

President's Council on Food Safety



U.S. Department
of Agriculture



Department of Health
and Human Services



Environmental
Protection Agency



Department
of Commerce

President's Council on Food Safety

Assessment of the NAS Report

Ensuring Safe Food from Production to Consumption

Executive Summary
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Executive Summary

Americans have one of the world's safest food supplies. This is largely a result of sustained regulatory and education programs along the farm to table continuum as well as surveillance and research efforts. The federal food safety system, comprised of multiple agencies, is authorized by a diverse set of statutes and is supported by numerous key partnerships with state, local, and tribal governments. Together these agencies have created a system that has given U.S. consumers confidence in the safety of their food purchases.

As good as the nation's food safety system is, there is room for improvement. Illnesses and deaths due to contaminated food, while preventable, continue to cause considerable human suffering and economic loss. That is why, at the very beginning of his first term, President Clinton set a course to strengthen the nation's food safety system. Under the President's leadership, surveillance and research have dramatically increased, programs are better coordinated, and regulations are more prevention-oriented and science-based. But this is only the beginning. The Council on Food Safety, with the help of the public, will continue to identify problems and promote solutions.

The Council welcomes the findings and recommendations provided by the National Academy of Sciences in its August 1998 report *Ensuring Safe Food From Production to Consumption*. This report lays out a clear rationale for a national food safety plan, one that is based on science and risk assessment.

- The Council supports **NAS recommendation I**, which states that the food safety system should be based on science. In its assessment of the NAS report, the Council provides numerous examples in which this is already the case and examples of areas that need to be strengthened.
- The Council supports **NAS recommendation IIa**, which calls for federal statutes to be based on scientifically supportable assessments of risk to public health. In this regard, the Council will conduct a thorough review of existing statutes and determine what can be accomplished with existing regulatory flexibility and what improvements will require statutory changes.
- The Council supports **NAS recommendation IIb**, which calls for the production of a

comprehensive national food safety plan. In fact, the development of such a plan is already underway and is one of the primary functions of the Council as specified in Executive Order 13100. One component of the plan will be exploring methods to assess the comparative health risks to the nation's food supply.

- The Council supports the goal of **NAS recommendation IIIa**. Here, the NAS calls for a new statute that establishes a unified framework for food safety programs with a single official with control over all federal food safety resources. The report acknowledges that there may be many organizational approaches to achieving the goal of a "single voice" for federal food safety activities. The Council will conduct an assessment of structural models and other mechanisms that could strengthen the federal food safety system through better coordination, planning, and resource allocation, keeping in mind that the primary goal is food safety and public health.
 - The Council supports **NAS recommendation IIIb**. This recommendation argues that agencies should have the legal authority and other tools needed to work more effectively with our partners in state, tribal, and local governments. Federal food safety agencies already have many of the tools identified by the NAS and have used them to establish extensive partnerships with state, tribal, and local governments. However, some tools are missing and much more needs to be done to better coordinate the federal government's interactions with other levels of government. The Council agrees that the roles of state, tribal, and local governments in the food safety system are critical and that their efforts deserve the formal recognition that partnership in a national food safety system conveys.
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Webmaster | Last updated on 1999-MAR-26 by rwk/dms



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

DECISION MEMORANDUM FOR THE SECRETARY

THROUGH:

Stephen B. Dewhurst
Director
Office of Budget and Program Analysis

SD 6/21/99

FROM:

Catherine E. Woteki *C. Woteki*
Under Secretary
Food Safety

MAY 27 1999

SUBJECT:

Charter for Food Emergency Rapid Response and Evaluation
Team (FERRET)

ISSUE:

Obtaining Approval of Charter for Food Emergency Rapid Response and Evaluation
Team

DISCUSSION:

Enclosed for your review and approval is the Charter for the Food Emergency Rapid Response and Evaluation Team (FERRET) which has been established at the request of Secretary Glickman. The draft charter has been reviewed by the members and significant modifications include:

1. Inclusion of the authorizing legislation, identified in Section 618, Subtitle B of the Agricultural Research Extension and Education Act of 1998.
2. Addition of Under Secretary for Food, Nutrition and Consumer Services, and Director of the Office of Communication as principal members.
3. Clarification that principal members shall designate primary and secondary alternates to represent them when they are unavailable for a FERRET meeting.

RECOMMENDATION:

The Food Emergency Rapid Response and Evaluation Team has been operating under a draft charter for the past 11 months. I strongly urge you to approve the enclosed charter.

Enclosure

DECISION BY THE SECRETARY:

Approve: _____

Disapprove: _____

Discuss with me: _____

Date: JUNE 22 1999

Reviewed by: _____

Lygi
FOR THE SECRETARY

May 17, 1999

Charter

USDA Food Emergency Rapid Response & Evaluation Team

Purpose:

The Food Emergency Rapid Response and Evaluation Team (FERRET) is established to:

1. Facilitate a prompt, effective and coordinated USDA response to food safety emergencies that cross USDA agency jurisdictions
2. Evaluate emergency episodes and use what is learned to improve long-term strategies for preventing food safety emergencies, particularly by returning information to the appropriate mission areas for evaluation and action

Team Charge:

Develop a prompt, effective and coordinated response to emergency food safety issues that cross USDA agency jurisdictions

Improve USDA's response to food emergencies by rapidly gathering and evaluating critical data for decision-making

Produce guidelines and procedures for USDA's rapid response to a food-safety emergency that crosses agency jurisdiction

Support the Foodborne Outbreak Response Coordination Group (FORCG)

Authorizing Legislation:

FERRET will carry out the responsibilities identified in Section 618, Subtitle B of the Agricultural Research Extension and Education Act of 1998 as they pertain to food safety emergencies.

Scope:

All food emergencies with potential public health implications that affect either regulated products or foods purchased by USDA

Team Values:

Fast, effective response which prevents public panic and applies current science

Coordination and commitment to cooperative resolution

Schedules:

FERRET is a permanent team and is authorized for an indefinite period of time. Principal team members (or designees) are expected to be available 24 hours/day, 7 days/week for responding to emergencies. Team members will designate a primary and secondary alternate to represent them when they are unavailable. If a principal team member is out of the country, the responsibility for FERRET should be specifically delegated to an alternate during the period of travel.

Coordinating Agency:

FERRET efforts and activities will be coordinated by the Food Safety and Inspection Service, Office of Public Health and Science.

Participants:

Membership includes the Under Secretary for Food Safety (chair), Under Secretary for Food Nutrition and Consumer Services, Under Secretary for Farm and Foreign Agricultural Services, Under Secretary for Research, Education, and Economics, Under Secretary for Marketing and Regulatory Programs, General Counsel, Inspector General, and Director of the Office of Communication.

In the event that a principal member of the team is unable to attend a specific meeting, he or she may choose to send an alternate who has decision-making authority.

Approved: _____

Secretary of Agriculture



JUN 23 1999

(Date)



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

Speeches

The Food Safety Revolution—How Far Have We Come?

Remarks prepared for delivery by Thomas J. Billy, Administrator of the Food Safety and Inspection Service, before the National Environmental Health Association, July 6, 1999, Nashville, TN.

It's a pleasure to be here to open this session on food safety and protection. The Food Safety and Inspection Service is committed to working with all professional groups, including the National Environmental Health Association, to improve food safety. In fact, it is only through partnerships among government, industry, academia, consumers, and professional groups that we can implement a strategy to further reduce the incidence of foodborne illness.

Much has changed in food safety over the past 6 years, and today, I want to discuss how far we have come, and what we have left to do.

We are fortunate that food safety has received attention at the highest level of government, because that has paved the way for significant progress. President Clinton took office the same month the Pacific Northwest *E. coli* outbreak began, which was attributed to undercooked hamburgers served at a fast food chain. Since then, we have seen much progress. Much of the work that has been accomplished is the direct result of the President's Food Safety Initiative, which, since 1997, has provided funds to Federal agencies for needed improvements in areas such as inspections, surveillance, outbreak response, risk assessment, research, and education. The activities underway through this initiative focus primarily on foodborne pathogens. The President's Food Safety Council, which was established in August 1998, is coordinating these and all other Federal food safety activities. I will talk more about the Council's goals and activities in a few moments.

Inspection

I will begin with our accomplishments in inspection, because that is at the heart of our USDA program, and many of you are involved in inspecting retail operations in your own communities. What we can accomplish within federally inspected establishments has a direct bearing on the safety of foods served at retail establishments.

FSIS inspects all meat, poultry, and egg products produced for interstate shipment and imported into the United States. FSIS also monitors State inspection programs, which inspect meat and poultry products that can be sold only within the State in which they were produced. As you well know, the Food and Drug Administration has jurisdiction over other foods.

The inspection program for the foods FSIS regulates has long been in need of modernization, and this need is well documented in a series of reports released over the past 15 years by the National Academy of Sciences and others. In 1996, FSIS took a major step toward modernization by publishing its landmark rule on Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) Systems, which required changes both in the production of meat and poultry products, and in how FSIS regulates industry.

Under the new regulations, each meat and poultry plant must develop and implement a written plan for meeting its sanitation responsibilities and must develop and implement a HACCP plan that systematically address all significant hazards associated with its products. In addition, all slaughter plants and plants that produce raw ground products must regularly test for generic *E. coli* to verify that their procedures for preventing and reducing fecal contamination are working. And, they must meet performance standards for *Salmonella* contamination—the first-ever regulatory performance standards for a broad range of raw products that are directed at reducing microbial contamination.

We began implementing these requirements in 1997, and implementation will be complete in January 2000. The requirements are being implemented in phases, with large plants meeting the requirements in January 1998, small plants in January 1999, and very small plants by January 2000. We recognized that HACCP would be a greater challenge to small and very small plants, and as a result, we established a technical assistance program to help these plants along. For example:

- We have established a network of contacts and coordinators in every State to provide information on training opportunities, coordinate available resources, and provide technical guidance and assistance.
- We have developed generic HACCP models for a variety of products to help small and very small plants develop their own HACCP plans.
- We recently produced a self-study training program that will be distributed to very small plants.
- And a number of land-grant universities, at our request, are having their meat and poultry plants available for very small plants to visit to see HACCP in action.

We have been pleased with how smoothly implementation has gone and with the data generated so far. Results for the first year of large plant *Salmonella* testing show that HACCP is indeed working. *Salmonella* prevalence in broilers, swine, ground beef, and ground turkey was significantly lower after HACCP implementation than in baseline studies conducted before HACCP.

As we proceed with HACCP implementation, FSIS also is developing new inspection models for plants that slaughter generally healthy, uniform animals. While HACCP changes inspection somewhat, it does not change the current labor-intensive system associated with our slaughter inspection approach. Right now, our inspectors are responsible for process control activities that we believe plants should take responsibility for, under FSIS oversight and verification. This is basically the HACCP philosophy extended to additional areas within the slaughter plant.

Surveillance

In addition to inspection, the surveillance of foodborne illness is another area where significant progress has been made. We need to know whether the changes we are making in inspection are working to reduce the incidence of foodborne illness. The FoodNet foodborne disease surveillance network, now 4 years old, is providing more precise information on the incidence of foodborne disease in the United States. FoodNet is a joint effort of the Centers for Disease Control and Prevention, FSIS, and FDA, and it involves direct links with eight state and local health departments nationwide.

We are learning important information from FoodNet. For example, we know that *Campylobacter* is the most frequently isolated pathogen. Following *Campylobacter*, in order of frequency, are *Salmonella*, *Shigella*, *E. coli* O157:H7, *Yersinia*, *Listeria*, and *Vibrio*.

Results from 1998 show a decline in the overall incidence of *Salmonella* and *Campylobacter* infections, two of the most common causes of foodborne illness in the United States. We believe these data show

that HACCP is resulting in reductions in foodborne illness.

In addition to expanded surveillance, we now have a national computer database--called PulseNet--to capture the molecular fingerprints of pathogens. This technology has been used many times to link specific food products to specific human illnesses and to link what appear to be sporadic cases to a common source. For example, it was used in 1997 during an outbreak of foodborne illness associated with *E. coli* O157:H7 in ground beef to link a patient isolate with an unopened package at retail, and more recently during an outbreak associated with *Listeria monocytogenes*.

Outbreak Response

In the area of foodborne outbreak response, Federal and State agencies have joined to form the Foodborne Outbreak Response Coordinating Group (FORCEG). Within USDA, we have established the Foodborne Outbreak Response Coordinating Group, which is coordinating food safety emergencies that cross agency jurisdictions within USDA. Because we work so closely with the States on outbreak response, one of our major goals has been to strengthen the infrastructure at State health departments.

Risk Assessment

We are also making progress in using microbiological risk assessments to identify and manage health risks from foods. Risk assessments help us to determine where our regulatory inspection resources should be applied. The application of risk assessment techniques to pathogenic microorganisms has been a challenge because unlike chemical, environmental or toxicological contaminants, bacteria can multiply and produce toxins as food moves through the farm-to-table continuum. So more variability and complexity are involved.

We have made good progress despite these challenges. Last year, we completed a quantitative, farm-to-table risk assessment on *Salmonella* Enteritidis in eggs and egg products that is helping us to develop a broad, farm-to-table strategy to improve egg safety.

We also are conducting a risk assessment for *E. coli* O157:H7 in hamburger, and we have entered into a cooperative agreement with Harvard University for a risk analysis of BSE. And FDA and USDA are jointly carrying out a risk assessment for *Listeria monocytogenes* in a variety of foods. We have a lot of work remaining to be done before we can fully integrate risk assessments into our policy-making activities, but we are making good progress.

Research

Research is another important way for us to meet our food safety goals. FSIS does not conduct research itself but works through other USDA agencies, such as the Agricultural Research Service and the Cooperative State Research, Education, and Extension Service. We are interested in research that will help to identify and characterize foodborne hazards, will provide tools for regulatory enforcement, and will provide effective interventions to improve food safety. Just one year ago, President Clinton announced formation of the Joint Institute for Food Safety Research, which is charged with developing a comprehensive strategic plan for food safety research and coordinating all Federal food safety research activities, including that conducted by the private sector and academia.

Education

Last but not least, food safety education is another tool we have to reduce the incidence of foodborne

illness. The Fight BAC! campaign—the result of a public-private partnership—is successfully spreading the word to consumers nationwide about taking basic sanitation and food handling steps. Education is important not only for consumers, but throughout the farm-to-table chain, and the education of food handlers in food service operations and at retail is being addressed by the Food Safety Training and Education Alliance. This alliance includes representatives from industry, consumer groups, trade associations and government agencies.

These are all positive steps, but we have many challenges for the future.

A Seamless System

As we make improvements in each of these areas, we also must work toward the integration of Federal, State, and local government activities and resources. I'm sure that in your communities, you feel that you could do more if you had additional resources, and Federal agencies feel the same way. By working more effectively together, we can do more with what we have.

This is not as easy to do as it may sound. Within government, we are talking about integrating the activities of numerous Federal agencies, and hundreds of State governments and local jurisdictions. We have different legislative authorities, different responsibilities, different structures, and different legislative bodies that appropriate our funds.

We have some success stories already. FoodNet is a good example of Federal-State cooperation that is indeed working. But we must do more.

The President's Food Safety Council, which was established last August, will help, because it was established to coordinate food safety. The Council is now developing, through a public process, a 5-year strategic Federal food safety plan that addresses the steps necessary to achieve a seamless, national food safety system. A public meeting on the strategic planning is being held on July 15 in Washington, DC., where participants will have the opportunity to provide input on the goals and objectives developed by the Council and to provide comments and suggestions on specific action items for inclusion in the plan. We look forward to your involvement in this strategic planning process. The plan will be used for a variety of purposes, including to set priorities, improve coordination and efficiency, and to identify and fill data gaps in the current system. It will be much broader than the Food Safety Initiative I mentioned at the outset, which focuses on the risks posed by microbial pathogens only.

Another way Federal agencies are helping to create a seamless system is by working to help strengthen State food safety programs. I already mentioned that Federal and State governments are working together to provide technical assistance to small and very small plants to help them implement HACCP.

In addition, under the FY2000 budget request for FSIS, \$2.4 million is earmarked to help the states implement with the HACCP rule. And \$0.5 million is earmarked to improve emergency response coordination with the States in investigating foodborne disease outbreaks. In addition, during FY2000, FSIS also intends to continue its assistance to States to help them automate their inspection systems. And FSIS is seeking cooperative agreement authority, which would allow it to enter into partnerships with organizations such as State and other Federal government agencies, academia, and industry.

Farm-to-Table Food Safety

Another challenge for the future is to keep a broad, farm-to-table approach when finding solutions to our food safety problems. It will require multiple steps, all along the farm-to-table chain, for real progress to

occur. There is no one quick fix to food safety.

Working to better integrate Federal, State, and local government activities and resources will also help to meet our farm-to-table goals. We are working closely with other government agencies that share food safety responsibilities, professional groups, academia, and industry to encourage the adoption of HACCP-type systems all along the farm-to-table continuum. Our interest in food safety outside of federally-inspected plants does not mean we believe that Federal regulatory measures are needed. We believe we must use a full range of options, in coordination with the States, including non-regulatory measures such as voluntary programs and education.

