Social Regulation Workbook  
By Peter May

Overview
This workbook is a companion to The Tools of Government: A Guide to the New Governance, edited by Lester M. Salamon. It includes original source documents that illustrate the operation of a government program that embodies social regulation as a tool of government. It is designed to help the reader better understand the process for implementing and managing a regulatory program involving social or environmental regulation.

Regulation, as a tool of government, consists of rules identifying permissible and impermissible activity on the part of individuals, firms, or government agencies along with accompanying sanctions and/or rewards. Social regulations are aimed at restricting behaviors that directly threaten public health, safety, welfare, or well-being. These include environmental pollution, unsafe working environments, unhealthy living conditions, and social exclusion. Social regulation is distinguished from economic regulation. The latter is aimed at ensuring competitive markets for good and services and avoiding consumer and other harms when such markets are not feasible.

Social regulation has been used as a tool of government to accomplish a number of public purposes. Many social regulations are aimed at preventing harms. Others are aimed at providing public benefits. Regulatory programs vary considerably in what they require and/or prohibit. Regulatory programs also differ in the timing of their intervention, especially as they concern potential harms from newly created products. While we normally think about regulation as entailing rules established by government to restrict behavior of private entities or citizens, social regulation also includes mandates from higher levels of government to lower levels.

This workbook addresses the mechanics of social regulation with particular attention to the operation of a regulatory program. This entails:

- Rules that govern expected behaviors or outcomes;
- Standards that serve as benchmarks for compliance;
- Sanctions for non-compliance with the rules (or rewards for compliance); and
- An administrative apparatus enforcing rules and administering sanctions.
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Document Listing and Description
This workbook contains 18 documents related to the regulation of food safety as illustrated by the meat inspection program carried out by the Food Safety and Inspection Service of the United States Department of Agriculture. The documents are grouped into six categories, as outlined below. This section first lists the documents and then briefly describes each set.

Links to the electronic images of the documents are provided within these descriptions. To jump to a particular document, click with Adobe Reader on the highlighted number. You can also navigate through the documents using the navigation pane of Adobe Reader.

The documents are appended as part of this portable document file (pdf). A guide to the different sections of the electronic file, to be used in jumping to different documents, can be found by opening up the navigation pane (on the toolbar) of Adobe Reader. Links to individual items are also contained within the study questions that follow this section.

A. Presidential Initiative for a New Program
   1. President Clinton's Radio Address, July 6, 1996

Social regulations are typically developed to prevent harm to society. While there is much conceivable harm that could be addressed, it is up to governmental officials to determine the particular harms that deserve attention. This section illustrates the selection of "food safety" for attention. The first document (A1) is a Presidential radio address that discusses the efforts that the Clinton administration was making to ensure that meat products and other foods are safe for consumption. The second document (A2) sets forth the Clinton Administration strategy for food safety. It discusses the problem of food safety and the limits of the current regulatory system.

B. Authorizing Legislation and Administrative Regulations
   1. Federal Meat Inspection Act, U.S. Code: Title 21, Chapter 12 [outline only]

Regulatory programs that embody social regulations are established by legislation that authorizes a program, defines purposes and objectives, and creates or assigns an agency to carry out the program. In the case of meat inspection, the original legislation was enacted in 1907 for which the provisions as amended are shown as the first document in this section (B1). The details of regulatory programs are contained within the administrative regulations that govern the program. An outline of these is the second document of this section (B2). Note the difference between (1) administrative regulations, which are agency rules that govern program operations, and (2) social regulations, which are tools of government that govern behavior of firms, individuals, or others. The relevant administrative agency for meat inspection is the Food Safety and Inspection Service. The third document of this section provides an overview of the agency functions (B3).

C. Rules: Setting Expectations
   1. Substantive requirements - "Labeling receptacles or coverings of meat or meat food products" 21 U.S. Code 607(a) (1998)
   2. Procedural requirements - "Record keeping requirements" 21 U.S. Code 642(a) (1998)
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The first step in the design and administration of a social regulation is the specification of rules that establish expectations of behavior. These are normally contained within the legislation that establishes a regulatory program. The specifics are provided as part of administrative regulations that govern regulatory agency actions. There are two basic types of rules, both of which are illustrated by the documents in this section. One type, illustrated with the first document concerning labeling of meats (C1), consists of substantive requirements that specify actions to be undertaken or to be avoided by regulated entities. The second type of rules, illustrated by record keeping requirements (C2), consists of procedural requirements that specify a process to be followed by regulated entities. Most regulations contain exemptions that specify the situations for which a given rule would not apply as illustrated by the exemptions listed in the third document of this section (C3).

The processes for developing rules, exemptions, standards, and enforcement systems as part of the administration of regulatory functions at the federal level in the United States is quite elaborate and is governed by the Administrative Procedures Act. The fourth document in this section contains an Executive Order on "Regulatory Planning and Review" (C4) issued by President Clinton in 1993 that was aimed at gaining control over unreasonable rules. As discussed in the chapter on social regulation in The Tools of Government, the Executive Order was one of a series of efforts over the years by the executive branch to regulate the proliferation of social and economic regulations.

D. Standards: Setting Benchmarks

Rules are often sufficiently complex that they require specification of standards for performance. Standards serve as the benchmarks for determining compliance with a given rule. Standards can be either of two types. The first, illustrated by the required features of labels on meat (D1), are design (or specification) standards that specify the use of particular materials or means to achieve compliance. The illustration specifies particular format and spacing of labels on meat packages. The second type, illustrated by requirements for scales to be used in weighing meats (D2), specifies performance levels. Either type of standard can reference provisions devised by independent entities as also illustrated by the second document concerning scales. Note that it references standards for scales established by the National Institute of Standards and Technology.

