the Quarterly Report on Budget Execution and Staffing.</p>	<p>October 28, 2000 Ray Bolyard</p>		<p>Quarterly to the House and Senate Appropriations Committees Beginning date: February 1, 2001</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>
<p><u>2. Regulations Prior to HACCP:</u> The conference report to the FY2001 appropriations bill directs the Agency to prepare a report on meat and poultry inspection regulations in place prior to publication of the HACCP Rule.</p>	<p>October 28, 2000 Judy Riggins</p>		<p>March 1, 2001 to the House and Senate Appropriations Committees</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>
<p><u>3. Ratite and Squab Inspection:</u> The conference report to the FY2001 appropriations bill directs effective 180 days after the date of the enactment of this Act and continuing for the remainder of FY01 and each subsequent FY, the PPIA is amended to include ratites and squab under mandatory inspection.</p>	<p>October 28, 2000 Judy Riggins/ John McCutcheon/ Kaye Wachsmuth</p>		<p>180 days after the date of the enactment of this Act (April 26, 2001) Letter to be sent on or about Dec. 1, 2000 to let Congress know the status.</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>

Name and Description of Report/Assigning Bill	Date Assigned/ Author	Other Agencies Involved	Date Due to Congress	Clearance Due Dates/ Current Status
<p>4. <u>National Advisory Committee on Microbiological Criteria for Foods:</u> The conference report to the FY2001 appropriations bill directs the Secretaries of Ag and HHS to:</p> <ul style="list-style-type: none"> • (1) appoint a number of members consistent with FDA and EPA scientific advisory committees; • (2) adhere strictly to applicable Federal conflict-of-interest requirements for Federal advisory committee membership; and • (3) report to the House and Senate Committees on Agriculture and Appropriations and the Secretaries of Ag and HHS on any conflicts of interest of NACMCF members involved in making recommendations to Federal agencies, whether waived under applicable Federal law or not, and what those conflicts are. 	<p>October 28, 2000</p> <p>Carol Maczka/ Mark Leking</p>	<p>HHS</p>	<p>Report "any conflicts of interest of NACMCF members involved in making recommendations to Federal agencies, whether waived under applicable Federal law or not, and what those conflicts are" to the House and Senate Agriculture and Appropriations Committees and to the Secretaries of Ag and HHS</p> <p>No date given</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>

Name and Description of Report/Assigning Bill	Date Assigned/ Author	Other Agencies Involved	Date Due to Congress	Clearance Due Dates/ Current Status
<p>5. <u>Microbiological Performance Standards:</u> The conference report to the FY2001 appropriations bill directs the Agency to provide a report to be prepared by the NACMCF regarding microbiological performance standards, including the role of such standards as a means of assuring meat and poultry product safety, as well as such other considerations as the Committee deems appropriate.</p>	<p>October 28, 2000 Eli Walker</p>		<p>March 1, 2001 to the House and Senate Appropriations Committees Letter to be sent on or about Dec. 1, 2000 to let Congress know the status.</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>
<p>6. <u>Microbiological Criteria:</u> The conference report to the FY2001 appropriations bill directs the Agency to provide \$500,000 to the National Research Council for an evaluation; at the earliest date practicable, by the National Research Council of the role of scientifically determined criteria, including microbiological criteria, in the production and regulation of meat and poultry products.</p>	<p>October 28, 2000 Eli Walker</p>	<p>National Research Council</p>	<p>“earliest date practicable” to the House and Senate Appropriations Committees</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>