At the retail level, for example, we are working with FDA, and with State officials, to ensure the adoption of science-based standards that foster HACCP-type preventive approaches. We recognize that the primary responsibility for overseeing food safety at the retail level resides properly with State and local governments. We fully support the *Food Code* process and the role of the Conference for Food Protection in developing the best regulatory code possible for State adoption.

In addition to working through the *Food Code*, we also want to provide assistance to State and local regulatory agencies through training and other means. For instance, working the Association of Food and Drug Officials, we have held several training sessions for State and local food inspection agencies on the potential health risks associated with meat and poultry products processed at the retail level and in food service operations.

Emerging Issues

For the future we also must keep ahead of the food safety challenges that face us. Research and new technology are providing us with new tools to make food safer, but at the same time, new food safety challenges continue to arise, for several reasons.

First, new pathogens are emerging. Pick up a microbiology textbook from 20 years ago and you won't even find mention of *E. coli* O157:H7. Even pathogens such as *Listeria monocytogenes*, which have been around for some time, are forcing us to re-evaluate our approaches. And the fact that *Campylobacter* is the most frequently isolated foodborne pathogen requires us address this pathogen as well.

Second, our population also is changing, and with those changes comes a greater susceptibility to foodborne illness. The elderly and immune-compromised, for example, are two groups that are growing in numbers. And we are finding that foodborne illness can have lasting consequences in some cases. An example is Guillain-Barré syndrome, which is associated with *Campylobacter*.

Third, several factors are creating opportunities for bigger outbreaks, including more people eating out at restaurants, an increase in imported foods, more convenience foods that are prepared in advance, and food handlers both in homes and in food service operations who are not as savvy about food safety as we would like them to be.

Closing

In closing, our continued success will depend on several things. First, we must continue progress in all of the areas I mentioned, such as inspection, surveillance, and risk assessment.

Second, we must work toward a national, seamless, integrated food safety system that recognizes the

need to work together on common goals.

Third, we must maintain a farm-to-table focus, with each of us taking our respective responsibilities for making needed improvements in food safety.

And last, we must be sure we are ready to address emerging food safety challenges.

I am confident that we can meet these challenges, and I look forward to working with NEHA in the future.

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Biotechnology

Release No. 0285.99

Remarks

As Prepared for Delivery
by

Secretary of Agriculture Dan Glickman
before the National Press Club on
New Crops, New Century, New Challenges:

How Will Scientists, Farmers, And Consumers Learn to Love Biotechnology
And What Happens If They Don't? Washington, D.C. - July 13, 1999

"Good afternoon. Thank you for coming.

"Let's think about this hypothetical situation for a moment: Let's suppose that today's salad was made with the new carrot from Press Club Farms, Inc. Farmers grow the new carrot on fewer acres because it yields more, and it's less expensive because it does not require any fertilizers or pesticides and can be harvested totally mechanically. In addition, it has more vitamin A & C than traditional varieties and stays crisper longer and keeps its fresh taste longer.

"But, because this carrot does not require as much labor, the farmers have had to lay off hundreds of employees. While it does not require any chemicals to flourish, this new carrot does affect the environment by making it difficult for other crops or plants in close proximity to survive. And though it's cheaper to begin with, it's only available from one company, which could result in a considerable premium over regular carrot seed.

"And what's the secret to this hypothetical new carrot? It's the latest advance from biotechnology -- produced with a gene from kudzu, an invasive weed.

"Sound far-fetched? It probably shouldn't: Remember the flavor-saver tomato? How many of you have heard of the so-called terminator gene which can keep a plant from reproducing? Today, nearly half the soybeans in the U.S. the stuff that is crushed and made into salad and cooking oil and that feeds most of the livestock we grow are produced from a variety that increases the plant's resistance to certain pesticides. Genetically-engineered corn with certain pest resistant characteristics is also rapidly displacing more traditional varieties. And, it gets even more interesting when you consider that researchers are looking at genetically-modified mosquitoes that cannot carry malaria.

"So, what do we think about this new carrot? Are we concerned about the environmental effects we still don't fully understand? What about the farm workers who are now unemployed? Should one company have a monopoly on it? And finally, are you concerned about these issues and about how it is produced? Would you still have eaten it if you knew about the kudzu gene? Should you have been told? Would you buy it?

"Folks, this is the tip of the biotechnology iceberg. There are many more questions that haven't yet been thought of, much less answered. But first of all, and if you come away with a dominant point from my remarks, it is that I want you to know that biotechnology has enormous potential.

"Biotechnology is already transforming medicine as we know it. Pharmaceuticals such as human insulin for diabetes, interferon and other cancer medications, antibiotics and vaccines are all products of genetic

engineering. Just yesterday I read that scientists at Virginia Polytechnic Institute will process drugs from milk from genetically altered cows. One new drug has the potential to save hemophiliacs from bleeding to death. Scientists are also looking at bananas that may one day deliver vaccines to children in developing countries.

"Agricultural biotechnology has enormous potential to help combat hunger. Genetically modified plants have the potential to resist killer weeds that are, literally, starving people in Africa and other parts of the developing world.

"Biotechnology can help us solve some of the most vexing environmental problems: It could reduce pesticide use, increase yields, improve nutritional content, and use less water. We're employing bioengineered fungi to remove ink from pulp in a more environmentally sensitive manner.

"But, as with any new technology, the road is not always smooth. Right now, in some parts of the world there is great consumer resistance and great cynicism toward biotechnology. In Europe protesters have torn up test plots of biotechnology-derived crops and some of the major food companies in Europe have stopped using GMOs genetically-modified organisms in their products.

"Yesterday's news was that the WTO affirmed our view that the EU is unjustifiably blocking US ranchers from selling beef produced with completely tested and safe growth hormones. Today we're seeing that the G-8 agreed to a new review of food safety issues and, having myself just come back from France a couple of weeks ago, I can assure you that trade in GMOs is looming larger over US-EU trade relations in all areas.

"Now, more than ever, with these technologies in their relative infancy, I think it's important that, as we encourage the development of these new food production systems, we cannot blindly embrace their benefits. We have to ensure public confidence in general, consumer confidence in particular, and assure farmers the knowledge that they will benefit.

"The important question is not, do we accept the changes the biotechnology revolution can bring, but are we willing to heed the lessons of the past in helping us to harness this burgeoning technology. The promise and potential are enormous, but so too are the questions many of which are completely legitimate. Today, on the threshold of this revolution, we have to grapple with and satisfy those questions so we can in fact fulfill biotechnology's awesome potential.

"To that end, today I am laying out 5 principles I believe should guide us in our approach to biotechnology in the 21st century. They are:

1. An Arm's Length Regulatory Process. Government regulators must continue to stay an arm's length, dispassionate distance from the companies developing and promoting these products; and continue to protect public health, safety and the environment.

2. Consumer Acceptance. Consumer acceptance is fundamentally based on an arm's length regulatory process. There may be a role for information labeling, but fundamental questions to acceptance will depend on sound regulation.

3. Fairness to Farmers. Biotechnology has to result in greater, not fewer options for farmers. The industry has to develop products that show real, meaningful results for farmers, particularly small and medium size family farmers.

4. Corporate Citizenship. In addition to their desire for profit, biotechnology companies must also understand and respect the role of the arm's length regulator, the farmer, and the consumer.

5. Free and Open Trade. We cannot let others hide behind unfounded, unwarranted scientific claims to block commerce in agriculture.

Arm's Length Regulatory Process

"When I was a school board member in Wichita, Kansas, one of my tasks was to study the level of student participation in the school lunch program. I quickly learned if the food didn't taste or look good, no matter how nutritious it was, the kids wouldn't eat it.

"With all that biotechnology has to offer, it is nothing if it's not accepted. This boils down to a matter of trust -- trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review -- including complete and open public involvement. The process must stay at arm's length from any entity that has a vested interest in the outcome.

"By and large the American people have trust and confidence in the food safety efforts of USDA, the FDA, EPA, CDC and others because these agencies are competent and independent from the industries they regulate, and are viewed as such. That kind of independence and confidence will be required as we deal with biotechnology.

"The US regulatory path for testing and commercializing biotechnology products as they move from lab to field to marketplace is over a decade old. We base decisions on rigorous analysis and sound scientific principles. Three federal agencies -- USDA, FDA, and EPA -- each play a role in determining the use of biotechnology products in the United States: USDA evaluates products for potential risk to other plants and animals. FDA reviews biotechnology's effect on food safety. And the EPA examines any products that can be classified as pesticides.

"Right now, there are about 50 genetically altered plant varieties approved by USDA. And so far, thanks to the hard work and dedication of our scientists, the system is keeping pace. But, as I said, the system is tried and tested, but not perfect and not inviolate and should be improved where and when possible.

"To meet the future demand of the thousands of products in the pipeline will require even greater resources, and a more unified approach and broader coordination.

"When I chaired the US delegation to the World Food Conference in Rome in 1996, I got pelted with genetically modified soybeans by naked protesters. I began to realize the level of opposition and distrust in parts of Europe to biotechnology for products currently on the market or in the pipeline.

"I believe that distrust is scientifically unfounded. It comes in part from the lack of faith in the EU to assure the safety of their food. They have no independent regulatory agencies like the FDA, USDA or EPA. They've had many food scares in recent years -- mad-cow disease, and in just the last several weeks, dioxin-tainted chicken -- that have contributed to a wariness of any food that is not produced in a traditional manner notwithstanding what

the science says. Ironically they do not share that fear as it relates to genetically modified pharmaceuticals.

"But, GMO foods evoke in many circles a very volatile reaction. And that has created a serious problem for the U.S. and other countries as we try to sell our commodities in international markets.

"We need to make sure our regulatory system has the foresight to begin addressing issues even before they arise. So to keep pace with the accelerating growth of agricultural biotechnology, I am taking several additional steps to ensure we are fully prepared to meet the regulatory challenges of this new technology.

"Today I'm announcing that I will be asking for an independent scientific review of USDA's biotech approval process. The purpose of this review will be to ensure that, as we are faced with increasingly complex issues surrounding biotechnology, our scientists have the best information and tools to ensure our regulatory capabilities continue to evolve along with advances in the new technology. And to address complex issues like pharmaceutical producing plants or genetically modified livestock we will need to consult the experts, many of whom are outside USDA.

"Two of the more significant challenges we face are grower and consumer awareness, and improving monitoring on a long term basis. We do not have evidence the heavily publicized Monarch butterfly lab study appears to be happening in the field. But, the resulting attention to the reports and ensuing debate underscore the need to develop a comprehensive approach to evaluating long-term and secondary effects of biotech products.

"So, USDA will propose the establishment of regional centers around the country to evaluate biotech products over a long period of time and to provide information on an ongoing basis to growers, consumers, researchers and regulators.

"To strengthen biotechnology guidelines to ensure we can stay on top of any unforeseen adverse effects after initial market approval, I am requesting all developers of biotech products to report any unexpected or potentially adverse effects to the Department of Agriculture immediately upon discovery.

"Finally, we need to ensure that our regulators just regulate and only regulate. A few years ago, we created a food safety agency separate and distinct from any and all marketing functions to ensure that no commercial interests have even the appearance of influence on our decisions regarding food safety. It needs to be the same with biotechnology. The scientists who evaluate and approve biotech products for the market must be free of any hint of influence from trade support and other non-regulatory areas within USDA.

"We at USDA will undertake a review to reinforce the clear line between our regulatory functions and those that promote and support trade. This reaffirms our basic principle that we will remain scrupulously rigid in maintaining an arm's length regulatory process.

Consumer Acceptance

"However strong our regulatory process is, it is of no use if consumer confidence is low and if consumers cannot identify a direct benefit to them.

"I have felt for some time that when biotechnology products from agriculture hit the market with attributes that, let's say, reduce cholesterol, increase disease resistance, grow hair, lower pesticide and

herbicide use, and are truly recognized as products that create more specific public benefits, consumer acceptance will rise dramatically.

"There's been a lot of discussion as to whether we should label GMO products. There are clearly trade and domestic implications to labeling to be considered in this regard. I know many of us in this room are sorting out these issues. At the end of the day many observers, including me, believe some type of informational labeling is likely to happen. But, I do believe that it is imperative that such labeling does not undermine trade and this promising new technology.

"The concept of labeling particular products for marketing purposes is not a radical one. For example, USDA has already decided that for a product to be certified as organic under our pending organic agriculture rules, a GMO product would not qualify. And that does not mean that USDA believes organic is safer or better than non-organic all approved foods are safe it just means that consumers are given this informed choice.

"There clearly needs to be a strong public education effort to show consumers the benefits of these products and why they are safe. Not only will this be the responsibility of private industry and government, but I think the media will play a vital role. It's important that the media treat this subject responsibly and not sensationalize or fan consumer fears. That's what we're seeing happen in the EU and the outcome is fear, doubt and outright opposition.

"What we cannot do is take consumers for granted. I cannot stress that enough. A sort of if-you-grow-it-they-will-come mentality. I believe farmers and consumers will eventually come to see the economic, environmental, and health benefits of biotechnology products, particularly if the industry reaches out and becomes more consumer accessible.

"But, to build consumer confidence, it is just like it is with the way we regulate our airlines, our banks and the safety of our food supply consumers must have trust in the regulatory process. That trust is built on openness. Federal agencies have nothing to hide. We work on behalf of the public interest. Understanding that will go a long way to solving the budding controversy over labeling and ensuring that consumers will have the ability to make informed choices.

Fairness to Farmers

"Like consumers, farmers need to have adequate choices made available to them. But today, American agriculture is at a crossroads. Farmers are currently facing extremely low commodity prices and are rightfully asking what will agriculture look like in the years to come and what will their roles be.

"That also means they have more responsibility and more pressure. And much of the pressure they face originates from sources beyond their control. We are seeing social and economic trends that have a powerful effect on how farmers do business. We are seeing increased market concentration, a rise in contracting, rapidly evolving technologies such as information power and precision agriculture in addition to biotechnology. We are seeing different marketing techniques such as organics, direct marketing, coops and niche markets, and an expansion of non-agricultural industrial uses for plants.

"One of my biggest concerns is what biotechnology has in store for family farmers. Consolidation, industrialization and proprietary research can create pitfalls for farmers. It threatens to make them servants to bigger masters, rather than masters of their own domains. In biotechnology, we're

already seeing a heated argument over who owns what. Companies are suing companies over patent rights even as they merge. Farmers have been pitted against their neighbors in efforts to protect corporate intellectual property rights.

"We need to ensure that biotechnology becomes a tool that results in greater -- not fewer -- options for farmers. For example, we're already hearing concerns from some farmers that to get some of the more highly desirable non-GMO traits developed over the years, they might have to buy biotechnology seeds. For some, that's like buying the car of your dreams but only if you get it in yellow. On the other hand, stress-tolerant plants are in the pipeline which could expand agricultural possibilities on marginal lands which could be a powerful benefit to poor farmers.

"The ability of farmers to compete on a level playing field with adequate choices available to them and without undue influence or impediments to fair competition must be preserved. As this technology develops, we must achieve a balance between fairness to farmers and corporate returns:

"We need to examine all of our laws and policies to ensure that, in the rush to bring biotech products to market, small and medium family farmers are not simply plowed under. We will need to integrate issues like privatization of genetic resources, patent holders rights and public research to see if our approach is helping or harming the public good and family farmers.

"It is not the government who harnesses the power of the airwaves, but it is the government who regulates it. That same principle might come to apply to discoveries in nature as well. And that debate is just getting started.

Corporate Citizenship

"If the promises hold true, biotechnology will bring revolutionary benefits to society. But that very promise means that industry needs to be guided by a broader map and not just a compass pointing toward the bottom line.

"Product development to date has enabled those who oppose this technology to claim that all the talk about feeding the world is simply cover for corporate profit-making. To succeed in the long term, industry needs to act with greater sensitivity and foresight.

"In addition, private sector research should also include the public interest, with partnerships and cooperation with non-governmental organizations here and in the developing world ensuring that the fruits of this technology address the most compelling needs like hunger and food security.

"Biotechnology developers must keep farmers informed of the latest trends, not just in research but in the marketplace as well. Contracts with farmers need to be fair and not result in a system that reduces farmers to mere serfs on the land or create an atmosphere of mistrust among farmers or between farmers and companies.

"Companies need to continue to monitor products, after they've gone to market, for potential danger to the environment and maintain open and comprehensive disclosure of their findings.

"We don't know what biotechnology has in store for us in the future, good and bad, but if we stay on top of developments, we're going to make sure

that biotechnology serves society, not the other way around.

"These basic principles of good corporate citizenship really just amount to good long-term business practices. As in every other sector of the economy, we expect responsible corporate citizenship and a fair return. For the American people, that is the bottom line.

Free and Open Trade

"The issues I have raised have profound consequences in world trade. Right now, we are fighting the battles on ensuring access to our products on many fronts. We are not alone in these battles. Canada, Australia, Mexico, many Latin American, African and Asian nations, agree with us that sound science ought to establish whether biotech products are safe and can move in international commerce.

"These are not academic problems. For 1998 crops 44% of our soybeans and 36% of our corn are produced from genetically modified seeds. While only a few varieties of GMO products have been approved for sale and use in Europe, many more have been put on hold by a de facto European moratorium on new GMO products.

"Two weeks ago I went to France and met with the French Agriculture Minister at the request of the US ambassador there, Felix Rohatyn, to see if we can break this logjam which directly threatens US-EU relations at a delicate time when we are commencing the next WTO round in Seattle.