E. Penalties and Rewards
   1. Food Safety and Inspection Service, "Quarterly Regulatory and Enforcement Report" [excerpts]

Penalties are the sanctions to be applied for failure to comply with a given rule and rewards are positive inducements for compliance. Most social regulations compel compliance through threats of issuing penalties for noncompliance. As discussed in the chapter on social regulation, some newer regulatory programs contain inducements for compliance or seek to obtain "voluntary" compliance. The first document (E1) in this section is an enforcement report of the Food Safety and Inspection Service that shows the range of penalties that are invoked for noncompliance and the circumstances under which they are applied. The second document (E2) is from a different regulatory program and is provided to illustrate the use of incentives to induce compliance with regulations. This is a program under which pork producers can voluntarily participate in audits of their environmental pollution controls undertaken by third parties. In return for participating in this program, pork producers are eligible for reduced penalties for any violations that they identify and self-report.
Enforcement systems are necessary to identify noncompliance and to invoke penalties or other measures for obtaining compliance. The first document in this section (F1) is a summary of the funding for the Food Safety and Inspection service. It provides a sense of the scale of enforcement resources for meat and poultry inspection. Enforcement actions typically entail a number of steps for which two are illustrated by the other documents in this section. One step, shown in the notification procedures document (F2), is a procedure for notifying regulatees about a violation, expected corrections, and potential subsequent regulatory actions. Another step, shown in the document about appeal procedures (F3), is establishment of a procedure under which regulatees can appeal enforcement actions and decisions.

Regulatory programs, like any program, can be evaluated according to how well they accomplished their goals. The two documents in this section illustrate the ways in which the Food Safety and Inspection Service attempts to evaluate agency performance. The first document (G1) discusses "customer service standards" and the performance of the agency in meeting those standards. The second document (G2) takes a broader view in considering the adequacy of regulatory approaches under the "reinventing government" program.
RADIO ADDRESS BY THE PRESIDENT
TO THE NATION

The Oval Office

10:06 A.M. EDT

THE PRESIDENT: Good morning. This holiday weekend we celebrate America's birthday and the values that hold us together as a community and a country. It's a time for family and fun, for games and fireworks and backyard barbecues.

Tonight, smoke will curl over homes on nearly every block as millions of families gather around the grill for the most American of meals: hamburgers and hotdogs and barbecued chicken.

Today I want to talk to you about the steps we're taking to make sure the food we cook in backyard barbecues is safe and wholesome. Our families have every right to expect the food they serve their children is safe. They have every right to expect the world's most bountiful food supply will also be the world's safest. And, in fact, our food is very safe.

Nearly a century ago, after muckrakers exposed dirty conditions in meat-packing plants, we made a national commitment to protect the public from unsafe food. It was one of the first ways we came together to meet the challenges of that new industrial age.

Last year, we put in place new safety precautions for seafood. And in recent years, we've learned that we all must continue to be vigilant on meat and poultry safety, and we learned it the hard way. For, every year, scores of Americans still die and tens of thousands become sick from eating meat or poultry that is contaminated with harmful bacteria.

We all remember how, in 1993, tragedy struck hundreds of families in the western United States. Undercooked hamburgers served in a fast food restaurant were contaminated with a deadly strain of E. coli bacterial. Five hundred people became ill and four children died.

The parents of many of the E. coli victims turned their grief into a determination to help others. Some of them are here with me today. In the face of this unspeakable tragedy, they had one insistent question: How could this have happened? I asked that question too, and I asked my administration: What can we do to prevent it from happening again?

Now, sometimes food makes us sick because it's undercooked. But sometimes, families have been exposed to illnesses because some meat and poultry shipped to our supermarket shelves contained invisible and deadly bacteria. The reason was shocking and simple: For all our
technological advances, the way we inspect meat and poultry had not changed in 90 years. Even though we know that killers such as salmonella can only be seen with a microscope, inspectors were still checking on meat and poultry by look, touch, smell. We relied on an overworked cadre of government inspectors, rather than working with the industry and challenging it to keep food safe.

Under the direction of Vice President Gore and Secretary Glickman, the United States Department of Agriculture has worked with industry, scientists, farmers, parents and consumers to completely revamp our meat and poultry inspection system, to revolutionize the way our nation protects food safety.

This morning, I want to announce the major changes that the U.S. Department of Agriculture will take to keep food safe and to protect our children from deadly bacteria.

First, we're challenging every meat-packing plant in America to do scientific tests or take other safety precautions at every step of production. Each company must design and put in place its own tough plan. We're not imposing a detailed list of dos and don'ts. We're working with industry as partners, challenging them to find ways to make our meat the safest it can be. Each plant will be held accountable for meeting high standards at every step of the process.

Second, we're insisting that every slaughterhouse begin to conduct rigorous scientific tests to make sure the meat is not contaminated with deadly strains of E. coli and salmonella bacteria.

Third, companies will have to improve their sanitation procedures. All too often, food is contaminated because simple sanitary rules are not followed.

All these changes will be phased in over the coming months to make sure they are done right. These new meat and poultry contamination safeguards will be the strongest ever. They are flexible and they do challenge the private sector to take responsibility. They also use the most up-to-date science to track down invisible threats. They protect the public without tangling business in red tape.

Parents should know that when they serve a chicken dinner they're not putting their children at risk. Parents should know that when a teenager borrows the car to get a fast food hamburger, the hamburger should be the least of their worries. Our new food safety initiative will give families the security to know that the food they eat is as safe as it can be.

To be sure, parents will also still have to take responsibility. There is no way to make food entirely free from risk; nature simply won't let us. So everyone should follow warning labels, be careful how you handle raw meat and poultry, and make sure it's well cooked before you serve it to your family. These days families have enough to worry about. They shouldn't have to fear the food they eat is unsafe. With the tough steps we're taking today, America's parents should be able to breathe a little easier.