Name and Description of Report/Assigning Bill	Date Assigned/ Author	Other Agencies Involved	Date Due to Congress	Clearance Due Dates/ Current Status
<p>7. HACCP Certification: The House and Senate reports to the FY2001 appropriations bill directs FSIS to prepare a list of:</p> <ul style="list-style-type: none"> • all FSIS personnel GS-14 and above in FO, OPHS, and OPPDE; • the date on which they became HACCP certified; and • the date and type of establishment in which they have observed operations. 	<p>October 28, 2000 John McCutcheon/ Vincent Fayne</p>		<p>March 1, 2001 to the House and Senate Appropriations Committees (In both Reports but not in the Conference Report)</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>
<p>8. Unscheduled Inspection: The House and Senate reports to the FY2001 appropriations bill directs FSIS to report its findings on the daily, unscheduled inspection in processing establishments and an evaluation of the expected greater flexibility and efficiency with this program.</p>	<p>October 28, 2000 Jane Roth</p>		<p>January 31, 2001 to the House and Senate Appropriations Committees (In both Reports but not in the Conference Report)</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>

Name and Description of Report/Assigning Bill	Date Assigned/ Author	Other Agencies Involved	Date Due to Congress	Clearance Due Dates/ Current Status
<p>9. <u>OIG Financial Management Review:</u> The House report to the FY2001 appropriations bill directs the IG to undertake an investigation of the adequacy of the FSIS financial management and project management, as well as the adequacy of management controls in those areas. The investigation should ascertain what deficiencies resulted in recent inspector shortages and why Anti-Deficiency Act violations occurred over the last two years.</p>	<p>October 28, 2000 Jeanne Axtell/OIG</p>	<p>OIG</p>	<p>March 1, 2001 to the House and Senate Appropriations Committee</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>
<p>10. <u>Irradiation:</u> The conference report to the FY2001 appropriations bill expect FDA to make final the regulations regarding labeling of irradiated foods.</p>	<p>October 28, 2000 FDA</p>	<p>FDA</p>	<p>Status: November 15, 2000 Final Rule: March 1, 2002 (House Report 9-30-01 and Senate Report 10-30-01)</p>	<p>Agency: Under Sec: Department: Other Agencies: OMB: Final:</p>

Release No. 0072.95

Mary Dixon (202) 720-4623
Jacque Knight (202) 720-9113

USDA UNVEILS SWEEPING NEW FOOD SAFETY PROPOSALS

WASHINGTON, Jan. 31, 1995--The U.S. Department of Agriculture today proposed sweeping changes in federal meat and poultry inspection, from a system based primarily on sight, touch and smell to one incorporating scientific testing and systematic prevention of contamination.

"These reforms demonstrate this administration's strong commitment to making meat and poultry safer for consumers," said Acting Secretary Richard Rominger at a press conference announcing a thorough modernization of USDA's food safety procedures.

"In keeping with the President's initiative to reform the way the federal government does business, we propose to reinvent the meat and poultry inspection system by incorporating science-based concepts to make our food supply safer. This initiative is not about more regulation. It's about better, more sensible regulation."

"We are proposing a system that would directly target and reduce harmful bacteria and build prevention of foodborne illness into meat and poultry inspection," said Michael R. Taylor, the acting under secretary for Food Safety and administrator of USDA's Food Safety and Inspection Service (FSIS).

"These proposals mark a fundamental shift. They are targeted to improve the safety of meat and poultry products by directly addressing the pathogenic microorganisms that cause most food-related illnesses and by increasing our ability to ensure that all meat and poultry companies follow sound food safety procedures," Taylor said.

The proposal would require the nation's nearly 6,200 federally inspected meat and poultry slaughter and processing plants to adopt science-based process control systems, called Hazard Analysis and Critical Control Points (HACCP). The HACCP systems would identify potential food safety hazards arising in slaughter and processing plants and build in science-based preventive controls. USDA's food safety proposals would also affect about 2,900 state inspected plants and foreign meat and poultry inspection programs, which under current law must be equivalent to the U.S. system.

Under the HACCP proposal, industry would verify the effectiveness of their operations by continuous monitoring of the controls, end product testing and careful record keeping. FSIS, the agency responsible for designing and carrying out USDA's food safety program, would review each plant's records and conduct other in-plant inspection activities to verify that proper food safety procedures are being followed.