"Quite frankly the food safety and regulatory regimes in Europe are so split and divided among the different countries that I am extremely concerned that failure to work out these biotech issues in a sensible way could do deep damage to our next trade round and effect both agricultural and non-agricultural issues. For that reason, the French Minister's agreement to have a short-term working group with USDA on biotech approval issues, and his willingness to come to the US in the fall to further discuss the situation, is encouraging.

"To forestall a major US-EU trade conflict, both sides of the Atlantic must tone down the rhetoric, roll up our sleeves and work toward conflict resolution based on open trade, sound science and consumer involvement. I think this can be done if the will is there.

"However, I should warn our friends across the Atlantic that, if these issues cannot be resolved in this manner, we will vigorously fight for our legitimate rights.

Conclusion

"Finally, I've established a Secretary's Advisory Committee on Agricultural Biotechnology -- a cross-section of 25 individuals from government, academia, production agriculture, agribusiness, ethicists, environmental and consumer groups. The committee, which will hold its first meeting in the fall, will provide me with advice on a broad range of issues relating to agricultural biotechnology and on maintaining a flexible policy that evolves as biotechnology evolves.

"Public policy must lead in this area and not merely react. Industry and government cannot engage in hedging or double talking as problems develop, which no doubt they will.

"At the same time, science will march forward, and especially in

agriculture, that science can help to create a world where no one needs to go hungry, where developing nations can become more food self-sufficient and thereby become freer and more democratic, where the environmental challenges and clean water, clean air, global warming and climate change, must be met with sound and modern science and that will involve biotechnological solutions.

"Notwithstanding my concerns raised here today, I would caution those who would be too cautious in pursuing the future. As President Kennedy said, "We should not let our fears hold us back from pursuing our hopes."

"So let us continue to move forward thoughtfully with biotechnology in agriculture but with a measured sense of what it is and what it can be. We will then avoid relegating this promising new technology to the pile of what-might-have-beens, and instead realize its potential as one of the tools that will help us feed the growing world population in a sustainable manner.

"Thank you."

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DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20250

NOV 2 1999

The Honorable Albert Gore, Jr., President
United States Senate
The Capitol
Washington, D.C. 20510

Dear Mr. President:

I am transmitting by this letter a draft bill "To reform the State inspection of meat and poultry in the United States, and for other purposes," for the Congress' consideration. The Department of Agriculture (USDA) recommends that it be enacted.

This draft bill is an important part of the Clinton Administration's initiative to improve food safety for American consumers. The key objective of the bill is to ensure that all meat and poultry products produced in the United States are inspected under a seamless system enforcing a single set of requirements and eliminating the prohibition on the interstate shipment of State-inspected meat and poultry products. Additionally, the bill is designed to improve consumer confidence in the safety of the food supply, increase the viability of small meat and poultry establishments, ensure the viability of State meat and poultry inspection programs, and ensure that meat and poultry inspected by State inspection systems can also be accepted in international trade as an ingredient or alone.

Specifically, major provisions of the draft bill would amend the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to:

- require State meat and poultry inspection programs to enforce Federal inspection requirements under new cooperative agreements with the Secretary;
- repeal current authority providing for State meat and poultry inspection programs enforcing requirements "at least equal to" Federal requirements;
- require State-inspected meat and poultry to be marked with the official mark of Federal inspection;
- allow for the interstate shipment of meat and poultry products produced at plants operating under State grants of inspection; and
- provide the Secretary the authority to reimburse up to 60 percent of a State's cost of meeting Federal inspection requirements.

Amendments to the FMIA in 1967 and the PPIA in 1968 mandated Federal oversight of the State meat and poultry inspection programs and established the statutory prohibitions on the distribution of State-inspected meat and poultry products in interstate commerce. Currently, 25 States have USDA-approved inspection programs covering about 3,000 slaughtering and processing plants. These plants account for about 7 percent of all meat and poultry products produced in the United States, but more than one-third of all meat and poultry plants under Federal or State inspection. USDA's Food Safety and Inspection Service (FSIS) reimburses the States for 50 percent of the cost of operating "at least equal to" programs, the maximum level allowed by current statutes.

The draft bill provides for a one year transition period during which existing State inspection programs will have the opportunity to transition from "at least equal to" programs to programs enforcing the same Federal requirements enforced by USDA. State programs not making the transition would be taken over by USDA. The transition period would begin on October 1, 2001, and end on September 30, 2002. State programs enforcing Federal requirements, and recognized as such in new cooperative agreements with the Secretary, will use the official mark of Federal inspection on products. These products will be eligible for shipment in interstate commerce. The States will retain the option of also using the State mark of inspection.

By October 1, 2001, States will have over a full year's experience operating Hazard Analysis and Critical Control Points-based inspection programs. By this date, USDA will have had sufficient time to conduct a comprehensive review of all State programs and to extend the Federal microbial testing program to include samples from products produced at State-inspected plants. The comprehensive reviews and testing program are provisions of the bill designed to maintain consumer confidence in the safety of the food supply and to ensure our trading partners of the integrity of the seamless national program. This is important because the products produced at State establishments will bear the official mark of Federal inspection and will be eligible for export.

There has been some controversy both among consumer groups and our international trading partners about what constitutes "at least equal to" inspection standards. Moving from a statute that requires States to operate "at least equal to" Federal inspection programs to a seamless system where national requirements are enforced at all meat and poultry plants will bolster consumer confidence in the meat and poultry supply. Any debate on what constitutes "at least equal to" will be put to rest. Federal microbial testing of both Federally- and State-inspected products, providing a quantitative measure of food safety gains, will have the effect of bolstering confidence in the national inspection system.

Interstate commerce may provide new markets for many very small State-inspected plants, particularly plants located near State or even international borders or catering to niche markets. This will help ensure the viability of these plants.

At the same time, it is important that the credibility of the entire meat and poultry industry of the United States be safeguarded, both domestically and internationally. For this reason, efforts were made to assure that the standards required of the States will make the product acceptable to our international partners, whether the inspected meat and poultry would be used as an ingredient in further processed product for export, or exported as inspected to neighboring countries or to niche marketers.

State programs have developed specialized experience in conducting inspection programs for primarily very small plants and the State programs may see an influx of applications for inspection when State inspected products become eligible for interstate shipment. Thus, the proposed bill includes two provisions to ensure the stability of the State programs. First, States may limit the maximum size of plants eligible for State inspection and second, the bill proposes raising the limit on the Federal reimbursement to States to up to 60 percent of the cost of operating their inspection programs. The Secretary will consider the burden placed on the State programs as a result of the draft bill in calculating the budget request for Federal reimbursement to the States.

USDA will need up to \$2 million beginning in FY01 to conduct the initial and subsequent comprehensive annual reviews of State programs. Up to \$8 million in additional funding beginning in FY02 may be needed to increase the reimbursement to State inspection programs above the current 50 percent cap if the Secretary determines there is an increased burden on State programs due to the bill.

The Office of Management and Budget advises that, from the standpoint of the Administration's program, there is no objection to the enactment of the enclosed draft legislation.

I am sending an identical letter to the Speaker of the House.

Sincerely,



DAN GLICKMAN

Secretary

Enclosure

A BILL

To reform the State inspection of meat and poultry in the United States, and for other purposes.

1 *Be it enacted by the Senate and House of Representatives of the United States of America*
2 *in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Federal Meat and Poultry State Inspection Act of 1999".

5 **SEC. 2. REVIEW OF STATE INSPECTION PROGRAMS.**

6 (a) IN GENERAL.-Except as provided in subsection (c), prior to September 30, 2001, the
7 Secretary of Agriculture shall conduct a comprehensive review of each State meat and poultry
8 inspection program which shall include-

9 (1) a determination of the effectiveness of the State program; and

10 (2) identification of necessary changes to enable future transition to the State
11 program enforcing Federal inspection requirements as described in sections 5 and 8 of
12 this Act.

13 (b) INTERESTED PARTIES INPUT.-In designing the review described in subsection
14 (a), the Secretary of Agriculture shall, to the extent practicable, obtain input from interested
15 parties.

16 (c) FUNDS.-

17 (1) IN GENERAL.-There is authorized to be appropriated such sums as may be
18 necessary to carry out this section.

19 (2) AVAILABLE FUNDS.-Notwithstanding any other provision of law, no funds,
20 other than funds specifically appropriated pursuant to paragraph (1), may be used to carry

1 out this section.

2 **SEC. 3. STATE MEAT INSPECTION PROGRAM FOR INTRASTATE**
3 **DISTRIBUTION.**

4 (a) REDESIGNATION.-Title III and section 301 of the Federal Meat Inspection Act (21
5 U.S.C. 661) are redesignated as title V and section 501, respectively.

6 (b) INTRASTATE PROGRAM.-Title V of the Federal Meat Inspection Act, as
7 redesignated by subsection (a), is amended--

8 (1) by adding "FOR INTRASTATE DISTRIBUTION" after "FEDERAL AND
9 STATE COOPERATION"; and

10 (2) in section 501(c)(1), by striking "section 301 of the Act" and inserting
11 "subsection (a)(4)".

12 (c) EFFECTIVE DATE.-This section is effective October 1, 2001.

13 **SEC. 4. REPEAL OF INTRASTATE INSPECTION PROGRAM.**

14 (a) REPEAL.-Title V of the Federal Meat Inspection Act, as redesignated by section 3(a),
15 is repealed.

16 (b) EFFECTIVE DATE.-Except as provided in section 10, this section is effective
17 October 1, 2002.

18 **SEC. 5. STATE MEAT INSPECTION PROGRAM.**

19 (a) IN GENERAL.-The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) is amended
20 by inserting after title II:

21 **"TITLE III-STATE MEAT INSPECTION PROGRAM.**

22 **"SEC. 301. POLICY AND FINDINGS.**

1 “(a) POLICY.-It is the policy of Congress to protect the public from meat and meat food
2 products that are adulterated or misbranded and to assist in efforts by State and other
3 Government agencies to accomplish this objective.

4 “(b) FINDINGS.-Congress makes the following findings:

5 “(1) The goal of a safe and wholesome supply of meat and meat food products
6 throughout the country will be better served if a consistent set of requirements,
7 established by the Federal government, are applied to all meat and meat food products,
8 whether produced under State or Federal inspection.

9 “(2) In such a system, State and Federal meat inspection programs can function
10 together to create a seamless inspection system that ensures food safety and inspires
11 consumer confidence in the food supply in interstate commerce.

12 “(3) Such a system also will ensure the viability of State meat inspection
13 programs, which should help to foster the viability of small meat establishments.

14 **“SEC. 302. APPROVAL OF STATE INSPECTION PROGRAM.**

15 “(a) IN GENERAL.-Notwithstanding any other provision of this Act, the Secretary may
16 approve a State inspection program and allow the shipment of carcasses or parts thereof, meat-
17 and meat food products inspected by such a State inspection program into commerce in
18 accordance with this title.

19 “(b) ELIGIBILITY.-

20 “(1) IN GENERAL.-To receive or maintain approval from the Secretary in
21 accordance with subsection (a), the State inspection program must-

22 “(A) implement a State meat inspection program that enforces the

1 mandatory ante mortem and post mortem inspection, reinspection, sanitation, and
2 related Federal requirements in titles I, II, and IV and the regulations issued
3 thereunder; and

4 “(B) enter into a cooperative agreement with the Secretary in accordance
5 with subsection (c).

6 “(2) ADDITIONAL REQUIREMENTS.-

7 “(A) IN GENERAL.-In addition to the requirements specified in paragraph
8 (1), a State inspection program shall, in the case of a State inspection program
9 reviewed in accordance with section 2 of the Federal Meat and Poultry State
10 Inspection Act of 1999, by October 1, 2002, implement all recommendations from
11 such review, in a manner approved by the Secretary.

12 “(B) REVIEW OF NEW STATE INSPECTION PROGRAMS.-

13 “(I) DEFINITION OF ‘NEW STATE INSPECTION
14 PROGRAM’.-For the purposes of this subparagraph, the term ‘new State
15 inspection program’ shall mean a State inspection program that was not
16 approved in accordance with subsection (a) between October 1, 2001, and
17 September 30, 2002.

18 “(ii) REVIEW REQUIREMENT.-One year after the Secretary
19 approves a new State inspection program, the Secretary shall conduct a
20 comprehensive review of such State meat inspection program, which shall
21 include-

22 “(I) a determination of the effectiveness of the State

1 program; and

2 “(II) identification of necessary changes to ensure
3 enforcement by the State program of Federal inspection
4 requirements.

5 “(iii) IMPLEMENTATION REQUIREMENTS.-In addition to the
6 requirements specified in paragraph (1), to continue to be an approved
7 State inspection program, the new State inspection program must
8 implement all recommendations from the review conducted in accordance
9 with this subparagraph, in a manner approved by the Secretary.

10 “(c) COOPERATIVE AGREEMENT.-Notwithstanding chapter 63 of title 31, United
11 States Code, the Secretary may enter into a cooperative agreement with a State that shall
12 establish the terms governing the relationship between the Secretary and the State inspection
13 program and shall provide for the following:

14 “(1) PROVISIONS CONSISTENT WITH THIS ACT.-The State will adopt
15 provisions identical to titles I, II and IV and the regulations issued thereunder.

16 “(2) MARKING OF PRODUCT.-

17 “(A) OFFICIAL MARKS.-State inspected and passed meat and meat food
18 products will be marked under the supervision of a State inspector with the
19 official mark and be deemed as having been federally inspected and having passed
20 such inspection.

21 “(B) ADDITIONAL MARKS.-In addition to the official mark, State
22 inspected and passed meat and meat food products may be marked with the mark

1 of State inspection, in accordance with requirements issued by the Secretary.

2 “(3) LABELING REQUIREMENTS.-The State will comply with all labeling
3 requirements issued by the Secretary governing meat and meat food products inspected by
4 the State inspection program.

5 “(4) AUTHORITY OF THE SECRETARY.-The Secretary shall have authority-

6 “(A) to detain and seize livestock, carcasses, and parts thereof, and meat
7 and meat food products under the State inspection program;

8 “(B) to obtain access to facilities, records, livestock, carcasses and parts
9 thereof, and meat and meat food products of any party who slaughters, processes,
10 handles, stores, transports, or sells meat or meat food products inspected under the
11 State inspection program to determine compliance with this Act and regulations
12 issued thereunder; and

13 “(C) to direct the State to conduct any activity authorized to be conducted
14 by the Secretary under this Act and regulations issued thereunder.

15 “(5) OTHER TERMS.-Other terms the Secretary determines are necessary to
16 ensure the actions of the State and the State inspection program are consistent with this
17 Act and the regulations issued thereunder.

18 “(d) ADDITIONAL REQUIREMENTS.-

19 “(1) IN GENERAL.-A State may impose additional requirements on
20 establishments under the State’s inspection program, as approved by the Secretary.

21 “(2) RESTRICTION ON ESTABLISHMENT SIZE.-The Secretary may authorize
22 a State to restrict the maximum size of establishments the State will accept into the State

1 inspection program.

2 “(e) REIMBURSEMENT OF STATE COSTS.-The Secretary may provide the State up to
3 60 percent of the State’s costs of meeting the Federal requirements for the State inspection
4 program.

5 “(f) SAMPLING.-

6 “(1) SALMONELLA SAMPLING AND TESTING.-To the extent that the
7 Secretary requires establishments to meet microbiological performance standards for
8 Salmonella, the Secretary shall sample and test for Salmonella in State inspected
9 establishments.

10 “(2) OTHER SAMPLING AND TESTING.-In addition to the activities described
11 in paragraph (1), the Secretary may perform other sampling and testing of meat and meat
12 food products in State inspected establishments.

13 “(g) NONCOMPLIANCE.-If the Secretary determines that a State inspection program
14 does not comply with the requirements of this title or with the terms of the cooperative
15 agreement, the Secretary shall take action, as the Secretary deems necessary, to ensure that the
16 carcasses and parts thereof, and meat and meat food products in such State are inspected in a
17 manner that effectuates the purposes of this Act and the regulations issued thereunder.

18 **“SEC. 303. AUTHORITY TO TAKE OVER STATE INSPECTION.**

19 “(a) NOTIFICATION.-If the Secretary has reason to believe that a State is not in
20 compliance with this Act, the regulations issued thereunder, or the terms of the cooperative
21 agreement and is considering the revocation or temporary suspension of the approval of the State
22 inspection program, the Secretary shall promptly notify and consult with the Governor of the

1 State.

2 “(b) SUSPENSION AND REVOCATION.-The Secretary may revoke or temporarily
3 suspend the approval of a State inspection program and take over a State inspection program if
4 the Secretary determines the State inspection program is not in compliance with this Act, the
5 regulations, or the cooperative agreement. A State inspection program that has been the subject
6 of a revocation may only be reinstated as an approved State inspection program under this Act in
7 accordance with the procedures under section 302(b)(2)(B).

8 “(c) PUBLICATION.-

9 “(1) IN GENERAL.-If the Secretary revokes or temporarily suspends the approval
10 of a State inspection program in accordance with subsection (b), the Secretary shall
11 publish such determination in the *Federal Register*.

12 “(2) 30 DAYS.-Upon the expiration of thirty days after such publication, an
13 establishment governed by a determination under subsection (b) shall be inspected by the
14 Secretary.