Have a safe and happy Fourth of July weekend.

END 10:11 A.M. EDT
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In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he will request $43 million in his 1998 budget to fund a nationwide early warning system for foodborne illness, enhance seafood safety inspections, and expand food safety research, risk assessment, training, and education. President Clinton also directed the Secretary of Health and Human Services and of Agriculture, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world. The President directed Secretaries Shalala and Glickman, and Administrator Browner to report back to him with recommendations in 90 days. He instructed them to explore opportunities for public/private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities.

We need your advice. Your perspective is essential in providing the President with a report that identifies current needs in food safety, as well as assuring the future safety of our food supply and the health of consumers. We need the perspective and suggestions of all groups who are concerned about food safety and public health to make this a successful endeavor.

The goal of this initiative is to reduce, to the greatest extent possible, the incidence of foodborne illness. The thoughts in this draft focus on the public health principle that society should identify and take preventive measures to reduce the risk of illness, and that it should focus its efforts on those hazards that present the greatest risks.

The ideas in this draft represent our preliminary thoughts on this subject. A comprehensive food safety plan, describing actions and resources necessary to achieve the goals of reduced foodborne illness, will require extensive deliberation and in-depth discussion with all stakeholders in food safety, including consumers, state, tribal, and local public health officials, industry, and members of the scientific community. This draft is intended not as a prelude to government action, but an exploration of what might result from the upcoming seminars and conferences. While this initiative focusses on reducing the incidence of microbial foodborne illnesses, we recognize that chemical contaminants are also a cause of foodborne illness, but with chronic long term...
The American food system provides consumers with an abundant supply of convenient, economical, high-quality, and safe food products. This system is built on the enterprise and innovative capacities of those who produce and market food in the United States, and it is driven by the high expectations of American consumers for the foods they purchase for their families. Foodborne illness, however, still occurs in the United States. Over the last four years the Clinton Administration has developed and implemented major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.

- The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.

- Beginning in 1994, the Centers for Disease Control and Prevention (CDC) embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.

- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help states and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

While these advances are significant, they may not be enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food safety programs. The food safety system is in need of reform, especially reform that builds on the preventive principles embodied in HACCP.
HISTORY OF THE FOOD SAFETY INITIATIVE

Achieving a significant reduction in the incidence of foodborne illnesses requires the cooperative efforts of public health and regulatory agencies at the federal, state, tribal and local levels, as well as all other parties responsible for and concerned about food safety and reducing the incidence of foodborne illness (i.e., consumers, industry, and academia). Partnerships - between public agencies and industry, federal agencies and state, tribal or local agencies, public agencies and academia, to name a few possibilities - will be invaluable in leveraging the resources focused on reducing the incidence of foodborne illness and enhancing communication.

Representatives of various government agencies have drafted a structure for the food safety initiative for your further deliberations. Ad hoc working groups, representing the varied perspectives of the FDA, CDC, the Department of Agriculture's Research, Education and Extension agencies, as well as the FSIS and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA), have been meeting for several months to identify major food safety concerns and propose recommendations on what resources and activities are needed to have a significant impact on reducing the incidence of foodborne illness both in the short term and over the long term. The working groups worked from the premise that an effective food safety initiative must have several, interrelated components which, together, have far greater impact on reducing the incidence of foodborne illness than is possible to attain with any single component. Moreover, these elements must form the groundwork for the design and implementation of strategies to meet current needs, for continually evaluating the effectiveness of ongoing activities, and for identifying and implementing strategies to meet future needs. These elements include surveillance, coordination, risk assessment, research, inspections, and education.

This draft, which primarily defines short-term activities, describes the elements of a food safety initiative and tentatively identifies critical issues and the working groups' current thinking on preliminary recommendations. In some cases these recommendations have been included as part of the President's FY98 budget. However, no specific decision as to what will constitute the final food safety initiative, including how the strategic planning process is structured, have been made. Input from groups and individuals such as yourself, state, tribal and local agencies, consumers, industry, academia, and other stakeholders will be incorporated into the food safety initiative.

Two open public meetings of all parties interested in food safety are planned to take place in Washington, DC. The first, scheduled for March 5, 1997, is an information meeting to familiarize interested parties with the President's initiative and introduce the draft discussion document. A second meeting is tentatively scheduled for late March-early April to discuss the food safety...
initiative. The purpose of the second meeting is to present the key issues and solicit both comment on the preliminary recommendations and additional suggestions for inclusion in the report to President Clinton.

Using this draft as a starting point, we are asking for your perspective on how best to enhance the safety of the food supply and reduce foodborne illness. Please consider the following questions in guiding your response, considering both the immediate future and the long term:

**Questions:**

1. Have the critical elements of an effective food safety initiative been identified? Are there others? What are they?
2. Have the appropriate issues within each element been identified? If not, what additional issues should be included?
3. What are the priorities among the issues identified or added to each element of the initiative?
4. What steps should be taken to begin to resolve issues within each element of the initiative?
5. What are the responsibilities of various stakeholders in working toward resolution of the issues?
6. How can we better utilize public/private partnerships to reduce foodborne illness?
7. How should food safety activities be better coordinated across the federal agencies, accommodating the needs and perspectives of state and local agencies, consumers, industry, and academia, to maximize the effect of available resources?
8. How do we ensure and measure the effectiveness of the food safety initiative?
9. How should the evaluation be structured so that the results of the early evaluation can be factored into the strategic planning process?
10. What recommendations do you have for the structure of the strategic planning process?

The comments, suggestions, and information from these meetings will be used in preparing the report to the President.