For the first time, targets would be set for reducing the incidence of contamination of raw meat and poultry products with harmful bacteria. Plants that do not achieve established targets for pathogen reduction within a specified time would be required to take corrective action under FSIS supervision to achieve the target.

The proposal would require slaughter plants to test raw products initially for Salmonella, a pathogenic bacteria that is the most common cause of foodborne illness in the United States. The proposal includes identifying the current baseline incidence of Salmonella contamination for each major

species and for ground meat and poultry. Slaughter plants would be required to reduce contamination to a level determined after FSIS reviews comments on the proposed rule. The proposal would require bacterial testing 90 days after publication of the final rule.

"The HACCP system clearly establishes the meat and poultry industry's responsibility for improving the safety of their products, and the interim targets will help achieve measurable progress toward pathogen reduction even as we develop our HACCP program," said Taylor, who was appointed the administrator of the Food Safety and Inspection Service in August and in October was named to the new position of acting under secretary for food safety.

"Our proposals will stimulate the innovative capacity of the meat and poultry industry to produce safer products," Taylor added. To facilitate the innovations, FSIS is reviewing its existing food safety regulations and will delete requirements that are obsolete or unnecessarily inhibit the incorporation of science-based preventive controls into meat and poultry production systems.

The new proposal also includes basic food safety procedures that Taylor says many plants have already implemented, including written sanitation plans, antimicrobial treatments and strict temperature controls for raw products.

USDA estimated the total implementation cost of the proposal to the meat and poultry industry at \$733.5 million over three years, or an average of \$244.5 million per year. Yearly public health benefits from reduced foodborne illness costs, including medical care and lost work time, would range from \$990 million to \$3.7 billion. These costs amount to slightly more than two tenths of a cent per pound.

According to Rominger and Taylor, the proposals to improve in-plant food safety procedures are part of a broad USDA food safety strategy that will stress preventive measures throughout the food chain.

"We will be working cooperatively with the producer community to find and implement solutions to food safety problems on the farm, and we will work jointly with FDA to ensure that appropriate food safety controls are in place during the transportation process," Taylor said. "We are also expanding our collaboration with the states to improve food safety at the retail level."

Noting that consumers also share the responsibility for the safety of their food, Taylor added, "As USDA works to do a better job to protect consumers, it is critical that consumers do their part by properly handling and cooking meat and poultry products."

FSIS plans extensive public outreach during the 120-day comment period to explain and receive comments on the proposal.

"It is only with the ideas, views and input of all interests that we can develop the best inspection system possible. We want to stimulate dialogue and draw out informed and constructive comments so we can make this proposed rule effective and workable. All parties, government and industry, consumers and the scientific community, need to work together to improve the safety of meat and poultry," Taylor said.

The proposed USDA HACCP/Pathogen Reduction rule is scheduled to be published in the Feb. 3 Federal Register. Comments will be accepted through June 5. Comments can be sent to: Policy, Evaluation and Planning Office, Attn: Diane Moore, FSIS Docket Clerk, Room 3171-South Building, Food Safety

and Inspection service, U.S. Department of Agriculture, Washington, D. C. 20250.

The USDA proposals for HACCP and pathogen reduction are the latest steps taken by the Administration to strengthen and update the federal inspection program for meat and poultry products. Initiatives since January 1993 include:

- started unannounced reviews in 1,000 meat and poultry plants,
- implemented mandatory safe cooking and handling instruction on labels of meat and poultry products,
- increased funding for food safety research,
- elevated food safety to a sub-cabinet level at USDA,
- declared E.coli O157:H7 in raw ground beef an illegal adulterant,
- initiated a sampling program for raw ground beef, and
- streamlined approval of antimicrobial treatments for use by industry.