15 **“SEC. 304. EXPEDITED AUTHORITY TO TAKE OVER STATE INSPECTED**
16 **ESTABLISHMENTS.**

17 “Notwithstanding any other provision of this title, if the Secretary determines that any
18 establishment operating under a State inspection program is not operating in accordance with this
19 Act, the regulations, or the cooperative agreement, and the State, after notification of the
20 Governor, has not taken appropriate action within a reasonable time as determined by the
21 Secretary, the Secretary may immediately determine any such establishment as an establishment
22 that shall be inspected by the Secretary, until such time that the Secretary determines the State

1 will meet the requirements of this Act, the regulations, and the cooperative agreement with
2 respect to such establishment.

3 **“SEC. 305. ANNUAL REVIEW.**

4 “(a) IN GENERAL.-The Secretary shall develop and implement a process to review each
5 State inspection program approved under this title annually and certify those State inspection
6 programs that meet the terms of the cooperative agreement.

7 “(b) INTERESTED PARTIES INPUT.-The Secretary shall solicit the input of interested
8 parties in designing the review process described in subsection (a).

9 **“SEC. 306. FEDERAL INSPECTION OPTION.**

10 “(a) IN GENERAL.-An establishment operating in a State with an approved State
11 inspection program may apply for inspection under the State inspection program or for Federal
12 inspection.

13 “(b) LIMITATION.-An establishment may not make an application under subsection (a)
14 more than once every four years.”

15 (b) AMENDMENTS TO TITLE IV OF THE FEDERAL MEAT INSPECTION ACT.-

16 Title IV of the Federal Meat Inspection Act (21 U.S.C. 671) is amended-

17 (1) by redesignating section 411 as section 414; and

18 (2) by inserting after section 410 the following:

19 **“SEC. 411. RESTAURANT AND RETAIL STORES.**

20 “The provisions of this Act requiring inspection of the slaughter of animals and the
21 preparation of carcasses, parts thereof, meat and meat food products shall not apply to operations
22 of types traditionally and usually conducted at retail stores and restaurants, when conducted at

1 any retail store or restaurant or similar retail-type establishment for sale in normal retail
2 quantities or service of such articles to consumers at any such establishments. For the purposes
3 of this section, operations conducted at a restaurant central kitchen facility shall be considered as
4 being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food
5 products that are ready to eat when they leave such facility and are served in meals or as entrees
6 only to customers at restaurants owned or operated by the same person, firm, or corporation
7 owning or operating such facility. Such facility shall be subject to the provisions of section 202
8 and may be subject to the inspection requirements under title I for as long as the Secretary deems
9 necessary, if the Secretary determines that the sanitary conditions or practices of the facility or
10 the processing procedures or methods at the facility are such that any of its meat or meat food
11 products are rendered adulterated.

12 **“SEC. 412. ACCEPTANCE OF INTERSTATE SHIPMENTS OF MEAT AND MEAT**
13 **FOOD PRODUCTS.**

14 “Notwithstanding any provision of State law, a State or local government may not
15 prohibit or restrict the movement or sale of meat or meat food products that have been inspected
16 and passed in accordance with this Act.

17 **“SEC. 413. ADVISORY COMMITTEES FOR FEDERAL AND STATE PROGRAMS.**

18 “The Secretary may appoint advisory committees consisting of representatives of
19 appropriate State agencies as the Secretary and the State agencies may designate to consult with
20 the Secretary concerning State and Federal programs with respect to meat inspection and other
21 matters within the scope of this Act.”

22 (c) EFFECTIVE DATE.-This section is effective on October 1, 2001.

1 **SEC. 6. STATE POULTRY INSPECTION PROGRAM FOR INTRASTATE**

2 **DISTRIBUTION.**

3 (a) REDESIGNATION.-Section 5 of the Poultry Products Inspection Act (21 U.S.C. 454)
4 is redesignated as section 34.

5 (b) INTRASTATE PROGRAM.-Section 34 of the Poultry Products Inspection Act, as
6 redesignated by subsection (a), is amended by adding "FOR INTRASTATE DISTRIBUTION"
7 after "FEDERAL AND STATE COOPERATION".

8 (c) This section is effective October 1, 2001.

9 **SEC. 7. REPEAL OF INTRASTATE INSPECTION PROGRAM.**

10 (a) REPEAL.-Section 34 of the Poultry Products Inspection Act , as redesignated by
11 section 7(a), is repealed.

12 (b) EFFECTIVE DATE.-Except as provided in section 10, this section is effective
13 October 1, 2002.

14 **SEC. 8. STATE POULTRY INSPECTION PROGRAM.**

15 (a) IN GENERAL.-The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) is
16 amended by inserting after section 4 the following:

17 **"SEC. 5. STATE POULTRY INSPECTION PROGRAM.**

18 "(a) POLICY.-It is the policy of Congress to protect the public from poultry products that
19 are adulterated or misbranded and to assist in efforts by State and other Government agencies to
20 accomplish this objective.

21 "(b) FINDINGS.-Congress makes the following findings:

22 "(1) The goal of a safe and wholesome supply of poultry products throughout the

1 country will be better served if a consistent set of requirements, established by the Federal
2 government, are applied to all poultry products, whether produced under State or Federal
3 inspection.

4 “(2) In such a system, State and Federal poultry inspection programs can function
5 together to create a seamless inspection system that ensures food safety and inspires
6 consumer confidence in the food supply in interstate commerce.

7 “(3) Such a system also will ensure the viability of State poultry inspection
8 programs, which should help to foster viability of small poultry establishments.

9 “(c) APPROVAL OF STATE INSPECTION PROGRAM.

10 “(1) IN GENERAL.-Notwithstanding any other provision of this Act, the
11 Secretary may approve a State inspection program and allow the shipment of poultry
12 products inspected by such a State inspection program into commerce in accordance with
13 this section and section 5A.

14 “(2) ELIGIBILITY.-

15 “(A) IN GENERAL.-To receive or maintain approval from the Secretary
16 in accordance with paragraph (1), the State inspection program must- —

17 “(I) implement a State poultry inspection program which enforces
18 the mandatory ante mortem and post mortem inspection, reinspection,
19 sanitation, and related Federal requirements in sections 1 through 4 and 6
20 through 33 and the regulations issued thereunder; and

21 “(ii) enter into a cooperative agreement with the Secretary in
22 accordance with paragraph (3).

1 “(B) ADDITIONAL REQUIREMENTS.-

2 “(I) IN GENERAL.-In addition to the requirements specified in
3 subparagraph (A), a State inspection program shall, in the case of a State
4 inspection program reviewed in accordance with section 2 of the Federal
5 Meat and Poultry State Inspection Act of 1999, by October 1, 2002,
6 implement all recommendations from such review, in a manner approved
7 by the Secretary.

8 “(ii) REVIEW OF NEW STATE INSPECTION PROGRAMS.-

9 “(I) DEFINITION OF ‘NEW STATE INSPECTION
10 PROGRAM’.-For the purposes of this clause, the term ‘new State
11 inspection program’ shall mean a State inspection program that
12 was not approved in accordance with paragraph (1) between
13 October 1, 2001, and September 30, 2002.

14 “(II) REVIEW REQUIREMENT.-One year after the
15 Secretary approves a new State inspection program, the Secretary
16 shall conduct a comprehensive review of such State poultry
17 inspection program, which shall include-

18 “(aa) a determination of the effectiveness of the
19 State program; and

20 “(bb) identification of necessary changes to ensure
21 enforcement by the State program of Federal inspection
22 requirements.

1 “(C) LABELING REQUIREMENTS.-The State will comply with all
2 labeling requirements issued by the Secretary governing poultry products
3 inspected by the State inspection program.

4 “(D) AUTHORITY OF THE SECRETARY.-The Secretary shall have
5 authority-

6 “(I) to detain and seize poultry and poultry products under the State
7 inspection program;

8 “(ii) to obtain access to facilities, records, and poultry products of
9 any party who slaughters, processes, handles, stores, transports, or sells
10 poultry products inspected under the State inspection program to
11 determine compliance with this Act and regulations issued thereunder; and

12 “(iii) to direct the State to conduct any activity authorized to be
13 conducted by the Secretary under this Act and regulations issued
14 thereunder.

15 “(D) OTHER TERMS.-Other terms the Secretary determines are necessary
16 to ensure the actions of the State and the State inspection program are consistent
17 with this Act and the regulations issued thereunder.

18 “(4) ADDITIONAL REQUIREMENTS.-

19 “(A) IN GENERAL.-A State may impose additional requirements on
20 establishments under the State’s inspection program, as approved by the
21 Secretary.

22 “(B) RESTRICTION ON ESTABLISHMENT SIZE.-The Secretary may

1 authorize a State to restrict the maximum size of establishments the State will
2 accept into the State inspection program.

3 “(5) REIMBURSEMENT OF STATE COSTS.-The Secretary may provide the
4 State up to 60 percent of the State’s costs of meeting the Federal requirements for the
5 State inspection program.

6 “(6) SAMPLING.-

7 “(A) SALMONELLA SAMPLING AND TESTING.-To the extent that the
8 Secretary requires establishments to meet microbiological performance standards
9 for Salmonella, the Secretary shall sample and test for Salmonella in State
10 inspected establishments.

11 “(B) OTHER SAMPLING AND TESTING.-In addition to the activities
12 described in subparagraph (A), the Secretary may perform other sampling and
13 testing of poultry products in State inspected establishments.

14 “(7) NONCOMPLIANCE.-If the Secretary determines that a State inspection
15 program does not comply with the requirements of this section, section 5A, or with the
16 terms of the cooperative agreement, the Secretary shall take action, as the Secretary
17 deems necessary to ensure that the poultry products in such State are inspected in a
18 manner that effectuates the purposes of this Act and the regulations issued thereunder.

19 “(d) ANNUAL REVIEW.-

20 “(1) IN GENERAL.-The Secretary shall develop and implement a process to
21 review each State inspection program approved under this section annually and certify
22 those State inspection programs that meet the terms of the cooperative agreement.

1 the Secretary concerning State and Federal programs with respect to poultry product inspection
2 and other matters within the scope of this Act.”

3 (c) EFFECTIVE DATE.-This section is effective on October 1, 2001.

4 **SEC. 9. REGULATIONS.**

5 The Secretary of Agriculture may promulgate regulations to implement sections 5 and 8
6 prior to October 1, 2001.

7 **SEC. 10. TERMINATION OF AUTHORITY TO ESTABLISH AN INTERSTATE**
8 **INSPECTION PROGRAM.**

9 If the Secretary of Agriculture does not approve a State inspection program by entering
10 into a cooperative agreement pursuant to title III of the Federal Meat Inspection and sections 5
11 and 5A of the Poultry Products Inspection Act as amended by this Act by September 30, 2002,
12 sections 4, 5, 7, and 8 of this Act are repealed.

Y2k Readiness

Release No. 0463.99

Remarks

As Prepared for Delivery
of
Secretary of Agriculture Dan Glickman
Y2k Readiness
Bethesda, MD -- November 18, 1999

"Thank you Jack

" I also want to thank John Koskinen, who come January 1 will be an unsung hero because of his tremendous behind-the-scenes job ensuring that this New Year's Day will be like any other...except that the 1 and the 9 will change but he couldn't do anything about that.

"With me today from USDA are Cathy Woteki, Under Secretary for Food Safety who does a terrific job year round ensuring that our food supply remains the safest in the world, and Chief Information Officer Anne Reed who's done a yeoman's job making sure that all of USDA's systems are ready for Y2K.

"I want to thank everyone for joining us here today and I want to thank our hosts Giant Foods. As some of you may know, I'm a big advocate in the fight against hunger. Last year Giant Foods was recognized by America's Second Harvest, The Food Bank Network, as Grocer of the Year for their efforts to mobilize communities and help feed the hungry. Barry, I want to thank you and Giant Foods for all your efforts to help strengthen the nutritional safety net.

"Of course the reason we are here today is to assure everyone that there will be plenty of food on market shelves come January 1. The Y2K computer problem has reared it's ugly head, and we've dealt with it.

"For the past year, the Food Supply Working Group, part of the President's Council on Year 2000 Conversion and chaired by the Department of Agriculture, has been looking at the readiness of our food supply.

"Today's announcement comes under the heading, 'No news is good news.' As usual consumers can expect that a safe and abundant supply of food will be available on January 1, 2000 and beyond. I'm not saying there might not be some spot shortages as a result of consumer overbuying or weather-related problems, but I'm confident that the Year 2000 problem's effect on the overall food supply will be negligible.

"Companies, both large and small, have announced their readiness, and many have contingency plans in place to deal with any unexpected mishaps. We also found that the Y2K readiness of our major trading partners has shown great improvement over the past year, including Mexico, a key supplier of winter fruits and vegetables.

"Getting to this point was no easy task. To give you an idea of what assessing Y2K readiness entailed, I call your attention to this chart which shows the complexity and magnitude of the U.S. food system. The production and distribution of food represents over 16% of our nation's economy and includes hundreds of thousands of producers and businesses, from small family farmers to huge multinational

corporations.

The Food Supply Working Group used a number of methods to study this very complex system, including outside contractors -- The Gartner Group and Performance Engineering Corporation -- and survey results from USDA agencies, trade associations, and food producers.

"In addition, USDA has the lead role for assessing the readiness of our food safety inspection programs. USDA has partnered with the Food and Drug Administration and state inspection programs to ensure that our food safety inspection programs are fully prepared for the year 2000.

"The bottom line of all this research is that the food system is not at risk because of the Y2K computer bug. There is plenty of choice from plenty of sources. And in the event of spot shortages, people should feel confident knowing that wholesalers and retailers carry in excess of 30-60 days supply of non-perishable food. So our food system can easily absorb any isolated disruptions that might occur.

"So today, we're urging consumers to relax and treat the New Year just like they would any other long holiday weekend. As John Koskinen advises, it is always a good idea, especially in the winter months, to have a few days worth of non-perishable foods in the pantry. But rest assured, on January 1 and the days following, Americans will find the same safe and abundant food supply they have every other day of the year."

#

President's Council on Food Safety



U.S. Department
of Agriculture



Department of Health
and Human Services



Environmental
Protection Agency



Department
of Commerce

EGG SAFETY

From Production to Consumption:

AN ACTION PLAN

to Eliminate Salmonella Enteritidis Illnesses Due to Eggs

December 10, 1999

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Egg Safety From Production to Consumption: An Action Plan to Eliminate Salmonella Enteritidis Illnesses Due to Eggs

Executive Summary

Purpose. The President's Council on Food Safety has identified egg safety as one component of the public health issue of food safety that warrants immediate federal, interagency action. The Egg Safety Action Plan presented in this report identifies the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of human *Salmonella* Enteritidis (SE) illnesses. The overarching public health goal of the Council is to eliminate SE illnesses associated with the consumption of eggs by 2010. The interim goal of the Egg Safety Action Plan is a 50 percent reduction in egg-associated SE illnesses by 2005.

Background. Americans consume an average of 234 eggs per person per year. While eggs are an important source of protein in the diet, an estimated 1 in 20,000 eggs in the U.S. supply will contain the SE bacteria and can cause illness if eaten raw in foods or not thoroughly cooked before consumption. Because eggs can become contaminated internally from the hen, common egg-handling practices are now considered to be unsafe. These practices include temperature abuse (i.e. holding eggs and egg-containing foods at room temperature instead of under refrigeration), inadequate cooking, and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked.

The SE risk assessment model for shell eggs and egg products, developed jointly by the Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) in 1998, predicted that using multiple interventions could achieve a more substantial reduction in SE illnesses than using any one intervention alone. This finding suggests that a broadly based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production to consumption continuum.

On August 26, 1999, the President's Council held a public meeting to obtain input during the development of the action plan to address egg safety. A single theme resounded from representatives of the consumer groups and the egg industry: The federal government needs a set of mandatory national standards. These standards should: (1) provide consumers an assurance that all eggs are subject to the same safety standards across the U.S. and (2) provide egg producers and processors a "level playing field" industry-wide.

Recommendations. The President's Council on Food Safety concluded that the development and implementation of the Action Plan outlined in this report is an effective way to prevent human SE infections due to the consumption of SE-contaminated eggs. The Action Plan reflects our current understanding of the steps needed to reduce egg-associated SE illness. As we move forward with the Plan and develop the proposals, we will assess the impact of the individual action items, consult with stakeholders, and refine the Plan to reflect the best information available to achieve our public health goal.

At each stage of the egg production-to-consumption continuum, the Plan identifies the systems and activities necessary to achieve our food safety public health goals. The Plan offers industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution and to the consumer at an equivalent level of safety. The strategy selection by egg producers and packer/processors determines the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion system on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

For the distribution and retail stages, the Plan specifies the safe handling practices necessary to ensure consumers receive a safe food product. Furthermore, the Plan clearly describes the surveillance, research, and education activities that must also be conducted to achieve the elimination of egg-associated SE illnesses. The relative difference in emphasis between the two strategies is highlighted in [Figure 1](#). A comparative summary of the activities in Strategy I and Strategy II is provided in [Table 1](#).