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**FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM**

Foodborne infections remain a major public health problem. The Council for Agricultural Science and Technology, a private non-profit organization,
estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Hospitalization costs alone for these illnesses are estimated at over $3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between $6 billion and $9 billion. Total costs for all foodborne illnesses are likely to be much higher. These estimates do not take into account the total burden placed on society by the chronic, often life-long consequences caused by some foodborne pathogens.

Additional, important safety concerns are associated with the greater susceptibility to foodborne infections of several population groups. These include persons with lowered immunity due to HIV/AIDS, those on medications for cancer treatment or for organ transplantation, as well as pregnant women (and their fetuses), young children, and elderly persons. Patients taking antibiotics, or antacids, are also at greater risk of infection from some pathogens. Other groups who may be disproportionately affected include persons living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless persons, migrant farm workers, and others of low socioeconomic status.

**Sources of Foodborne Contamination**

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella enteritidis* enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables in the field. Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage. Seafood may become contaminated from agricultural and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments. Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animal. Milk, eggs, seafood, poultry, and meat from food-producing animals may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, or disposal of solid waste on land. Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; and improper storage. Foods may become contaminated in retail facilities and in the home through use of poor food handling practices.

Although many hazards threaten the safety of our food, certain foodborne hazards are of particular public health concern, and would be targeted for immediate attention by this initiative. Studies have shown that the following microbial pathogens are the predominant foodborne pathogens. They are: *Salmonella* species, *Campylobacter jejuni/coli*, *Escherichia coli* O157:H7 and
other related strains; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus.

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. The microbial pathogens described below are not listed in order of importance or severity.

**Salmonella**

*Salmonella* species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immuno-compromised, the very young, and the elderly. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate foods such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. Between 128,000 and 640,000 of these infections are associated with *Salmonella enteritidis* (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with over 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

**Campylobacter**

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 170,000 and 2.1 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (2 closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, perhaps as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

**Escherichia coli O157:H7**

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a
particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools, and has been associated with HUS. HUS is a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. It has been estimated that approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with an estimated 6 deaths. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996 in 3 western states and British Columbia, was associated with unpasteurized apple juice and sickened 66 people and caused the death of one child.

**Toxoplasma gondii**

*T. gondii* is a parasitic protozoan. It has been estimated that 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Otherwise healthy adults who become infected usually have no symptoms, but may get diarrhea. Pregnant women who become infected during pregnancy may pass the disease to their fetuses. In infants infected before birth, fatal results are common. Should the infant survive, the effects of infection are typically severe. The disease can also be serious in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables may contribute to these infections.

**Cryptosporidium parvum**

*C. parvum* is a parasitic protozoan. The most common consequence of infection in otherwise healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among persons with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak that occurred in Milwaukee, Wisconsin in 1993, affecting over 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths attributed to *Cryptosporidium*. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. This outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* is found in feces of infected mammals and has been transmitted through contaminated water and food.

**Norwalk virus**
Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease, that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multi-state outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis, involved seventy ill people and was associated with the consumption of raw oysters. In 1992, another outbreak occurred which included 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Ensuring the safety of food is one of the core functions of government. It is carried out by a system that, while generally successful in protecting the public, can be confusing for its complexity and diversity. Authority is divided among federal, state, and local governments; and the private sector also plays an important role. From the farm to the consumer's dinner table, the responsibilities can be summarized as:

- **On the farm**, food is regulated by state agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, by the FDA, which oversees use of drugs and feed in milk- and food-producing animals, and by APHIS, which is concerned with food-animal disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and ground waters, and solid waste to land, all of which could contaminate growing and process waters or grazing land.

- **Food processing** for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA has fewer than 700 inspectors and analysts devoted to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,500 slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.

- **Food being transported** in interstate commerce is subject to federal and
state regulation, although that area has received little attention in the past. USDA's FSIS and HHS's FDA have jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to harmful bacteria during transportation.

- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.

- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by states and local health authorities, and FDA publishes the Food Code, which consists of model recommendations for safeguarding public health when food is offered to the consumer. Recommendations are developed by consensus of state government representatives at the Conference for Food Protection. FSIS and FDA are working with states to update the Food Code in light of the changing retail and food service environment and emerging food safety issues, especially with regard to meat, poultry, egg products, and seafood. The Conference for Food Protection serves as one forum for fostering cooperation among federal, state and local governments in the oversight of food products and the conditions under which they are produced, processed, transported, stored, and handled through retail sale or food service to the consumer.

- National standards for drinking water are set by EPA, and enforced generally by local public water authorities; FDA establishes complementary standards for bottled water.

- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected.

- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. As a result of this knowledge, FSIS promulgated safe handling labels for raw meat and poultry products.

- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA, FDA, CDC, EPA, the National Institutes of Health, other federal components, and the states. Basic biomedical research on pathogenic organisms is conducted at the National Institutes of Health. The federal government also supports related research in universities. The private sector supports research within its own laboratories and in universities.
● Develop drugs and other therapies to prevent initial colonization.
● Develop new methods to reduce or eliminate contaminants from animals and plants before slaughter or harvest.
● Develop new disinfection methods and equipment and systems modifications for processing and production plants, and wholesale and retail outlets.
● Develop new methods of surface decontamination of fresh fruits, vegetables, meat, poultry.
● Develop heat-based and/or other disinfection methods for seafood, meat, eggs, produce, and animal feeds.