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Clinton Administration Accomplishments in Food Safety

Release No. 0035.98

Johna Pierce (202) 720-4623
johna.pierce@usda.gov
Tom Amontree (202) 720-4623
tom.amontree@usda.gov

Clinton Administration Accomplishments in Food Safety

October, 1997. President Clinton announces new initiative to enhance FDA oversight over imported foods and to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

October, 1997. Administration announces public-private partnership to promote food safety education, that includes the "Fight BAC" campaign.

May, 1997. President announces comprehensive new initiative to improve the safety of the nation's food supply -- "Food Safety from Farm to Table"-- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

January, 1997. President announces new Early Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems.

January, 1997. Administration requires generic E.coli testing for all meat and poultry slaughter plants and Sanitation Standard Operating Procedures.

August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

July, 1996. President announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. The HACCP systems approach emphasizes science based controls and microbiological testing directly targeted at E. coli O157:H7 and Salmonella.

December, 1995. Administration issues new rules to ensure the safety of seafood using the HACCP regulatory approach.

October, 1994. Administration declares E.coli O157:H7 an adulterant in raw ground beef and initiates a nationwide sampling program in federally inspected plants and retail stores that process ground beef.

March, 1994. Administration requires safe handling and cooking instructional labels on raw meat and poultry products.

January 26, 1998

Release No. 0362.96

Johna Pierce (202) 720-4623
Jacque Knight (202) 720-9113

PRESIDENT CLINTON ANNOUNCES NEW FOOD SAFETY RULES TO PROTECT CONSUMERS

WASHINGTON, July 6, 1996--President Bill Clinton today announced sweeping reform of federal food safety rules for meat and poultry. The new rules will modernize a 90-year-old inspection program and fulfill the Clinton administration's broad commitment to protecting the public's health by improving food safety.

The rules replace a system based on sight and smell with more scientific methods and will, for the first time, require plants that slaughter and process meat and poultry to target and reduce harmful bacteria on their products.

President Clinton said, "Our families have every right to expect that the food they serve their children is safe. They have every right to expect that the world's most bountiful food supply would be the world's safest. We have a national responsibility to protect the safety of the food we eat. We have learned that we must all be vigilant."

"This regulation updates a 90-year-old system for meat and poultry inspection developed before many of our grandparents were even born," said Agriculture Secretary Dan Glickman at a White House press conference. "Today, consumers purchasing meat and poultry inspected by USDA will have the assurance that their food has been inspected using the most modern, the most scientific methods available.

"This is the fundamental change in meat and poultry inspection called for by the National Academy of Sciences and many other experts throughout government, industry, and the consumer community," Glickman said. "The power of the new HACCP-based food safety system is that it scientifically targets the important hazards and builds the public health principle of prevention into every meat and poultry production process."

The four major elements of the new rules are:

- Hazard Analysis and Critical Control Points (HACCP, an acronym pronounced "HAS-SIP") -- Every plant must adopt and carry out its own HACCP plan that systematically addresses all the significant hazards associated with its products. The effectiveness of the HACCP plan must be demonstrated by the plant and will be continually verified by inspectors from USDA's Food Safety and Inspection Service.
- Mandatory E.coli testing in slaughter plants -- Every slaughter plant must regularly test carcasses for generic E. coli to verify the effectiveness of the plant's procedures for preventing and reducing fecal contamination, which is the major source of contamination with harmful bacteria like E.coli 0157:H7 and Salmonella. Generic E.coli is the best microbial indicator of the process control of fecal contamination.
- Pathogen Reduction Performance Standards for Salmonella -- All slaughter plants and plants producing raw ground products must ensure that their Salmonella contamination rate is below the current national baseline incidence. This first ever regulatory

performance standard for a pathogen on raw meat and poultry will ensure real progress in reducing harmful bacteria. USDA will begin comprehensive Salmonella testing this summer and enforce the Salmonella standards in conjunction with implementation of HACCP.