To consolidate egg safety oversight responsibilities and provide clarity, the President's Council on Food Safety identified one responsible agency for each stage of the farm-to-table continuum, based on the strengths of each agency, as follows:

- FDA develops standards for the producer and the States provide inspection and enforcement on the farm.
- FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement for both.
- FDA and CDC conduct surveillance and monitoring activities. CDC focuses on human health and FDA on the food supply.

The performance measures that will be used to assess the progress of the Plan toward its goal are the numbers of SE cases, isolates, and outbreaks annually. The data will be collected using the following existing systems: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System. The new data will be compared to the 1998 baseline values of: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.

Figure 1. Depiction of Program Strategies for Action Plan

Eggs: From Farm to Table

Problem: *Salmonella* Enteritidis in Eggs
Goal: Eliminate It as a Source of Human Illness

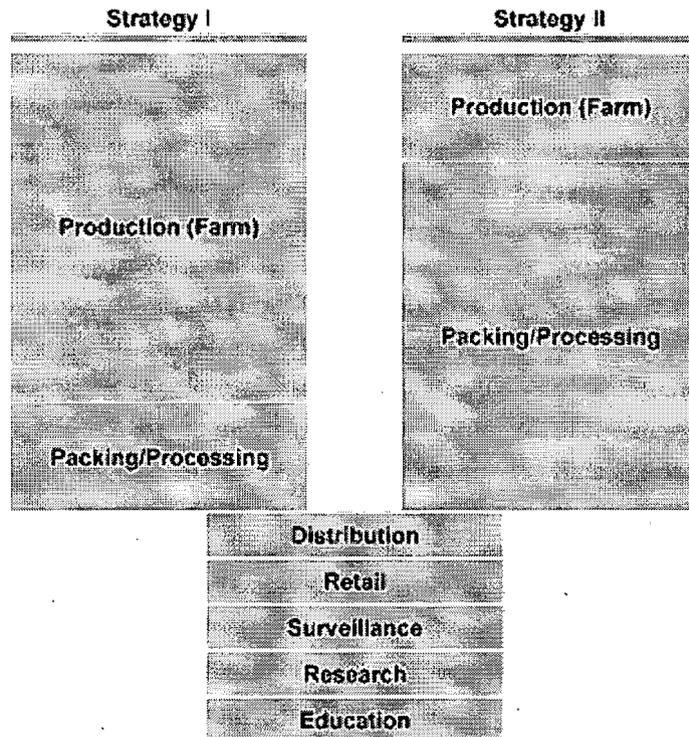


Table 1. Comparison of Program Strategies for Action Plan		
<i>Activity</i>	Strategy I	Strategy II
PRODUCTION (On-Farm): Objective 1.1		
Chicks from SE-free breeder flocks	X	X
SE Environmental Testing (chicks, pullets, layers)	X	
SE Environmental Testing (at depopulation)	X	X
SE Egg Testing (w/positive environmental results)	X	
Diversion of shell eggs to pasteurization	X	
Biosecurity	X	X
Rodent/Pest control	X	X
Decontamination (Cleaning & Disinfection)	X	X
PACKING¹: Objective 1.2		
Prerequisite programs	X	X
HACCP system with a "kill" step		X
PROCESSING¹: Objective 1.3		
Prerequisite programs	X	X

HACCP system with a "kill" step	X	X
DISTRIBUTION²: Objective 1.4		
Refrigeration during transport and storage	X	X
RETAIL: Objective 2		
Food Code (egg-relevant provisions)	X	X
SURVEILLANCE: Objectives 3-6		
Monitoring human and poultry SE infections	X	X
RESEARCH: Objective 7		
	X	X
EDUCATION: Objective 8		
	X	X
<p>¹ Prerequisite programs must address: basic sanitation of facilities and premises; rodent and pest control; employee hygiene and health; safety of water and food packing materials; and washing, sanitizing, and packaging.</p> <p>² FSIS Final Rule; FDA Proposed Rule</p>		

Egg Safety From Production to Consumption:

An Action Plan to Eliminate SE Illnesses Due to Eggs

Introduction

Americans consume an average of 234 eggs per person per year. While eggs are an important source of protein in the diet, an estimated 1 in 20,000 eggs in the U.S. supply will contain the *Salmonella* Enteritidis (SE) bacteria and can cause illness if not thoroughly cooked before consumption. The federal agencies responsible for ensuring the safety of eggs, under the auspices of the President's Council on Food Safety, have jointly developed an Action Plan to eliminate SE illnesses due to the consumption of contaminated eggs.

The Action Plan presented in this report is an aggressive, comprehensive approach to address egg safety that will reduce the number of SE illnesses attributed to eggs in the United States by 50 percent by the year 2005. The Plan identifies systems that must be designed and implemented and activities that must be conducted at each stage of the farm-to-table continuum to reach the overarching goal of eliminating egg-associated SE illnesses. The Plan also recognizes and encompasses federal, state, and local systems already in place and industry activities already occurring. The Action Plan reflects our current understanding of the steps needed to reduce egg-associated SE illness. As we move forward with the Plan and develop the proposals, we will assess the impact of the individual action items, consult with stakeholders, and refine the Plan to reflect the best information available to achieve our public health goal.

Scope

This comprehensive, science-based plan contains elements identified by the National Academy of

Sciences' Committee to Ensure Safe Food from Production to Consumption as necessary components of an effective food safety system⁽³⁾.

- To promote consistency, the Plan calls for a consistent, nationwide program that addresses each stage of the farm-to-table continuum, including on the farm, at the packer or processor, during distribution, as well as for proper handling and preparation practices at retail. The Plan also highlights the proposed and final rules requiring refrigeration at retail and during distribution, respectively, as well as a proposed rule that would require a safe handling statement on the package.
- To provide a science-based foundation, the development of the Plan began with a review of the comprehensive, quantitative risk assessment of SE for shell eggs and egg products. The findings and research needs identified in the risk assessment report were incorporated into the Plan.
- The Plan identifies promising developments in science and technology, such as SE vaccines and in-shell pasteurization, for further research including field and pilot studies.
- The Plan recognizes the need for adequate surveillance, including active surveillance of SE illnesses in regions of the country where the most contaminated eggs are produced and consumed, and calls for expansion of FoodNet activities.
- The Plan identifies gaps in the scientific understanding of the SE bacterium and its route of on-farm transmission to SE-free chicks. The Plan also highlights the federal government's current education efforts focused on the use of safe egg handling practices by food preparers at retail and at home.
- In development of the Plan, the personnel and funds necessary to implement and maintain the specific systems and activities listed, through FY2005, were considered. Therefore, the Plan highlights existing partnerships and encourages the formation of new ones.
- The Plan clearly identifies the agencies responsible for the development and implementation of the new egg safety activities proposed.

The Egg Safety Action Plan presented in this report clearly and concisely describes a way to reduce the number of SE-contaminated eggs in the marketplace and to eliminate SE illnesses caused by consumption of eggs. By combining new and existing systems and activities targeted at both eggs and illnesses, the plan presents a comprehensive, integrated nationwide approach to address an important food safety and public health concern so that Americans can continue to enjoy one of the safest food supplies in the world.

Background

President's Food Safety Initiative. On January 25, 1997, the President directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify specific steps to further improve the safety of the food supply and to further reduce the incidence of foodborne illness to the greatest extent feasible⁽⁴⁾. In May 1997, they presented the President with a report entitled, "Food Safety from Farm to Table: A National Food Safety Initiative." Under this initiative, the federal government, in concert with state and local governments, industry and academia, are conducting research, risk assessments, and cost-benefit analyses to determine how foodborne illnesses occur and can be prevented or controlled in the most efficient and cost-effective

manner. The federal government is also improving surveillance and investigative efforts to locate and monitor illnesses caused by food, updating its approach to inspections of food processors to monitor the safety of the food supply, and reinvigorating education of food preparers focusing on the use of safe practices⁽⁵⁾.

President's Council on Food Safety and Its Strategic Plan. In August 1998, the President established a Council on Food Safety under Executive Order No. 13100 to protect the health of the American people by preventing foodborne illness using science-based regulation and well-coordinated surveillance and investigation, inspection, enforcement, research, and educational programs⁽⁶⁾. In the Order, the President directed the Council to "develop a comprehensive strategic food safety plan for Federal food safety activities" and "advise Federal agencies in setting priority areas for investment in food safety⁽⁷⁾." He also ordered the Council to make recommendations to him on how to implement a comprehensive science-based strategy to improve the safety of the food supply and enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council's Food Safety Strategic Plan will focus on "core food safety activities" including activities intended to enhance the safety of the nation's food supply and to protect public health by reducing the annual incidence of acute and chronic foodborne illness. The strategic plan will include Federal programs for research, monitoring, surveillance, regulation, prevention, voluntary and mandatory certification and inspection, enforcement, labeling, and education⁽⁸⁾. The plan will be used to set priorities, improve coordination and efficiency, identify and close gaps in the current food safety system, enhance and strengthen prevention and intervention strategies, and develop performance measures to monitor progress⁽⁹⁾.

Council's Egg Safety Action Plan. The President's Council on Food Safety has identified egg safety as one component of the overall public health issue of food safety that warrants immediate federal, interagency action. Under the auspices of the President's Council, the Strategic Planning Task Force commissioned an Egg Safety Task Force composed of designees of the federal food safety agencies responsible for egg safety to develop an action plan to eliminate egg-associated SE illnesses. Those agencies are DHHS' Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) and USDA's Food Safety and Inspection Service (FSIS), Animal and Plant Health Inspection Service (APHIS), Agriculture Marketing Service (AMS), and Agriculture Research Service (ARS). The Egg Safety Action Plan developed by the Task Force and presented in this report identifies the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of SE illnesses.

Salmonella Enteritidis Contamination of Eggs. *Salmonella* of various serotypes are commonly found in the digestive tracts of animals and frequently contaminate our environment. Originally, *Salmonella* contamination of shell eggs was believed to occur primarily when organisms present on the egg passed through the shell into the egg's contents. However, more recently transovarian SE contamination of egg contents has been determined to occur from SE-infected laying hens. The rate of transovarian egg contamination has been estimated at about 1 SE-positive egg in every 20,000 eggs produced in the U.S.⁽¹⁰⁾

Human SE illnesses. From 1985 to 1998, there have been a total of 794 SE outbreaks reported to CDC involving 28,644 illnesses, 2,839 hospitalizations, and 79 deaths⁽¹¹⁾. In 1997 alone, an estimated 300,000 infections may have occurred⁽¹²⁾. A typical case of salmonellosis is characterized by diarrhea, abdominal cramps, nausea, vomiting, fever, and headache. Symptoms usually begin within 6 to 72 hours after consuming food, last 4 to 7 days, and resolve without antibiotic treatment for most people who do not have underlying health problems. However, the infection can enter the bloodstream leading to severe and fatal illness. The invasive, life-threatening form of the disease is more likely in highly susceptible

populations, including children, the elderly, and persons with weakened immune systems. CDC reported that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in nursing homes⁽¹³⁾. In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis.

CDC surveillance data show that the rate of isolation of SE from infected humans increased throughout the U.S. during 1976-1994 from 0.5 to 3.9 per 100,000 population. Evaluation of regional trends for the years 1990-1994 actually indicates a decrease in the SE isolation rate from 8.9 to 7.0 per 100,000 population in the Northeast, where egg quality assurance efforts had been the most intensive. In contrast, the rate increased approximately threefold in the Pacific region, with California reporting an increase in SE isolates from 11% in 1990 to 38% in 1994⁽¹⁴⁾.

The benefits associated with preventing human salmonellosis are: (1) the economic benefits of reducing loss of productivity associated with human illness, (2) reduced pain and suffering, and (3) reduced expenditures on medical treatment. The costs associated with human salmonellosis due to SE are estimated to range from \$150 million to \$870 million annually⁽¹⁵⁾.

Egg-Handling Practices. Traditionally, practices such as the use of raw eggs in foods and the undercooking and non-refrigeration of eggs were not considered unsafe. More recently, however, the potential for internal SE contamination of eggs has been established and egg-handling practices have been reevaluated. Common egg-handling practices now considered to be unsafe include: temperature abuse (i.e. holding eggs and egg-containing foods at room temperature instead of under refrigeration); inadequate cooking; and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked. The presence of SE bacteria in a raw egg, alone, does not guarantee illness upon consumption. However, the likelihood of developing an SE infection increases when the egg is not handled safely by permitting the bacteria to multiply and a greater number of bacteria to be ingested with the food. Investigations of SE outbreaks show that the consumption of foods prepared with SE-contaminated eggs that are not cooked or are undercooked or that are held at room temperature is a common scenario. In fact, many of the SE outbreaks that occurred between 1985 and 1998 were attributed to commercial establishments, such as restaurants, hospitals, nursing homes, schools, and prisons, and greater than 75 percent of those SE outbreaks with an identified source were associated with foods containing undercooked eggs. In addition, the 1996-97 Food Consumption and Preparation Diary Survey showed that 27 percent of all egg dishes consumed were undercooked, described as being runny or having a runny yolk or runny white⁽¹⁶⁾. On average, each person in the survey consumed undercooked eggs 20 times a year. Within those subgroups at risk, women over 65 and children under 6 consumed undercooked eggs 21 times a year and 8 times a year, respectively.

U.S. Egg Industry. On a per capita basis, Americans consume about 234 eggs per year. In 1998, the U.S. table egg industry produced 67.3 billion eggs, up 3 percent from 1997⁽¹⁷⁾. U.S. production is relatively stable and has increased only slightly from about 60 billion eggs in 1984. The total value of the table eggs (eggs produced for human consumption, not hatching) produced in the U.S. in 1995 was estimated at \$3.96 billion⁽¹⁸⁾. Generally, about 70 percent of the table eggs produced are sold as shell eggs while the remainder are processed into liquid, frozen or dried pasteurized egg products. The majority of egg products are destined for institutional use or further processing into foods such as cake mixes, pasta, ice cream, mayonnaise, and bakery goods.

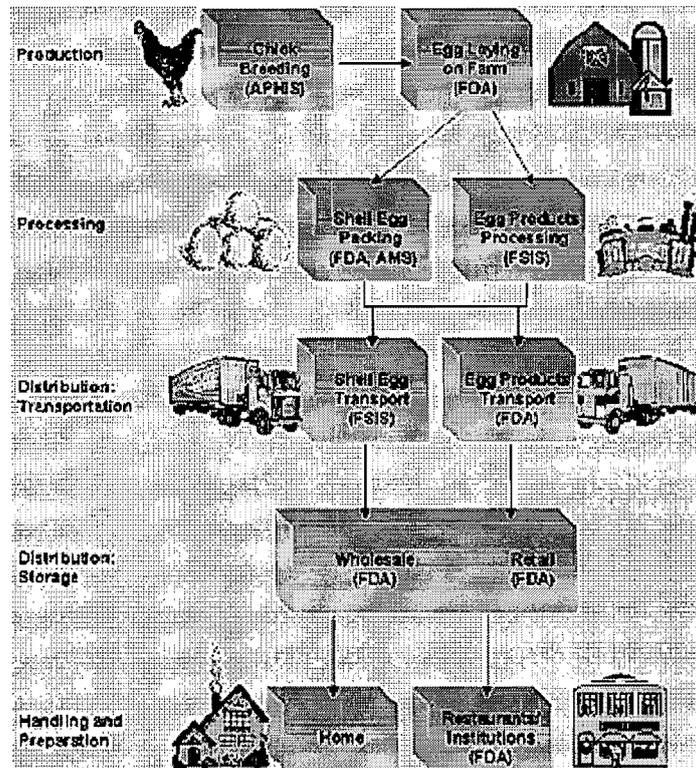
Flocks associated with egg production fall into three categories: breeders (grandparents), multipliers (parents), and laying flocks (including both immature hens, or pullets, and laying hens, or layers). There

were roughly 300,000 breeding hens, 3 million multipliers, and 300 million layers. The value of laying flocks alone is estimated to be nearly \$1 billion⁽¹⁹⁾. Geographically, commercial egg production in the western U.S. is concentrated in California and in the eastern U.S. is centered in Ohio, Indiana, and Pennsylvania. Other states in which major producers are located include Iowa, Texas, Minnesota, and Georgia. About 5,000 producers have 3,000 or more layers, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production⁽²⁰⁾. An additional 65,000 farms have less than 3,000 egg-laying hens accounting for the balance of eggs produced⁽²¹⁾.

Current Regulation of Shell Eggs. Federal authority to regulate egg safety is shared by the Department of Health and Human Services' (HHS') Food and Drug Administration (FDA) and the United States Department of Agriculture's (USDA's) Food Safety Inspection Service (FSIS). In addition, USDA's Animal and Plant Health Inspection Service (APHIS) conducts a control program that certifies poultry breeding stock and hatcheries as SE-free and USDA's Agricultural Marketing Service (AMS) conducts a surveillance program to ensure proper disposition of restricted shell eggs. (See [Figure 2](#), glossary.)

FDA has jurisdiction over the safety of foods generally, including shell eggs, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq.*). Under the Public Health Service Act (PHSA; 42 U.S.C. 201 *et seq.*), FDA also has the authority to prevent the spread of communicable diseases, including the authority to regulate foods when the foods may act as a vector of disease, as in the case of SE in eggs. FDA is responsible for: (1) investigating SE outbreaks, reported by CDC and State/local health departments, due to foods in interstate commerce, (2) performing trace backs to identify the source of the implicated eggs, (3) testing flocks, (4) diverting eggs from SE-positive flocks, (5) collecting flock data to help track the spread of SE among layer flocks, and (6) promoting better quality control.