5) Food handling, distribution, and storage

Food production and processing often occur thousands of miles apart. Transportation systems for live animals, fresh produce, and packaged foods offer many opportunities for contamination, such as heat, cold, and other stresses that make animals and plants more susceptible to infection, and cross-contamination from the vehicle itself. Possible research recommendations include the following:

● Investigate immune system "biomarkers" of stress that might indicate predisposition to infection during transport.
● Develop in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

INSPECTIONS

Background

Inspection of commercial food processors is an integral part of the food safety assurance system. Inspections are carried out by federal, state and local authorities, with state and local officials focusing primarily on restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has carcass-by-carcass inspection in meat, poultry, and slaughter plants while they are operating, and continuous inspection in meat, poultry, and egg-product processing plants--in all, about 8,000 inspectors for 6,500 domestic plants and for all imported meat, poultry, and egg products. FDA does periodic, random inspections of all other food processing plants--less than 700 inspectors and analysts for 53,000 U.S. plants and for all other imported foods.

Preliminary Problem Identification

At FDA, the number of inspections has decreased steadily since 1981, when
21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. The result is that an FDA-regulated plant gets inspected by FDA, on the average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, the inspectional coverage of imported foods has dropped as well, as the same number of import inspectors are now inspecting almost twice as many imports as just five years ago. Certainly FDA is finding greater problems, e.g., the number of products recalled for life-threatening microbial contamination has increased almost 5-fold since 1988 and inspectors are finding more hazardous conditions in the plants they inspect. FSIS is faced with a similar challenge of continually providing the most effective inspection program with limited resources and growing threats to food safety.

**Current Thinking**

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the application of the HACCP concept of built-in preventive controls. FDA has begun to implement HACCP for the seafood industry, and FSIS for the meat and poultry industries; FSIS intends to publish an ANPR requesting comments on HACCP systems for egg processing plants, and FDA plans to work with the food industry, as it has in a pilot program over the last 2 years. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, the following preliminary recommendations are being made.

1) **Enhance development of HACCP procedures**

FDA is considering whether and how to implement HACCP throughout the non-meat/poultry food industry for all appropriate food commodities. It is recognized that staged implementation, by commodity, might be necessary because of resource limitations. To ensure that HACCP is being properly implemented, FDA should conduct inspections and provide necessary training and outreach activities. FSIS will continue development of a HACCP-based inspection system. FSIS plans to conduct a public meeting and then subsequent field trials to gather data to support future decisions on designing new inspection procedures in a HACCP environment.

2) **Upgrade FDA’s food inspection program**

FDA has included implementation of seafood HACCP in its FY98 budget request. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food safety procedures in effect, FDA must improve its inspection capabilities, so that the highest risk food plants (such as seafood) are inspected at least once per year. To maximize the joint federal/state role in inspections, development of new partnerships with the states may be considered, that focus on coordinating the inspection coverage
and preventing duplication of effort.

FSIS and FDA may consider expanding and re-focussing existing cooperative agreements under which plants producing both meat and non-meat foods are inspected solely by FSIS inspectors, who have been trained in FDA inspectional standards. FSIS inspectors are already in these plants; their presence could be better utilized to maximize use of federal resources.

FSIS and FDA are considering whether and how to regulate the transportation of meat, poultry, seafood, eggs and other foods in order to safeguard the public from pathogenic microorganisms, as reflected in the ANPR published on November 22, 1996.

3) Enhance federal/state inspection partnerships

Additional federal/state partnerships can ensure improved coordination between the federal food safety agencies and state regulators for the training of state inspectors in federal food safety standards, as well as provide the states with equipment and technology for the rapid sharing of inspection results and for a national database for the monitoring of all food inspections. This information sharing would help both federal and state regulators make inspections more effective and efficient.

FDA may consider establishing a process for certifying private laboratories that would be authorized to test samples of food products for contaminants. This may embody a similar process currently being discussed by a coalition of industry, private laboratories, professional associations, and accrediting bodies with input from federal agencies. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

4) Enhance inspectional coverage of imported food, to address the problem of rising imports and FDA's inability to provide adequate inspections of them

FDA should develop more Mutual Recognition Agreements (MRAs) with foreign countries, under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety. Once such MRAs are in place, FDA could better focus its import inspections on foods coming from countries with the least reliable safety standards.
(a) Labeling receptacles or coverings of meat or meat food products inspected and passed; supervision by inspectors

When any meat or meat food product prepared for commerce which has been inspected as hereinbefore provided and marked "Inspected and passed" shall be placed or packed in any can, pot, tin, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained, the person, firm, or corporation preparing said product shall cause a label to be attached to said can, pot, tin, canvas, or other receptacle or covering, under the supervision of an inspector, which label shall state that the contents thereof have been "inspected and passed" under the provisions of this chapter; and no inspection and examination of meat or meat food products deposited or inclosed in cans, tins, pots, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained shall be deemed to be complete until such meat or meat food products have been sealed or inclosed in said can, tin, pot, canvas, or other receptacle or covering under the supervision of an inspector.

(b) Information on articles or containers; legible form
CHAPTER II--GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION (PACKERS AND STOCKYARDS PROGRAMS), DEPARTMENT OF AGRICULTURE

Part
200 [Reserved]
201 Regulations under the Packers and Stockyards Act
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203 Statements of general policy under the Packers and Stockyards Act
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CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

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Protecting the Public From Foodborne Illness: The Food Safety and Inspection Service

The Food Safety and Inspection Service (FSIS), a public health agency in the U.S. Department of Agriculture, protects consumers by ensuring that meat and poultry products are safe, wholesome, and accurately labeled.

FSIS regulates meat and poultry products that account for a third of consumer spending for food, with an annual retail value of $120 billion. FSIS regulates all raw beef, pork, lamb, chicken, and turkey, as well as approximately 250,000 different processed meat and poultry products, including hams, sausage, soups, stews, pizzas, and frozen dinners (any product that contains 2% or more cooked poultry or 3% or more raw meat). Consumers purchase these products packaged with 500,000 different USDA approved labels.