- Sanitation Standard Operating Procedures (SOPs) -- As the foundation for HACCP, every plant must adopt and carry out a written plan for meeting its sanitation responsibilities. Effective sanitation in slaughter and processing plants is essential to preventing direct adulteration of meat and poultry products.

The new system will be phased in beginning this summer with USDA's Salmonella testing program, followed early next year by implementation of the sanitation SOP and E. coli testing requirements. The HACCP system will be implemented first in the larger meat and poultry plants, with 75 percent of slaughter production to be under HACCP-based process control and subject to Salmonella performance standards within 18 months. Small plants will have 30 months to comply with HACCP, and very small plants (ones having fewer than 10 employees or less than \$2.5 million in annual sales) will have 42 months.

"We will make the transition to the new system as rapidly as possible," said Michael R. Taylor, Acting Under Secretary for Food Safety. "Our implementation schedule takes into account both the public health importance of the new rules and the time it will take to bring about such fundamental changes within our own program and within an enormously complex and diverse industry."

USDA estimates that as many as 4,000 deaths and 5,000,000 illnesses result annually from the consumption of meat and poultry contaminated with four major bacterial pathogens: Salmonella, Campylobacter, E.coli O157:H7, and Listeria monocytogenes.

The new rules apply to over 6,200 slaughter and processing plants that operate under federal inspection. The same or equivalent requirements will apply to state-inspected meat and poultry plants and to foreign plants that export to the United States.

"We cannot totally eliminate harmful bacteria. People will still have to properly handle and cook their fresh meat and poultry," said Taylor. "Our new system will substantially reduce harmful contamination and reduce the risk of illness for American consumers."

The FSIS "farm-to-table" food safety strategy for meat and poultry also includes collaboration with the Food and Drug Administration to set and enforce standards designed to minimize growth of harmful bacteria during transportation and storage. The strategy calls for cooperation between state and Federal food safety agencies to improve food safety standards and practices in retail and food service establishments, such as restaurants and grocery stores.

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Editor's Note: In December 1995, the Food and Drug Administration adopted rules to require HACCP systems in the seafood processing industry. In January 1996, Vice President Gore's National Performance Review reported on the administration's comprehensive effort to reform and improve food regulation.

USDA news releases and media advisories are available on the Internet. Access the USDA Home Page on the World Wide Web at <http://www.usda.gov>

Release No. 0268.93

Steve Kinsella (202) 720-4623
Mary Dixon (202) 720-4623

MEAT INSPECTION BIG WINNER IN USDA BUDGET PROPOSAL

WASHINGTON, April 9--Funds for USDA meat inspection operations were increased by \$18 million in President Clinton's 1994 budget proposal, said Secretary of Agriculture Mike Espy.

"We are putting an additional \$10 million into this budget to hire more meat inspectors and an additional \$8 million to fund our Pathogen Reduction Strategy," Espy said.

Espy, who took office during the E. coli outbreak in the western states, said the increased funding in this area demonstrates that "our FY 94 budget proposal doesn't just call for business as usual. We must develop new scientific ways to inspect our meat supply to ensure that our families can continue to benefit from the safest food supply in the world."

The \$10 million provides funding for 200 additional meat inspectors.

The additional \$8 million for the Pathogen Reduction Strategy will use a battery of scientific techniques to reduce the likelihood of harmful microorganisms entering the food supply at key points throughout the production, distribution and consumption chain.

Espy said that in pursuing this new strategy, "USDA will be making a decisive break with the past.

"In the future USDA will not wait for pathogens to become a problem; nor will it be satisfied with holding the line against contamination: USDA will strive to reduce contamination from the farm to the table."

Espy added, "Since being sworn in, I've traveled all across America...in my travels I have found that people all across rural America and elsewhere support President Clinton because he represents change...Well, this budget represents change."