Figure 2. Egg Safety from Production to Consumption



USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA; 21 U.S.C. 1031 et seq.). Under EPIA, FSIS has primary responsibility for the inspection of processed egg products to prevent the distribution of adulterated or misbranded egg products. Also under EPIA, AMS conducts a surveillance program to ensure proper disposition of restricted shell eggs and visits producer/packers periodically to ensure: (1) that eggs packed for commercial sale contain no more restricted eggs than permitted for US Consumer Grade B, (2) that restricted and inedible product is properly labeled, and (3) that restricted and inedible eggs are denatured and properly disposed of. Under current federal regulations, all major commercial egg producers are required to register with AMS and are subject to periodic onsite inspections by AMS. In FY1998, 698 producer/packers were registered with AMS, with a balance of about 4,300 producers that do not process (pack)⁽²²⁾.

Quantitative Risk Assessment of SE in Eggs. In December 1996, FSIS and FDA jointly began a comprehensive risk assessment in response to an increasing number of human illnesses associated with the consumption of eggs⁽²³⁾. A team of scientists developed a quantitative model to characterize the risks associated with the consumption of eggs contaminated internally with SE, using information obtained from academic, government, and industry sources and scientific literature. The risk assessment model consists of discrete modules that may be used independently to evaluate the effect of variable changes during a particular stage of the farm-to-table continuum. However, the overall model encompasses the entire continuum, from the chicken through egg production, to egg consumption and human illness. The model continues to serve as a quantitative tool for FSIS and FDA decision-makers to use in the design of a comprehensive, integrated risk reduction strategy.

The risk assessment of SE in eggs: (1) established the unmitigated risk of foodborne illness from SE; (2) evaluated potential risk reduction strategies; and (3) identified knowledge gaps where future research is needed. First, the model predicted the risk of a hen laying an SE-contaminated egg to be 1 in 20,000. Second, two interventions showed great promise in reducing the number of SE illnesses associated with contaminated egg consumption: (1) lowering the temperature at which shell eggs are maintained and (2) diverting eggs produced by SE-positive flocks from the shell egg market to the pasteurized, egg products market. In addition, the model predicts that the probability of any cases of SE illness resulting from the consumption of pasteurized egg products is low. However, the risk of illness may be further reduced by basing the egg product pasteurization time-temperature standards on: (1) the amount of bacteria in the raw product, (2) the specific process used to treat the raw product, and (3) the intended use of the finished egg product. Third, several research needs were identified and have been incorporated into the research objective of this Action Plan. Overall, the model predicted that while using any one intervention could achieve a modest reduction in human SE illnesses, using multiple interventions could achieve a more substantial reduction for those interventions tested. This finding suggests that a broadly based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production to consumption continuum.

FDA and FSIS Egg Safety Regulations. As a result of the risk assessment findings, FDA has proposed a rule to require: (1) safe handling statements on labels of shell eggs that have not been treated to destroy *Salmonella* bacteria and (2) that shell eggs be stored and displayed under refrigeration at a temperature of 7.2° C (45° F) or less when held at retail establishments⁽²⁴⁾. These proposed actions complement FSIS' final rule that requires: (1) shell eggs be stored and transported at an ambient air temperature of 7.2° C (45° F) or less and (2) consumer containers of shell eggs be labeled to indicate that refrigeration is required⁽²⁵⁾. The label statements are intended to ensure that consumers have the information necessary to protect themselves from eggs contaminated with SE. The refrigeration requirements are intended to ensure that eggs be held at temperatures that restrict pathogen growth. Careful coordination of these efforts in the overall strategy presented in the SE Action Plan will amplify their individual impact and will provide early progress toward meeting the public health goals of the Action Plan.

An Action Plan For Egg Safety

On August 26, 1999, the President's Council held a public meeting to obtain input during the development of the action plan to address egg safety. A single theme resounded from representatives of the consumer groups and the egg industry. The federal government needs a set of national, mandatory standards. These standards should: (1) provide consumers an assurance that all eggs are subject to the same safety standards across the U.S. and (2) provide egg producers and processors a "level playing field" industry-wide.

With this in mind, the Council concluded that the further development and implementation of the Action Plan presented in this section of the report is the most effective way to achieve its public health goals. This comprehensive Action Plan identifies the sum of activities necessary to reach the overarching goal of the elimination of SE illnesses associated with the consumption of eggs. While the Plan focuses on SE and eggs, major components of the Plan offer food safety benefits well beyond the specific goal of eliminating egg-associated human SE illnesses. For example, upgrading the information systems at public health departments will contribute to reductions in all foodborne illnesses.

The Action Plan consists of 8 objectives, each with at least one performance measure, covering all stages of the farm-to-table continuum as well as support functions. The farm-to-table continuum encompasses: egg production, shell egg processing (or packing), egg products processing, egg distribution, and egg handling and preparation. The support functions are surveillance of human and poultry SE infections (including outbreak and traceback investigations) and eggs, research, and education.

Regulatory approach. The Action Plan presented in this report clearly lays out the components for an effective program to prevent human SE infections resulting from consumption of contaminated eggs. At each stage of the egg production-to-consumption continuum, the Plan identifies the systems and activities necessary to achieve our food safety public health goals. The Plan offers industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution at an equivalent level of safety. The strategy selection by egg producers and packer/processors determines the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

For the distribution and retail stages, the Plan specifies the safe handling practices necessary to ensure consumers receive a safe food product. Furthermore, the Plan clearly describes the surveillance, research, and education activities that must also be conducted to achieve the elimination of egg-associated SE illnesses.

Both Strategies I and II require an on-farm regulatory presence and a packer/processor regulatory presence; therefore, an industry shift over time from one strategy to the other should not change the overall human resource needs. Because reaching our public health goals requires that each stage of the farm-to-table continuum achieve its objectives, oversight and enforcement at every stage will be key to the Plan's success.

As the federal agencies develop consistent nationwide standards through the public process, they encourage States and the egg industry to adopt, in the interim, measures such as the Pennsylvania Quality Assurance program (PEQAP), United States Animal Health Association (USAHA) SE

Reduction Program or equivalent.

Organizational structure. To consolidate egg safety oversight responsibilities and provide clarity, the Council identified one responsible agency for each stage of the farm-to-table continuum, based on the strengths of each agency, as follows:

- FDA develops standards for the producer and the States provide oversight and enforcement on the farm.
- FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement for both.
- FDA and CDC conduct surveillance and monitoring activities. CDC focuses on human health and FDA on the food supply.

Therefore, the plan can be implemented quickly without legislation.

The performance measures that will be used to assess the progress of the Plan toward its goal are the numbers of SE cases, isolates, and outbreaks annually. The data will be collected using the following existing systems: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System. The new data will be compared to the 1998 baseline values of: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.

EGG SAFETY ACTION PLAN

OVERARCHING GOAL:

To eliminate SE illnesses associated with the consumption of eggs by 2010. The Egg Safety Action Plan has set an interim goal of a 50% reduction in egg-associated SE illnesses by 2005.

Performance measures: Numbers of SE cases and outbreaks decrease annually. Data from: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System.

1998 Baseline data: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively⁽²⁶⁾.

Objective 1:

Reduce the number of SE-containing eggs marketed to the consumer.

Performance measure: Number of production sites testing positive for SE reduces annually, according to agency and producer data. (Proxy measure for eggs marketed baseline to be determined.).

- 1.1 Establish a consistent, nationwide SE reduction program for egg production that includes components such as:
 - 1.1.1 SE environmental testing
(For example, chick papers; pullets at 12-14 weeks and layers at 25-30 weeks of age; post-molt, if molted; 2-4 weeks prior to de-population.)
 - 1.1.2 Restricting access and movement of personnel and equipment
 - 1.1.3 Using SE-negative feed
 - 1.1.4 Using chicks from SE-negative breeders
 - 1.1.5 Cleaning and disinfection of poultry houses and equipment
 - 1.1.6 Improving rodent and pest control in houses
 - 1.1.7 Diverting of eggs to pasteurization if SE testing yields a positive.
(With option to test eggs and sell SE-negative eggs as shell eggs.)
 - 1.1.8 Training agency inspection force

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

- 1.2 Establish a HACCP-based system for shell egg processing and prerequisite programs that includes components such as:
 - 1.2.1 Basic sanitation of premises and facilities
 - 1.2.2 Rodent and pest control
 - 1.2.3 Employee hygiene and health
 - 1.2.4 Safety of water and food packing materials
 - 1.2.5 Washing, sanitizing, grading, packaging, cooling, and repackaging

Timeline: Proposed rule - FY2002; final rule - FY2003; implementation following.

- 1.3 Establish a HACCP-based system for egg products processing and prerequisite programs that includes components such as:
 - 1.3.1 Basic sanitation of premises and facilities
 - 1.3.2 Rodent and pest control
 - 1.3.3 Employee hygiene and health
 - 1.3.4 Safety of water and food packing materials
 - 1.3.5 Washing, sanitizing, packaging

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

- 1.4 Finalize and implement refrigeration and labeling regulations for eggs from processor to consumer.

Timeline: Final rule - FY2000; implementation following.

Objective 2:

Reduce exposure of consumers to SE-containing foods.

Performance measure: Number of egg-associated SE illnesses due to unsafe handling practices at the retail stage decreases annually.

- 2.1 Establish safe egg handling and preparation practices using egg-relevant sections of FDA's 1999 Food Code, specifically practices such as:

- 2.1.1 Acquisition
- 2.1.2 Storage
- 2.1.3 Preparation
- 2.1.4 Service

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

- 2.2 Identify and address barriers to implementing Food Code provisions in facilities serving high-risk populations, through the collaborative efforts of interagency Federal Food Safety Coalition. These facilities include:

- 2.2.1 Child and adult day care centers
- 2.2.2 Senior centers and home-delivered meals
- 2.2.3 Preschools and elementary schools
- 2.2.4 Nursing homes
- 2.2.5 Hospitals
- 2.2.6 Detention and penal facilities

Timeline: Ongoing

Objective 3:

Expand and upgrade surveillance systems for human SE infection

Performance measures: Number of public health laboratories that rapidly report SE isolates and SE outbreak surveillance data electronically increases; number of SE isolates phage-typed increases

- 3.1 Conduct active surveillance in a location where SE is prevalent. (Requires an additional FoodNet site.)

Timeline: By FY2005

- 3.2 Upgrade information systems, at State and local public health departments, for electronic reporting of laboratory-confirmed SE isolations (via Public Health Laboratory Information System) and SE outbreak surveillance data.

Timeline: By FY2005

- 3.3 Maintain CDC's role as the national SE phage typing reference and support center for human isolates. Continue phage-typing SE isolates submitted through the National Antimicrobial Resistance Monitoring system-Enteric Bacteria (NARMS-EB).

Timeline: Ongoing

- 3.4 Begin phage typing human SE isolates from FoodNet sites.

Timeline: By 2001

- 3.5 Conduct SE case-control studies at FoodNet sites to monitor changes in risk factors for human SE infection and association with egg consumption.

Timeline: By FY2005

Objective 4:

Expand surveillance and upgrade surveillance systems for poultry SE infection

Performance measures: Availability of data on prevalence of SE infections in poultry increases;

number of SE-isolates phage-typed increases.

4.1 Monitor SE prevalence in layer breeding flocks.

Timeline: Ongoing

4.2 Complete USDA NAHMS Layers '99 Study.

Timeline: By FY2000. (Repeat survey in FY2005.)

4.3 Phage-type SE isolates submitted through Layers '99 Study.

Timeline: By 2001

4.4 Define, assess and enhance surveillance capacities and data at industry and animal health agencies.

Timeline: By 2005

4.5 Maintain USDA's National Veterinary Services Laboratories (NVSL) role as the national SE phage typing reference and support center for feed and animal isolates.

Timeline: Ongoing

Objective 5:

Accelerate SE outbreak detection and initiation of outbreak investigations and improve completeness of outbreak investigations.

Performance measures: Number of SE outbreaks investigated completely increases; number of egg-associated outbreaks in which source of eggs is identified increases.

5.1 Develop and implement new outbreak detection algorithms. Use Salmonella Outbreak Detection Algorithm (SODA) to analyze SE surveillance data.

Timeline: Ongoing

- 5.2 Identify and address reasons for delayed investigation and reporting of SE outbreaks from state agencies.

Timeline: By FY2005

- 5.3 Assess practices and environmental circumstances during outbreak investigations to identify common contributing factors.

Timeline: By FY2005

- 5.4 Establish product identification and tracking system requirements to facilitate identification of egg sources during outbreaks.

(Note: May require new statutory authority to access product records.)

Timeline: By FY2005

- 5.5 Establish national egg traceback procedures.

Timeline: By FY2005

Objective 6:

Improve communication among Federal, State, and local agencies involved in SE outbreak and traceback investigations and by agencies with industry and the public about outbreaks.

Performance measure: Number of days to notify other relevant government agencies of outbreaks decreases.

- 6.1 Establish a listserv to communicate SE outbreak information among public health authorities and other partners.

Timeline: By FY2001

- 6.2 Conduct an SE outbreak information needs assessment with industry and the public.

Timeline: By FY2001

- 6.3 Develop and maintain an internet site for posting SE surveillance and outbreak data for industry and public access.

Timeline: By FY2001

Objective 7:

Ensure adequate, current information is available to make decisions about SE preventive controls, surveillance, and education based on sound science.

Performance measure: Number of research questions answered increases.

- 7.1 Conduct research to develop and evaluate on-farm intervention strategies or technologies including:

- 7.1.1 Forced molting and other stress factors
- 7.1.2 Vaccines and immunomodulators
- 7.1.3 Competitive exclusion
- 7.1.4 Ion air scrubbers in hatcheries

Timeline: By FY2005

- 7.2 Conduct research to provide additional information about commercial processing technologies and practices including:

- 7.2.1 In-shell pasteurization of eggs
- 7.2.2 Rapid cooling before and after processing
- 7.2.3 Continuous rewashing
- 7.2.4 Repackaging
- 7.2.5 Pasteurization of egg products with additives

Timeline: By FY2003

- 7.3 Conduct research to improve testing methodologies for SE on the farm and in eggs, including the identification of virulence factors and development of rapid tests, screening tests, sampling protocols, and molecular methods for subtyping SE isolates.

Timeline: By FY2005

7.4 Conduct research to understand the ecology and epidemiology of SE in the hen and farm environment, including:

- 7.4.1 Sources of SE in the environment
- 7.4.2 Mechanism of colonizing the layer house
- 7.4.3 Factors affecting infection of the hen and contamination of the egg
- 7.4.4 Characteristics of SE that promote infection in hens and humans
- 7.4.5 Biochemical characteristics of SE strains causing variations in virulence
- 7.4.6 Immunological and other factors in humans that affect infectivity
- 7.4.7 Risk factors associated with the on-farm presence of SE isolates.

Timeline: By FY2008

Objective 8:

Educate individuals throughout the production to consumption continuum using science-based materials.

Performance measures: Number of partnerships increases; number of education materials available increases; percentage of consumers using unsafe egg-handling practices decreases.

8.1 Develop and distribute materials for the egg, retail, and foodservice industries, using partnerships:

- 8.1.1 For egg producers and processors/packers about their role in egg safety, using egg industry organizations.
- 8.1.2 For retailers and food service workers about regulations and adoption of the Food Code, using retail and institutional organizations.
- 8.1.3 For food packages including safe food handling tips, using food industry representatives.

Timeline: FY2000-2005

8.2 Develop and distribute materials for target audiences of:

- 8.2.1 Healthcare practitioners, including physicians, about diagnosing and treating foodborne illness, through professional organizations, such as the AMA.
- 8.2.2 Patients and at-risk populations, about safe handling and preparations of foods, including eggs, through professional organizations, such as the AMA.
- 8.2.3 Food preparers at facilities serving highly susceptible populations, including nursing homes, daycare centers, and hospitals, about proper egg handling and preparation practices.
- 8.2.4 Under-served populations, including Hispanics and African-Americans, about proper egg handling and preparation practices, through magazines and newspapers.
- 8.2.5 Senior citizens, about proper egg handling and preparation practices, using the Food Safety Information for Seniors, the Senior food safety website, the Senior food safety video, and the Senior food safety publication.
- 8.2.6 Women and men, about proper egg handling and preparation practices, through women's, men's, and health magazines.
- 8.2.7 Students and parents, advice on not eating foods containing uncooked eggs, such as homemade raw cookie dough.

Timeline: FY 1999-2000

- 8.3 Conduct a nationwide telephone survey to assess consumer knowledge about and proper practices of egg handling and consumption, including:
 - 8.3.1 Consume raw or undercooked (runny) eggs, by age group
 - 8.3.2 View eggs as a high-risk food
 - 8.3.3 Awareness of safe handling and warning label statements
 - 8.3.4 Cooking time-temperatures
 - 8.3.5 Pooling
- 8.4 Conduct a survey at retail establishments (e.g. restaurants, institutions) to assess food preparer knowledge and proper practices of egg handling, as in 8.3.