FSIS Activities

Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Approximately 7,400 Federal inspectors carry out inspection laws in some 6,200 plants.

Inspectors check animals before and after slaughter, visually examining over 6 billion poultry carcasses and 125 million livestock carcasses, including beef, pork, and lamb, each year. They prevent diseased animals from entering the food supply and examine carcasses for visible defects that can affect safety and quality. FSIS also inspects products during processing, handling, and packaging to ensure that they are safe and truthfully labeled.

To address specific concerns, inspectors can test for the presence of pathogenic microorganisms and violative drug and chemical residues. The Agency operates three field laboratories to provide analytical support.

FSIS sets standards for a range of activities associated with the production of meat and poultry products. For instance, the Agency evaluates and sets standards for food ingredients, additives, and compounds used to prepare and package meat and poultry products. All plant facilities and equipment must adhere to FSIS standards and be approved before they can be used. The Agency sets labeling standards and approves labels for meat and poultry products. Standards are also set for certain slaughter and processing activities, such as plant sanitation and thermal processing.

FSIS develops and improves analytical procedures for detecting microbiological and chemical adulterants and infectious and toxic agents in meat and poultry products. The Agency also develops new methods of inspection to better protect the public health.

The Agency evaluates the effectiveness of its programs through systematic and special reviews. It also responds to microbiological, residue, and other contamination incidents and, when appropriate, seeks voluntary recall of products by firms.

Through the Agency's Meat and Poultry Hotline (1-800-535-4555) and consumer education programs, the public is informed on how to properly handle, prepare, and store meat and poultry products to minimize the growth of foodborne pathogens.

Current Initiatives

Foodborne illness is recognized as a significant public health problem in the United States. While precise data on the incidence of illness associated with meat and poultry products are limited, data from varied sources suggest that foodborne microbial pathogens may account for up to 7 million cases of foodborne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products.

FSIS is pursuing a broad and long-term science-based strategy to improve the safety of meat and poultry products and to better protect public health. FSIS is undertaking a farm-to-table approach by taking steps to improve the safety of meat and poultry at each step in the food production, processing, distribution, and marketing chain. These steps are designed to focus more attention on the risk of microbial contamination, the Nation's most significant food safety problem. The Agency's goal is to reduce contamination as much as possible by setting public health-oriented standards for pathogenic microorganisms, building the principle of prevention into the production and inspection processes, and fostering the development and use of new technology.

In addition to a number of in-plant improvements, FSIS is working closely with the Food and Drug Administration to ensure food safety at the retail level and to establish Federal standards for the safe handling of food during transportation, distribution and storage. FSIS also will work with producers and others to develop and implement food safety measures that can be taken on the farm and before animals enter the slaughter facility to reduce the risk of harmful contamination of meat and poultry products.

For More Information

- Media Inquiries: (202) 720-9113
- Congressional Inquiries: (202) 720-3897

For Further Information Contact:
FSIS Food Safety Education and Communications Staff
Room 2932-S; 1400 Independence Ave. S.W.
Washington, D.C. 20250-3700
Phone: (202) 720-7943
Fax: (202) 720-1843

FSIS Home Page | USDA Home Page
Sec. 607. Labeling, marking, and container requirements

(a) Labeling receptacles or coverings of meat or meat food products inspected and passed; supervision by inspectors

When any meat or meat food product prepared for commerce which has been inspected as hereinbefore provided and marked "Inspected and passed" shall be placed or packed in any can, pot, tin, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained, the person, firm, or corporation preparing said product shall cause a label to be attached to said can, pot, tin, canvas, or other receptacle or covering, under the supervision of an inspector, which label shall state that the contents thereof have been "inspected and passed" under the provisions of this chapter; and no inspection and examination of meat or meat food products deposited or inclosed in cans, tins, pots, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained shall be deemed to be complete until such meat or meat food products have been sealed or inclosed in said can, tin, pot, canvas, or other receptacle or covering under the supervision of an inspector.

(b) Information on articles or containers; legible form
Sec. 642. Recordkeeping requirements

(a) Classes of persons bound; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples

The following classes of persons, firms, and corporations shall keep such records as will fully and correctly disclose all transactions involved in their businesses; and all persons, firms, and corporations subject to such requirements shall, at all reasonable times upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory upon payment of the fair market value therefor:

(1) Any persons, firms, or corporations that engage, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;

(2) Any persons, firms, or corporations that engage in the business of buying or selling (as meat brokers, wholesalers or
and labeled as required by the regulations in this subchapter.


PART 303—EXEMPTIONS

Sec.

303.1 Exemptions.

303.2 Experimentation: Intensity of inspection coverage.


§ 303.1 Exemptions.

(a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:

(1) The slaughtering by any individual of livestock of his own raising, and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock exclusively for use by him and members of his household and his nonpaying guests and employees;

(2) The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of his own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of his own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees:

Provided, That the following requirements are met by such custom operator:

(i) The establishment in which the custom operations are conducted is maintained and operated in accordance with the provisions of §§ 308.11, 308.13, 308.14, and 308.3 (except § 308.3(d)) (2) and (3), of this subchapter:

(ii) The custom prepared products shall be prepared and handled in accordance with the provisions of §§ 318.5, 318.6, 318.7, 318.10, and 318.300 through 318.311 of this subchapter and shall not be adulterated as defined in paragraph 1(m) of the Act:

Provided, That the provisions of said sections relating to inspection or supervision of specified activities or other action by a Program employee shall not apply to the preparation and handling of such exempted products:

Provided, further, That the requirement of § 308.4 for separate facilities for men and women workers shall not apply to such establishments when the majority of the workers in the establishment are related by blood or marriage and this arrangement will not conflict with municipal or State requirements, and the requirement of § 308.4 for separation of toilet soil lines from house drainage lines to a point outside the buildings will not apply to such establishments when positive acting backflow devices are installed:

And provided, further, That the requirements of § 308.13 for paved driveways, approaches, yards, pens, and alleys shall not apply to such establishments. However, if custom operations are conducted in an official establishment, all of the provisions of part 308 shall apply to such establishment.