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Steve Kinsella (202) 720-4623
Mary Dixon (202) 720-4623

ESPY SAYS NOT-READY-TO-EAT MEAT AND POULTRY TO HAVE CARE & HANDLING LABELS

WASHINGTON, Aug. 11 -- Secretary of Agriculture Mike Espy today said that all raw and partially-cooked meat and poultry products will soon have a label outlining care and handling instructions.

"When you and I go to the grocery store, we will see this new handling and cooking label on not-ready-to-eat meat and poultry packages. Through the new labeling effort, we hope to increase consumer awareness of safe food practices for controlling bacterial growth and that consumers will follow the safe handling instructions to protect themselves and family members from food-borne pathogens," said Espy.

"I want to make it clear, we are not relinquishing USDA from its responsibility of inspecting the nation's meat supply. USDA has an important responsibility as meat and poultry moves from the farm to the table. And we need to do much better than in the past. But I know it is also our responsibility to keep the consumer informed and to pass on to the consumer helpful information so they can protect themselves and their families."

Under the new USDA rule, manufacturers and retailers must label all not-ready-to-eat meat and poultry products. The care and handling instructions must accompany each product and must appear either on the principal display panel or the information panel of the product label.

The new labels that will appear on product in grocery stores required by USDA show four care and handling instructions and illustrations: 1) how to safely store and thaw raw products; 2) how to avoid cross-contamination; 3) cooking instructions; and 4) how to store leftovers.

Though today's announcement outlined an interim final rule, only comments that come in during the first 30 days of publication of the rule will be considered. However, the labels will be mandatory after 60 days.

"Our goal is to improve public awareness about the necessity of safe food handling," Espy said. "Until we have rapid tests to detect the presence of unseen harmful bacteria or vaccines to prevent the occurrence of bacteria in food animals, we must do everything we can to help inform consumers about proper preparation and storage of not-ready-to-eat meat and poultry."

Today's announcement marks another step by Espy to improve the meat and poultry inspection system at USDA.

On Feb. 5, Espy announced plans for a USDA pathogen reduction program for meat and poultry that included the mandating of safe-handling instructions on raw meat and poultry labels. He has also ordered special unannounced reviews of meat and poultry plants throughout the country.

Espy, who took office the same week the E. coli outbreak in the western states was reported to USDA, has said he is directing USDA "to reinvent and rethink every aspect of meat inspection."

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Release No. 0815.93

(Joint Release by the U.S. Environmental Protection Agency, Food and Drug Administration and U.S. Department of Agriculture)

Tuesday, September 21, 1993

**CLINTON ADMINISTRATION PROPOSES STRENGTHENING THE NATION'S
PESTICIDE AND FOOD SAFETY LAWS**

USDA - Tom Amontree (202)720-4623

EPA - Al Heier (202)260-4374

FDA - Brad Stone (202)205-4144

The Clinton Administration today proposed comprehensive reforms of the nation's pesticide and food safety laws to reduce the risks pesticides pose to Americans, especially infants and children. The reforms were presented at a joint House and Senate committee hearing by the Environmental Protection Agency, the United States Department of Agriculture and the Food and Drug Administration.

The reform package represents the first significant, realistic attempt to improve and update the nation's food safety and pesticides laws in the last 20 years. It stems from the three agencies' joint commitment earlier this year to seek the reforms, which contain specific provisions to protect infants and children, as well as incentives to achieve a real reduction in the use of pesticides in the United States.

The Administration's reform package will:

Extend the strict FDA health-based standard of a "reasonable certainty of no harm" for food safety across the board for all pesticide treated foods, including raw fruit and vegetables.

Initiate a USDA-EPA one year project to establish commodity specific pesticide use reduction goals to be met by 2000.

Require that most high risk pesticides meet the safety standard within three years and all other pesticides meet the standard within seven years.

Eliminate the consideration of economic benefits in the pesticide review and approval process, except in exceptional cases involving significant disruption of the food supply and even then the benefit consideration would be limited to only five years.