Timeline: FY 2001-2002

[End of Action Plan]

Appendix 1. Action Plan Timeline

Task/Date	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
	01	02	03	04	05	06	07	08	09	10	11
1.1 Establish a consistent, nationwide SE reduction program for egg production.											
1.2 Establish a HACCP-based system for shell egg processing and prerequisite programs.											
1.3 Establish a HACCP-based system for egg products processing and prerequisite programs.											
1.4 Finalize and implement refrigeration and labeling regulations for eggs from processor to consumer.											
2.1 Establish safe egg handling and preparation practices using egg relevant sections of FDA's 1689 Food Code.											
2.2 Identify and address barriers to implementing Food Code provisions in facilities serving high-risk populations through the collaborative efforts of the interagency Federal Food Safety Coalition.											
3.1 Conduct active surveillance in a location where SE is prevalent.											
3.2 Upgrade information systems, at State and local public health departments, for electronic reporting of laboratory-confirmed SE isolations and SE outbreak surveillance data.											
3.3 Continue phage-typing SE isolates submitted through National Antimicrobial Resistance Monitoring system-Enteric Bacteria (NARMS-EB) and isolates from SE outbreaks.											
3.4 Begin phage typing human SE isolates from Food Net sites.											
3.5 Conduct SE case-control studies to monitor changes in risk factors for human SE infection and association with egg consumption.											
4.1 Monitor SE prevalence in layer breeding flocks.											
4.2 Complete USDA NAHMS Layers '98 Study.											
Repeat USDA NAHMS Layers '99 Study.											
4.3 Phage-type SE isolates submitted through Layers '98 Study.											
4.4 Define, assess and enhance surveillance capacities and data at industry and animal health agencies.											
4.5 Maintain USDA's National Veterinary Services Laboratories (NVSL) role as the national SE phage typing reference and support center for feed and animal isolates.											
5.1 Develop and implement new outbreak detection algorithm. Use SQDA to analyze SE surveillance data.											
5.2 Identify and address reasons for delayed investigation and reporting of SE outbreaks from state agencies.											
5.3 Assess practices and environment circumstances during outbreak investigations to identify common contributing factors.											
5.4 Establish product identification and tracking system requirements to facilitate identification of egg sources during outbreaks.											
5.5 Establish national egg traceback procedures.											
6.1 Establish a listserv to communicate SE outbreaks among public health authorities and other partners.											
6.2 Conduct an SE outbreak information needs assessment with industry and the public.											
6.3 Develop and maintain an internet site for posting SE surveillance and outbreak data for public access.											
7.1 Conduct research to develop on-farm intervention strategies or technologies.											
7.2 Conduct research to provide additional information about commercial processing technologies and practices.											
7.3 Conduct research to improve testing methodologies for detection of SE on the farm and in eggs.											
7.4 Conduct research to understand the ecology and epidemiology of SE in the hen and in the farm environment.											
8.1 Develop and distribute materials for the eggs, retail, and foodservice industries, using partnerships.											
8.2 Develop and distribute materials for target audiences.											
8.3 Conduct a nationwide telephone survey to assess consumer knowledge about and proper practices of egg handling and consumption.											
8.4 Conduct a survey of retail establishments (e.g. restaurants, institutions) to assess food preparer knowledge and proper practices of egg handling.											

Appendix 2. Glossary

Biosecurity.

The term refers to procedures designed to prevent SE from being carried into poultry houses from outside sources and may include all or some of the following: use of chicks from SE-negative breeder flocks, use of SE-negative feed ingredients; proper use of medications and pesticides; and restricted access and movement of personnel and equipment in/out of hen houses.

Eggs.

The term is used in this document to include both shell eggs and egg products.

Egg products processing.

The processing of shell eggs into egg products involving breaking, filtering, mixing, stabilizing, blending, pasteurizing, cooling, freezing or drying, and packaging.

Egg production.

The on-farm activities of egg-laying and collection.

Egg products.

The term refers to eggs that have been removed from their shells and processed. The term applies to whole eggs, whites, yolks, and various blends with or without non-egg ingredients, regulated by FSIS. The term does not apply to freeze-dried products, imitation egg products, and egg substitutes which are the responsibility of FDA.

Federal Food Safety Coalition.

The interagency working group consists of members from: Department of Veterans Affairs, Veterans Health Administration; USDA, Food and Nutrition Service's School Lunch Program, WIC Program, and Infant Formula Program; Department of Justice, Bureau of Prisons; HHS, Head Start Program, Administration on Aging, Indian Health Service, Health Care Financing Administration, and CFSAN.

Food Code.

A reference document for regulatory agencies responsible for overseeing food safety in retail outlets, such as restaurants, grocery stores, and institutions (including nursing homes and daycare centers), consisting of recommendations for adoption by local, state, and federal governmental jurisdictions, offered by FDA.

FoodNet (Foodborne Diseases Active Surveillance Network).

A network consisting of 8 sites that conduct active surveillance, investigations, and epidemiologic studies. The information is used to: (1) determine the frequency and severity of foodborne diseases; (2) determine the proportion of common foodborne diseases that result from eating specific foods; (3) describe the epidemiology of new and emerging foodborne pathogens; and (4) assess the effectiveness of new food safety control measures. It is a collaborative project among CDC, the 8 sites, FSIS and FDA.

HACCP (Hazard Analysis-Critical Control Points).

The process of identifying the hazards (hazard analysis) present in a process and determining critical points throughout the process (critical control points) at which loss of control would result in the presence of a hazard posing a serious risk to human health.

Layers.

Hens (including those being molted) or pullets producing table or commercial type shell eggs, usually at least 20 weeks of age.

"Layers 99" NAHMS Survey.

A study to: (1) describe baseline health and management practices used by the U.S. layer industry; (2) estimate the national prevalence of SE in layer flocks by testing the environment and at layer operations; (3) identify potential risk factors associated with the presence of SE; and (4) describe biosecurity practices.

Molt.

A process during which hens stop laying and shed their feathers, occurring naturally every 12 months. May be artificially induced by withholding feed or water for a period of time. Forced molting is done to improve egg production.

National Animal Health Monitoring System (NAHMS).

An animal health monitoring system, established by APHIS in 1990, (1) to help government officials and industry organizations define public risks and identify research needs and (2) to identify opportunities for producers and veterinarians to improve management and product quality.

National Antibiotic Resistance Monitoring System (NARMS).

A system for monitoring emerging resistance to antibiotics in foodborne pathogens, established in 1996 as an interagency cooperative activity.

National Poultry Improvement Plan (NPIP).

A program that certifies that poultry breeding stock and hatcheries are free from egg-transmitted and hatchery-disseminated diseases, including SE.

National Veterinary Services Laboratories (NVSL).

A national laboratory providing veterinary diagnostic, laboratory support, and reference services related to domestic and foreign livestock and poultry diseases for programs, including NAHMS and NPIP, and administered by APHIS.

Outbreak.

Two or more people having a similar illness that has been traced to eating a common food.

Public Health Laboratory Information System (PHLIS).

An electronic reporting system used by State public health laboratories to report isolates of *Salmonella* from human sources to CDC's National Salmonella Surveillance System.

Pullet.

A female chicken that has not yet started to lay eggs.

Restricted eggs.

Eggs with cracks or checks in the shell, dirty eggs, incubator rejects, and inedible, leaker, or loss eggs.

Salmonella Enteritidis (SE).

A bacterium of the genus *Salmonella*, species *enterica*, and serotype Enteritidis.

SE Isolation Rate.

The rate of isolation of *Salmonella* Enteritidis from infected humans.

"Sell by" period.

The time within which retailers must sell shell eggs.

Shell eggs.

The term refers to eggs still in their shells.

Shell egg handlers.

Firms that grade and pack shell eggs for commercial distribution (packing plants) and hatcheries.

Shell egg processing.

The phase of processing involving the washing, segregation and packaging of shell eggs for distribution to retail, institutional, and other commercial users.

Shell Egg Surveillance program.

A quarterly inspection program, mandatory for shell egg handlers, to verify that: (1) restricted eggs are properly disposed of and (2) no more restricted shell eggs than permitted in U.S. Consumer Grade B are sold to the consumer

Salmonella Outbreak Detection Algorithm (SODA).

A statistical algorithm designed to detect unusual clusters of isolates of Salmonella infection and to compare current Salmonella isolates reported through PHLIS by serotype to an historical baseline for that serotype, implemented in 1996.

Spent Hen.

A breeder or commercial type egg hen that no longer performs at desired production levels.

Undergrade.

Any edible shell eggs that does not meet the requirements (standards) for the indicated grade, Grade AA, Grade A, or Grade B.

Whole Eggs.

Consist of yolk (yellow portion) and albumen (white or clear portion). For the various types of egg products - liquid, frozen, and dried - the yolks and albumen are separated during the breaking. Customers may request whole eggs (entire contents of egg) or a combination of yolks and albumen to produce egg product for specific uses.

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Footnotes

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

Backgrounders

December 1999

Regulatory Reform Initiatives

Introduction

On December 23, 1999, the Food Safety and Inspection Service (FSIS) published a final rule to streamline the approval process for food ingredients by ending the requirement that they be approved separately by both the Food and Drug Administration (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 rule, entitled *Food Ingredients and Sources of Radiation for Use in the Preparation of Meat and Poultry Products*, becomes effective on January 24, 2000.

This rule is the latest in a series of regulatory reform initiatives published by the Agency to: (1) improve food safety, (2) make regulations less burdensome and easier to use, (3) make regulations more consistent with Hazard Analysis and Critical Control Point (HACCP) Systems, and (4) eliminate outdated regulations.

These regulatory reform initiatives are part of the National Performance Review effort, headed by Vice President Gore, to make government work better and cost less.

Background

On Dec. 29, 1995, FSIS published an advance notice of proposed rule making in the *Federal Register* announcing that it would conduct a comprehensive review of its regulations to reduce regulatory burden and prepare for the implementation of the Pathogen Reduction and HACCP rule. HACCP is designed to reduce reliance on command and control regulations and increase reliance on science-based preventive measures and performance standards to improve food safety. Under a HACCP system, each company must meet the same, rigorous safety standards, yet each has the flexibility to devise and adopt food safety plans uniquely suited to its circumstances.

Many of FSIS' existing regulations, however, are written in a "command and control" format, consisting of the specific steps that must be taken to meet regulatory requirements. These regulations are inconsistent with HACCP and represent a regulatory burden to industry. In addition, they provide inadequate incentives and flexibility for meat and poultry plants to address the most significant food safety hazards in innovative ways.

Regulatory Reform Accomplishments

Date	Type of Notice	Title and Summary
Dec. 29, 1995	Final rule; effective	Prior Label Approval System: Eliminated prior approval

	July 1, 1996	for certain types of product labels.
Aug. 25, 1997	Final rule; effective Sept. 24, 1997	Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs: Eliminated prior approval requirements for facility blueprints, equipment, and certain partial quality control programs.
Feb. 13, 1998	Notice	Elimination of Prior Approval for Proprietary Substances and Nonfood Compounds: Announced FSIS was eliminating the prior approval requirement for proprietary substances and nonfood compounds, which include cleaning compounds and food processing chemicals.
Sept. 11, 1998	Proposed rule; scheduled to be finalized in 2000	Retained water in raw meat and poultry products; poultry chilling performance standards: Would eliminate the amount of water retained by raw, single-ingredient meat and poultry products as a result of post-evisceration processes, such as carcass washing and chilling. Also would require labeling to disclose maximum percentage of retained water in product and consolidate now separate regulations for meat and poultry.
Jan. 6, 1999	Final rule; effective March 8, 1999	Performance Standards for the Production of Certain Meat and Poultry Products: Set performance standards for the production of certain meat and poultry products such as cooked beef and roast beef.
May 18, 1999	Proposed rule; scheduled to be finalized in spring 2000	Elimination of Requirements for Partial Quality Control Programs: Removed requirements for partial quality control programs except with respect to the irradiation of poultry products.
Oct. 20, 1999	Final rule; effective Jan. 25, 2000	Sanitation Requirements for Official Meat and Poultry Establishments: converts highly prescriptive sanitation requirements to performance standards and consolidates the sanitation regulations for meat and poultry
Nov. 29, 1999	Final rule; Effective Jan. 25, 2000	Rules of Practice: establishes a single Rules of Practice that covers both meat and poultry products. The rules clearly set out the types of enforcements FSIS may take, the conditions under which it is likely to take each of these actions, and the procedures it will follow in doing so.

Dec. 23, 1999	Final rule; effective Jan. 24, 2000	Food Ingredients and Sources of Radiation for Use in the Preparation of Meat and Poultry: Harmonizes and streamlines the procedures used by FSIS and the Food and Drug Administration (FDA) for reviewing and approving the use of food ingredients and sources of radiation in meat and poultry products.
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Future Initiatives

In addition to these regulatory reform actions already taken, FSIS is now developing regulations to:

- set performance standards for a variety of ready-to-eat products,
- set performance standards for egg products and require egg processing plants to adopt HACCP and Sanitation Standard Operating Procedures,
- amend existing standards of identity for meat and poultry products to allow greater flexibility and encourage innovation in the marketing of reduced fat and other nutritionally improved meat and poultry products, and
- revise its approach for verifying that meat and poultry products are not mislabeled, economically adulterated, or otherwise unacceptable for reasons other than food safety concerns.

For More Information

- Technical questions: Dr. Daniel Engeljohn, Director, Regulations Development and Analysis Division, Office of Policy, Program Development, and Evaluation, (202) 720-5627
- Media inquiries: (202) 720-9113
- Congressional inquiries: (202) 720-3897
- Constituent inquiries: (202) 720-8594
- Consumer inquiries: Call USDA's Meat and Poultry Hotline at 1-800-535-4555. In the Washington, DC, area, call (202) 720-3333. The TTY number is 1-800-256-7072.
- FSIS Web site: <http://www.fsis.usda.gov>

For Further Information Contact:

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Phone: (202) 720-3897

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DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

March 3, 2000

Gerard Viatte
Secretariat
Ad Hoc Group on Food Safety
Organization for Economic Cooperation and Development
Paris, France

Dear Mr. Viatte:

On behalf of U.S. Food and Drug Administration Commissioner of Food and Drugs Jane E. Henney, M.D., and myself, I have enclosed the United States' food safety system country report, which was requested under the OECD Ad Hoc Group on Food Safety's program of work. The document includes the required one-page synthesis identifying the food safety system's key principles, changes, and areas of continuing development. In addition to submitting the paper to the Ad Hoc Group, we will make it available to the public on the U.S. government's food safety Internet site (<http://www.foodsafety.gov>) and will hold a public meeting on March 22, 2000, prior to the next Ad Hoc Group meeting,

An annex, including a description of how the U.S. government uses precaution in its food safety risk analysis decision-making process, remains under review by federal food safety agencies and will be sent under separate cover in a few days.

Members of the U.S. delegation look forward to discussing the OECD member country food safety papers at the Ad Hoc Group's meeting later this month in Paris.

Sincerely,

/S/

Catherine E. Woteki, Ph.D., RD
Under Secretary for Food Safety
U.S. Department of Agriculture

Enclosure

I. Synthesis: The United States Food Safety System

The United States Constitution prescribes the responsibilities of the government's three branches: executive, legislative and judicial, which all have roles that underpin the nation's food safety system. Congress, the legislative branch, enacts statutes designed to ensure the safety of the food supply. Congress also authorizes executive branch agencies to implement statutes, and they may do so by developing and enforcing regulations. When enforcement actions, regulations, or policies lead to disputes, the judicial branch is charged to render impartial decisions. General U.S. laws and statutes and Presidential Executive Orders establish procedures to ensure that regulations are developed in a transparent and interactive manner with the public. Characteristics of the U.S. food safety system include the separation of powers among these three branches and transparent, science-based decision-making, and public participation.

The U.S. food safety system is based on strong, flexible, and science-based federal and state laws and industry's legal responsibility to produce safe foods. Federal, state, and local authorities have complementary and interdependent food safety roles in regulating food and food processing facilities. The system is guided by the following principles: (1) only safe and wholesome foods may be marketed; (2) regulatory decision-making in food safety is science-based; (3) the government has enforcement responsibility; (4) manufacturers, distributors, importers and others are expected to comply and are liable if they do not; and (5) the regulatory process is transparent and accessible to the public. As a result, the U.S. system has high levels of public confidence.

Precaution and science-based risk analyses are long-standing and important traditions of U.S. food safety policy and decision-making. U.S. food safety statutes, regulations, and policies are risk-based and have precautionary approaches embedded in them.

The agencies' well-qualified science and public health experts work cooperatively to ensure the safety of U.S. food. Scientists from outside government are regularly consulted to provide additional recommendations regarding technical and scientific methods, processes, and analyses used by regulators. The cutting-edge science that informs U.S. regulators is routinely shared internationally through interactions with organizations like the Codex Alimentarius Commission, World Health Organization, and the Food and Agriculture Organization.

The U.S. routinely and effectively deals with technological advances, emerging problems, and food safety incidents. It is enhancing early warning systems about pathogens in food. The legislation granting authorities to agencies generally enables them to revise regulations and guidance consistent with advances in technology, knowledge, and need to protect consumers.

U.S. food agencies are accountable to the President, to the Congress which has oversight authority, to the courts which review regulations and enforcement actions, and to the public, which regularly exercises its right to participate in the development of statutes and regulations by communicating with legislators, commenting on proposed regulations, and speaking out publicly on food safety issues.