(iii) If the custom operator prepares or handles any products for sale, they are kept separate and apart from the custom prepared products at all times while the latter are in his custody:

(iv) If exempted custom slaughtering or other preparation of products is conducted in an official establishment, all facilities and equipment in the official establishment used for such custom operations shall be thoroughly cleaned and sanitized before they are used for preparing any products for sale:

(b)(1) The exempted custom prepared products shall be prepared and handled in accordance with the provisions of §§ 318.5, 318.6, 318.7, 318.10, and 318.300 through 318.311 of this subchapter and shall not be adulterated as defined in paragraph 1(m) of the Act:

Provided, That the provisions of §§ 318.5, 318.6, 318.10, and 318.300 through 318.311 relating to inspection or supervision of specified activities or other action by a Program inspector, and the provisions
of § 318.6(b)(9) and (10), shall not apply to the preparation and handling of such exempted products.

(2) The exempted custom prepared products shall comply with the requirements of §§ 316.16 and 317.16 of this subchapter.

(3) The custom operators claiming exemption under paragraph (a)(2) of this section shall keep records, in addition to records otherwise required by part 320 of this subchapter, showing the numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products.

(4) Articles capable of use as human food, resulting from the exempted custom slaughter or other preparation of products shall be promptly denatured or otherwise identified in accordance with § 325.13 of this subchapter and not removed from the establishment where the custom operations are conducted until so identified, unless they are delivered to the owner of the articles for use in accordance with paragraph (a)(2) of this section.

(c) It has been determined that it is impracticable to provide inspection of the preparation of products at establishments in any unorganized Territory at which livestock are slaughtered or their products are prepared for distribution solely within such jurisdiction and that exempting such establishments from requirements of the Act for such inspections under the conditions stated in this section will otherwise facilitate enforcement of the Act. Therefore, such inspection requirements of the Act and of the regulations in this subchapter shall not apply at such establishments if they are operated in accordance with the regulations in part 308 of this subchapter, except §§ 308.1, 308.2, and 308.15. However, the Administrator may refuse, withdraw, or modify any exemption under this paragraph when he determines in any specific case in accordance with the applicable rules of practice that such action is necessary to effectuate the purposes of this Act.

(d) (1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants are the following:

(a) Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts;

(b) Grinding and freezing products made from meat;

(c) Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;

(d) Breaking bulk shipments of products;

(e) Wrapping or rewrapping products.

(ii) Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to be a normal retail quantity if the quantity so purchased does not, in the aggregate, exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified:

<table>
<thead>
<tr>
<th>Species</th>
<th>One-half carcass pounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>300</td>
</tr>
<tr>
<td>Calves</td>
<td>37.5</td>
</tr>
<tr>
<td>Sheep</td>
<td>27.5</td>
</tr>
<tr>
<td>Swine</td>
<td>100</td>
</tr>
<tr>
<td>Goats</td>
<td>25</td>
</tr>
</tbody>
</table>

(iii) A retail store is any place of business where:

(a) The sales of product are made to consumers only;

(b) At least 75 percent, in terms of dollar value, of total sales of product represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first
quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds $500. Notice of the adjusted dollar limitation will be published in the Federal Register.1

(c) Only federally or State inspected and passed product is handled or used in the preparation of any product, except that product resulting from the custom slaughter or custom preparation of product may be handled or used in accordance with paragraph (a)(2) and (b) of this section but not for sale;

(d) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(i) of this section;

(e) The preparation of products for sale to household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section; and

(f) The preparation of products for sale to other than household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section. (A retail store at which custom slaughtering or preparation of products is conducted is not thereby disqualified from exemption as a retail store under this paragraph (d).)

(iv) Restaurants. (a) A restaurant is any establishment where:

1 Product is prepared only for sale or service in meals or as entrees directly to individual consumers at such establishments;

2 Only federally or State inspected and passed product or such product prepared at a retail store exempted under paragraph (d)(2)(iii) of this section is handled or used in the preparation of any product;

3 No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(i) of this section; and

4 The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(b) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

(c) For purposes of this paragraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirements of this paragraph: Provided, That the requirements of §§ 320.1 through 320.4 of this subchapter apply to such facility. Provided further, That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary, if the Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator’s determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) Similar retail-type establishment: Any establishment which is a combination retail store and restaurant; any

1The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food and Safety Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447-3219.
delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraphs (d)(2)(iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) Consumer: Any household consumer, hotel, restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail store claiming exemption under this paragraph (d), in any designated State or organized Territory that is identified under section 205 of the Act (as one that does not have or is not exercising adequate authority with respect to recordkeeping requirements) has been operated in violation of the conditions prescribed in this section for exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail store and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator still has reason to believe that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail store would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of total monthly purchases and of total monthly sales of meat, meat byproducts, and meat food products, in terms of dollar values of the products involved. Such records shall separately show total sales to household consumers and total sales to other consumers and shall be maintained for the period prescribed in §320.3 of this subchapter. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to meat pizzas containing meat food product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the meat pizzas are to be served in public or private nonprofit institutions, provided that the meat pizzas are ready-to-eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1–102, except 1–102(z) and the provisions of Chapters 2 through 8, except sections 2–102(a) and (b), 2–302(d), 2–403(a), 2–403(c), 2–404, 2–405, 2–407, 2–502 through 2–506, 2–508, 2–509, 4–105, 4–201(c), 4–208, 5–101(a), 5–103, 5–104, 5–202(c), 5–203, and 6–105, part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78–2081, which is incorporated by reference, shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, N.W., Washington, DC, or the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.)