Mandate that EPA issue specific findings that a tolerance is safe for infants and children.

Make it easier to remove from the market pesticides suspected of posing a risk to health and the environment and make lower-risk pesticides a top priority in the approval process.

Significantly enhance the enforcement provisions of existing laws for violations of statutes and regulations.

Establish a national goal for use of Integrated Pest Management (IPM).

Prohibit the export of pesticides that have been banned or voluntarily withdrawn in the United States because of health concerns.

Protect farm workers from the hazards of working with pesticides.

"Today's proposal is a giant step toward protecting all Americans--especially our children--from the risks of harmful pesticides on the foods we eat," said Carol M. Browner, EPA Administrator. "For the first time ever, the federal government is breaking the logjam of competing and vested interests to ensure that Americans will be able to rely on a single, rigorous standard for food safety."

Secretary of Agriculture Mike Espy said, "This proposal for meaningful pesticide reform is another good example of the interagency cooperation under the Clinton Administration. It is a significant step forward as we continue our effort to make the world's safest food supply even safer. The agreement also protects the environment and public health, while maintaining the economic viability of the American farmer."

"The time has come to streamline and modernize our pesticide laws," said FDA Commissioner David A. Kessler, M.D. "The shift we have proposed to a strict health-based standard for all pesticide residues represents real food safety reform."

Under this proposal, EPA for the first time must identify--within six months--all pesticide-residue levels on foods that may exceed the safety standard. Within three years, regulatory action must be taken against the highest risk pesticides. Within seven years, EPA must officially have reviewed all pesticide-residue levels, or tolerances, to ensure that all foods are safe from unacceptable risks from pesticides.

The legislative proposals call for setting tolerances or allowable pesticide residues at levels that ensure a "reasonable certainty of no harm to consumers of food," the same strict standard FDA applies to food additives today and the same standard recommended by the National Academy of Sciences.

The proposal also calls for a seven year phase-out of all pesticides that do not meet the "no harm" standard. If the pesticide is a potential carcinogen, the residue can pose no more than a negligible risk.

Currently the negligible risk standard is interpreted to mean that the increase in risk above the background cancer risk is no greater than one in one million persons exposed over a 70 year lifetime. Because of the conservative nature of risk assessment, in reality this means the risk consumers actually face will likely be far less. Only in exceptional cases involving indispensable consumer benefits would EPA have the authority to set time-limited tolerances (up to five years) that exceed negligible risk.

The Administration called for reducing the use of high-risk pesticides, particularly through increased use of IPM techniques, which utilize a combination of agricultural practices such as crop rotation, cultivation of predator insects, biological pesticides, and other practices, together with judicious and limited chemical pesticide use. By the year 2000, the Administration's goal is that 75% of all farms will use integrated pest management (IPM) techniques that reduce pesticide use.

The Administration's proposals recognize that infants and children may receive greater exposure to pesticide residues because they consume more food for their size than adults. Other provisions call for more comprehensive surveys of food consumed by children of all ages, races and geographic areas. Under the proposals, EPA and USDA would more accurately identify the foods children eat in large quantities and to focus on child safety when setting tolerances for these foods.

Some of the other major proposals include:

- provisions for giving greater priority to safer and reduced-risk pesticides;

- a requirement to "sunset" all pesticide registrations every 15 years to ensure they either meet the public health standards or are automatically cancelled;

- a phase down and phase out of those pesticide uses which credible science indicates may pose a significant risk to the public or the environment;

- authority to suspend the immediate use of a pesticide in the face of significant potential risks without also having to take simultaneously a time-consuming cancellation action;

- incentives to the pesticide industry to support the continued registration of lower-risk pesticides for use on minor crops; and

- expedited cancellation procedures, which currently can take

up to five or more years to remove a pesticide from the market.

The three agencies presented their testimony before a joint hearing of the Senate Committee on Labor and Human Resources and the House Subcommittee on Health and the Environment.

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