II. United States Food Safety System

Introduction

The U.S. food safety system is based on strong, flexible, science-based laws and industry's legal responsibility to produce safe foods. Coordinated interactions among federal authorities having complementary and interdependent food safety missions, in partnership with their state and local government counterparts, provide a comprehensive and effective system. The implementation of the statutes and the food safety system over many years has resulted in very high levels of public confidence in the safety of food in the U.S.

Principal federal regulatory organizations responsible for providing consumer protection are the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA). The Department of Treasury's Customs Service assists the regulatory authorities by checking and occasionally detaining imports based on guidance provided. Many agencies and offices have food safety missions within their research, education, prevention, surveillance, standard-setting, and/or outbreak response activities, including DHHS's Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); USDA's Agricultural Research Service (ARS); Cooperative State Research, Education, and Extension Service (CSREES); Agricultural Marketing Service (AMS); Economic Research Service (ERS); Grain Inspection, Packers and Stockyard Administration (GIPSA); and the U.S. Codex office; and the Department of Commerce's National Marine Fisheries Service (NMFS).

The FDA is charged with protecting consumers against impure, unsafe, and fraudulently labeled food other than in areas regulated by FSIS. FSIS has the responsibility for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. EPA's mission includes protecting public health and the environment from risks posed by pesticides and promoting safer means of pest management. No food or feed item may be marketed legally in the U.S. if it contains a food additive or drug residue not permitted by FDA or a pesticide residue without an EPA tolerance or if the residue is in excess of an established tolerance. APHIS' primary role in the U.S. food safety network of agencies is to protect against plant and animal pests and diseases. FDA, APHIS, FSIS, and EPA also use existing food safety and environmental laws to regulate plants, animals, and foods that are the results of biotechnology.

A. Laws And Implementing Regulations

The three branches of U.S. government -- legislative, executive, and judicial -- all have roles to ensure the safety of the U.S. food supply. Congress enacts statutes designed to ensure the safety of the food supply and that establish the nation's level of protection. The executive branch departments and agencies are responsible for implementation, and may do so by promulgating regulations, which the U.S. publishes in the *Federal Register* and which are also electronically available. Characteristics of the U.S. food safety system are the separation of powers and

science-based decision-making. Agency decisions under U.S. food safety laws can be appealed to the courts which are empowered to settle such disputes.

Food safety statutes enacted by Congress provide regulatory agencies with broad authority but also set limits on regulatory actions. The statutes are drafted to achieve specific objectives. Food safety 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.

Major U.S. food safety authorizing statutes include the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), Food Quality Protection Act (FQPA), and Public Health Service Act.

Procedural statutes, which regulatory agencies must follow, include the Administrative Procedure Act (APA), the Federal Advisory Committee Act (FACA), and the Freedom Of Information Act (FOIA). The APA specifies 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. The FOIA provides the public with a statutory right to access federal agency information.

U.S. food safety programs are risk-based to ensure the public is protected from health risks of unsafe foods. Decisions within these programs are inherently science-based and involve risk analyses. Risk assessment is useful in understanding the magnitude of the problem faced, and it assists the agency in determining an appropriate risk management response.

The regulatory development process is conducted in an open and transparent manner. Regulations are developed and revised in a public process that not only allows, but encourages, participation by the regulated industry, consumers, and other stakeholders throughout the development and promulgation of a regulation. In developing new regulations and revising existing regulations, the agencies often provide the public a preliminary discussion and opportunity for comment by publishing an Advance Notice of Proposed Rulemaking (ANPR). It 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 significant public comments must be addressed in the final regulation. The next steps are publication of a proposed regulation and publication of a final regulation, which is enforceable, with opportunities for public comment. The APA requires that

the final regulation be justified by policy rationale, scientific bases, and legal authority.

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, 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. 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.

If a person or organization wishes to challenge an agency decision, the complainant may take the agency to court. Thus, even after an agency issues a final regulation which responds to all comments received, an individual or organization may still challenge the agency decision. This legal action involves the third branch of the federal government, the judicial branch. The judiciary (the federal court system) 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, fulfil the procedural requirements, or have a rational basis for its action, the judicial system can overturn the agency's action. The judicial system also serves as a forum for agency-initiated enforcement actions.

Just as it is the responsibility of the food industry to sell only safe food, it is likewise its responsibility to obey applicable laws and regulations.

B. Risk Analysis And the U.S.'s Precautionary Approach

1. Risk Analysis

Science and risk analysis are fundamental to U.S. food safety policymaking. In recent years, the federal government has focused more intently on risks associated with microbial pathogens and on reducing those risks through a comprehensive, farm-to-table approach to food safety. This policy emphasis was based on the conclusion that the risks associated with microbial pathogens are unacceptable and, to a large extent, avoidable; and that multiple interventions would be required throughout the farm-to-table chain to make real progress in reducing foodborne pathogens and the incidence of foodborne disease. This effort followed many years of concentration on managing chemical hazards from the food supply by regulation of additives, drugs, pesticides, and other chemical and physical hazards considered potentially dangerous to human health. It reflects the recognition that the approaches to analyses and review of biological hazards and safety concerns differ from those presented by chemicals.

The President's Food Safety Initiative, announced in 1997, recognized the importance of risk assessment in achieving food safety goals. The Initiative called for all federal agencies with risk

management responsibilities for food safety to establish the Interagency Risk Assessment Consortium. The Consortium is charged with advancing the science of microbial risk assessment by encouraging research to develop predictive models and other tools.

The U.S. government has completed a risk analysis on *Salmonella enteritidis* in eggs and egg products which included the first farm-to-table quantitative microbial risk assessment. It is also conducting a risk analysis for *E. coli* 0157:H7 in ground beef and has entered into a cooperative agreement with Harvard University for a risk assessment of the transmission of Bovine Spongiform Encephalopathy by foods. The U.S. is also carrying out a risk analysis for *Listeria monocytogenes* in a variety of ready-to-eat foods.

Regulatory agencies also have made progress in implementing various risk management strategies. An example can be found in Hazard Analysis Critical Control Point (HACCP) regulations. Instead of including in the text of the regulation those specific steps industry must take under a HACCP system, food safety agencies provide general requirements and direct those being regulated to apply the guidelines and develop specific steps to achieve an effective HACCP program. HACCP systems are a risk management tool because they enable the user to identify hazards reasonably likely to occur and to develop a comprehensive and effective plan to prevent or control those hazards.

Performance standards for pathogen reduction and control represent another risk management tool. For example, the U.S. has in place pathogen reduction performance standards for *Salmonella* that slaughter plants and raw ground product must meet, and it also tests product to ensure that these standards are met. In the future, the government may establish performance standards for other pathogens of public health concern and define what food establishments that produce, process, or handle food must achieve.

Fair and objective regulatory decisions regarding food safety standards and requirements rely on risk analysis performed by competent authorities, qualified to make scientifically sound decisions. Risk analysis consists of risk assessment, risk management, and risk communication, which are interdependent.

Risk Assessment – Risk assessments are conducted in an objective manner. However, since data and scientific knowledge on any issue are never totally complete, an assessment of absolute risk is impossible. By explicitly considering uncertainties in the data and analyses, decisions can be made regarding the amount of uncertainty that is acceptable. U.S. policy decisions on procedures used for risk assessment can also ensure that risks are unlikely to be underestimated.

The first component of risk assessment, hazard identification, requires decisions on the effort expended to identify hazards. In the U.S., these are established by law and experience. Laws regarding the use of new food ingredients or pesticides require a prescribed effort to uncover any hazards before introduction into the food supply. For products already on the market, hazards may be identified by experience (e.g., emerging pathogens) that require efforts to control risk.

The second component, hazard characterization, considers data regarding the potential hazard at different exposure levels and modes, including which data are most relevant for characterizing the hazard. While human data are always most relevant, animal data are usually used to characterize a hazard. The U.S. generally relies on data from the most sensitive species to characterize the risk. Where a safety threshold cannot be assumed, the U.S. may rely on linear mathematical models that are not likely to underestimate a risk. It is important to use the most realistic data and models consistent with current scientifically sound knowledge. When information is not available that can identify which is most realistic, data or models that can be shown not to underestimate hazards are used.

The third component, exposure assessment, must differentiate between short term exposure for acute hazards and long term exposure for chronic hazards. For acute hazards, such as pathogens, data on levels of pathogens causing illness in vulnerable population groups are important. For chronic hazards, such as chemicals that may cause cumulative damage, a lifetime averaged exposure is relevant.

Risk Management – Risk management is exercised by highly qualified regulatory authorities with the sole objective to provide high levels of protection to the U.S. consumer. 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 judgement to reduce risk to the lowest practical, or achievable, level.

U.S. laws require that the safe use of a food additive, an animal drug, and a pesticide be established before marketing; therefore risk management decisions are based on very substantial scientific evidence. For hazardous substances that are inherent components of foods (e.g., low levels of natural toxicants produced in potatoes) or unavoidable contaminants of food (e.g., mercury in fish, aflatoxin in grains), government intervention occurs when presence of a substance reaches a level known to present significant risk. The quantity and quality of scientific evidence may vary with the type of risk management decision.

As an example of risk management, every year the U.S. federal food agencies work together to develop a comprehensive, risk-based, annual sampling plan to detect drug and chemical residues in U.S. food. Violative residue information is used as the basis for standard-setting and for enforcement and other follow-up activities.

Risk Communication – Routine risk communication is inherent in the transparent regulatory process which is more fully described in Part D entitled, "Transparency." Transparent standards are employed to ensure fairness to all members of the food industry while protecting public health. U.S. law requires the government to allow and consider comment on the factual basis for a decision when it establishes regulations. Anyone can comment, including persons outside the U.S. There must be a substantial basis in law and fact for every rule. Information relied on by the government is made available for anyone to review. Government scientists use public communication media to explain to the public the science behind regulations.

When there is a need for emergency risk communication, alerts are conveyed through a nationwide telecommunication system linking all levels of the food safety system with the nationwide media so all citizens are made aware of the risk, and through global information sharing mechanisms by which international organizations (WHO, FAO, Office of International Epizootics and the World Trade Organization, if appropriate), regions such as EU, and individual countries are informed immediately.

Risk communication is critical during 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 recalls is also provided on the agency's 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.

Another example of risk management are U.S. federal agency activities on the emerging issue of resistance from the use of antimicrobials in animals. Antimicrobial risk management includes establishment of monitoring and resistance thresholds before a drug can be approved; continuous monitoring of resistance in enteric bacteria from humans and food animals; obtaining information on factors responsible for promoting resistance; and taking regulatory actions as needed, including restrictions on a drug or removing it from the market.

2. Precautionary Approach

(This approach is described in detail in the annex on Precaution In U.S. Food Safety Decision Making.)

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. The precautionary approach is exercised in a variety of ways.

An example of the U.S. precautionary approach to risk 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 this country. In implementing this prohibition through a regulation, the government followed existing APA procedures to explain in the *Federal Register* why it is proposed to take the action, including a description of the risk, and to evaluate the comments received from industry, academia, private citizens, and government agencies before publishing its final regulation.

Another illustrative example of the precautionary approach is the pre-market approval requirements established by law 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 exposure. The data or the lack of data drive a decision for approval. The evaluation of all is documented. The final decision explaining the basis for all significant conclusions is published in the *Federal Register*. Persons disagreeing with the decision may file an objection with the reasons for disagreeing and request a hearing. After administrative remedies for appeal are exhausted, the government may be challenged in court on its approval or denial of a petition.

C. Dealing With New Technologies, Products, and Responding to Problems

In achieving the nation's farm-to-table food safety objective, the federal government is only one part of the equation. Federal agencies collaborate with state and local agencies and other stakeholders to encourage food safety practices and to offer assistance to industry and consumers on practices that promote food safety.

The U.S. recognizes the regulated industry as a stakeholder and as the party principally responsible for food safety. Establishments are responsible for producing food products that meet regulatory requirements for safety. The government's role is to set appropriate standards and do what is necessary to verify that the industry is meeting those standards and other food safety requirements. Consistent with modernization of inspection systems and the farm-to-table initiatives, federal agencies use their resources as efficiently and effectively as possible to protect the public from foodborne illness. As an extension of HACCP, the U.S. is testing new meat and poultry inspection models to determine whether or not additional protections can be provided consumers through redeployment of some in-plant resources to the distribution segment of the farm-to-table chain, which includes transportation, storage, and retail sale of products.

Federal food safety agencies regularly enter into partnerships with states and others such as grower organizations and public interest groups to encourage improved production practices, to develop and foster food safety measures that can be taken on the farm and in marketing channels to decrease public health hazards in food, to develop and implement safer pest management practices, and to develop good agricultural practices to minimize pesticide residues and microbial risks.

The country's emergency response capability is sound and being enhanced continually. For example, U.S. food safety regulatory agencies participate in FoodNet, a network whose objectives are to determine the frequency and severity of foodborne diseases and the proportion of common foodborne diseases that result from eating specific foods and describe the epidemiology of new and emerging bacterial, parasitic, and viral foodborne pathogens.

Information on possible foodborne disease outbreaks from FoodNet and reports to state and local health departments are followed up by those health departments in cooperation with federal food agency authorities to determine the course and nature of the outbreak. Appropriate public

advisories are issued and enforcement actions taken about the products involved as soon as possible.

In addition, a new technique has been developed using pulsed-field gel electrophoresis (PGE), which permits CDC to match distinctive patterns of pathogenic materials that cause foodborne illness. Using these "fingerprinting" techniques, the single casual factor of a foodborne illness outbreak can be traced using epidemiological investigation and PGE. This has led to intervention and, in at least one recent case, cessation of a serious foodborne illness outbreak. Both FoodNet and PulseNet are basic building blocks for the U.S. system of foodborne illness prevention.

D. Transparency

Various U.S. statutes and executive orders establish procedures to ensure that regulations are developed in an open, transparent, and interactive manner and that, as appropriate, the regulatory process is similarly open to the public. Regulations and their implementation must lead to fulfillment of objectives for the public good such as protecting health, safety, and environment.

The APA specifies 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. Under the APA, a notice of proposed rulemaking must be published in the *Federal Register*, an official daily publication which is available through subscription and through the Internet at no cost. All regulations and legal notices issued by federal agencies and the President are published in the *Federal Register*. In addition, though the Internet is not an official publication, U.S. government agencies make extensive use of it to provide information on regulatory activities and enhance the transparency of their processes.

The President issued an Executive Order to strengthen agencies' processes for promulgating regulations. Also, several states require analysis of the impacts of regulations: there are requirements to analyze the impact of the regulation on small business (the Regulatory Flexibility Act); the impact of the regulation on the environment (the National Environmental Policy Act); and the impact of any information collection requirements contained in the regulation (the Paperwork Reduction Act).

FACA requires that certain kinds of groups whose advice is relied upon by the government for establishing regulations be chartered as an advisory committee, be constituted to provide balance and to avoid conflicts of interest, and to hold its advisory meetings in public with an opportunity for comment from those outside the committee.

FOIA's purpose is to expand the areas of public access to information beyond those originally set forth in the APA. Any person residing in the United States has a right of access to a wealth of government information and records, subject only to certain limited exemptions.

To ensure the broadest possible participation by the public, agencies publish their proposals on Internet sites and call attention to the proposed or final rule through press releases. The U.S. news media and interest groups follow the *Federal Register* and agency Internet sites closely and publish information about proposed and final regulations. In addition, U.S. agencies may hold public meetings to solicit input from interested persons. Meetings often include media coverage. For example, numerous public meetings were held to solicit input on the Food Safety Strategic Plan being developed by the President's Council on Food Safety; on the draft Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; as part of the process to develop the Food Safety Initiative; and on bioengineered foods, among other topics.

Regulatory agencies often offer guidance on ways to achieve compliance with regulatory requirements. Such guidance may describe situations where a food could become adulterated or misbranded or may describe data that would be needed to establish safety. Although such guidance does not have the effect of law (one need not follow it to demonstrate that a food is safe and lawful, provided that all statutory and regulatory requirements are met), such advice is helpful to the food industry and to the consumer.

The Codex Alimentarius Commission (Codex) is the major international body for promoting the health and economic interests of consumers while encouraging fair international trade in food. Within the United States, Codex activities are coordinated by officials from USDA, HHS, and EPA. The U.S. Codex Office provides information via the *Federal Register* and the Internet concerning the Codex and its activities internationally and in the U.S.

E. System Accountability

U.S. food agencies are highly accountable to government's three branches and to the people:

- U.S. food agencies are accountable to the President – the chief executive – who has constitutional responsibility to assure that laws are faithfully executed; who appoints senior officials, and whose Office of Management and Budget clears significant regulations.
- U.S. food agencies are accountable to the Congress, the legislative branch of the U.S. government, which provides the food agencies their authority and budget; whose committees hold frequent oversight hearings; and the Senate must confirm the nomination of cabinet officers and senior officials.
- U.S. food agencies are accountable to the courts, the judicial branch of the U.S. government, which review food agency regulations and enforcement actions.
- Most importantly, U.S. food agencies are accountable directly to members of the public, who regularly exercise their right to participate in the development of laws and regulations, such as commenting on proposed regulations; whose guidance is sought in frequent public meetings; and who provide strong support for food safety regulation, the nutrition label, and other regulatory initiatives.