(3) Facilities and operations of businesses claiming this exemption shall also conform to the following requirements:

(i) Manual cleaning and sanitizing. (A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink
§ 303.1

compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be prefushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

1. Sinks shall be cleaned prior to use.
2. Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.
3. Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.
4. Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(ii)(E)(1) through (4) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

1. Immersion for at least ½ minute in clean, hot water at a temperature of at least 170 °F; or
2. Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or
3. Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or
4. Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or
5. Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or
6. Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(ii)(E)(4) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

1. An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and
2. A numerically scaled indicating thermometer, accurate to ±3 °F, convenient to the sink for frequent checks of water temperature; and
3. Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) Mechanical cleaning and sanitizing.

(A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils.

(G) When chemicals are used for sanitization, these machines and devices shall be properly installed and maintained in good repair.

Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and
equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A \( \frac{1}{4} \)-inch IPS valve shall be provided immediately up stream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to \( \pm 3 \) °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or the use of easily movable dish tables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewash cycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: Provided, That,

(1) The temperature of the wash water shall not be less than 120 °F.
(2) The wash water shall be kept clean.
(3) Chemicals added for sanitization purposes shall be automatically dispensed.
(4) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(5) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(6) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(7) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(1) Single-tank, stationary-rack, dual-temperature machine:
   - Wash temperature ................................150 °F
   - Final rinse temperature ........................180 °F

(2) Single-tank, stationary-rack, single-temperature machine:
   - Wash temperature ................................165 °F
   - Final rinse temperature ........................165 °F

(3) Single-tank, conveyor machine:
   - Wash temperature ................................140 °F
   - Final rinse temperature ........................180 °F

(4) Multitank, conveyor machine:
   - Wash temperature ................................150 °F
   - Pumped rinse temperature ........................160 °F
   - Final rinse temperature ........................180 °F

(5) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):
   - Wash temperature ................................140 °F
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Final rinse temperature ........................180 °F

(I) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) Steam. Steam used in contact with food or food-contact surfaces shall be free from any materials or additives other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term “private nonprofit institution” means “a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.”

(5) The Administrator may withdraw or modify the exemption set forth in §303.1(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department’s Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect ending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(f) The adulteration and misbranding provisions of the Act and the regulations in this subchapter, other than the requirement of the official inspection legend, apply to articles which are exempted from inspection or not required to be inspected under this section. This includes the requirement that any pork and any product containing pork be prepared only in compliance with any applicable requirement for the destruction of trichina as provided in §318.10 of this subchapter.

(g) The Administrator may extend the requirements of titles I and IV of the Act to any establishment in any State or organized Territory at which products are prepared for distribution solely within such jurisdiction, if he determines in accordance with the provisions of paragraph 301(c)(1) of the Act that it is producing adulterated products which would clearly endanger the public health.

(h) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in this subchapter in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to
facilitate definite improvements: Provided, That such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Act.

(Approved by the Office of Management and Budget under control number 0583-0015)


§ 303.2 Experimentation: Intensity of inspection coverage.

(a) Pursuant to the Processed Products Inspection Improvement Act of 1986, Title IV of the Futures Trading Act of 1986 (Pub. L. 99-641), in establishments preparing products at which inspection under the Act and regulations is required, the frequency with which and the manner in which meat food products made from livestock previously slaughtered in official establishments are examined and inspected by Program employees is to be based on considerations relevant to effective regulation of meat food products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, is so, to what extent the intensity of inspection coverage exceeds that which should be considered necessary pursuant to section 6 of the Act, as amended by section 403(a) of the Futures Trading Act of 1986, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Program employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(b) The determinations referred to in paragraph (a) of this section shall be made by the program and shall reflect evaluations of the performance and the characteristics and such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person conducting operations at such establishment or by anyone responsibly connected with the business conducting operations at such establishment, as “responsibly connected” is defined in section 401(g) of the Act,

(ii) The competence of the person conducting operations at such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Program employees and otherwise assuring compliance with applicable regulatory requirements,

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Poultry Products Inspection Act also are prepared at such establishment, and

(vi) The size of such establishment.
harder and longer, I think is a pretty hard argument to make.

NOTE: The President spoke at 10:45 a.m. in the Cabinet Room at the White House.

Executive Order 12866—Regulatory Planning and Review
September 30, 1993

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achiev-
ing the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of its own regulations, and, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people. (a) The Agencies. Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) The Office of Management and Budget. Coordinated review of agency rulemaking is necessary to ensure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President, the Vice President, and other regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations, as provided by this Executive order.

(c) The Vice President. The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order. In fulfilling their responsibilities under this Executive order, the President and the Vice President shall be assisted by the regulatory policy advisors within the Executive Office of the Presi-
Sec. 3. Definitions. For purposes of this Executive order: (a) "Advisors" refers to such regulatory policy advisors to the President as the President and Vice President may from time to time consult, including, among others: (1) the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Assistant to the President for Science and Technology; (7) the Assistant to the President for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Deputy Assistant to the President and Director of the White House Office on Environmental Policy; and (12) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" or "rule" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations or rules that are limited to agency organization, management, or personnel matters;

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Sec. 4. Planning Mechanism. In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law: (a) Agencies' Policy Meeting. Early in each year's planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to
coordinate regulatory efforts to be accomplished in the upcoming year.

(b) Unified Regulatory Agenda. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) The Regulatory Plan. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;

(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies, the Advisors, and the Vice President.

(4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency, the Advisors, and the Vice President.

(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies, the Advisors, and the Vice President.

(6) The Vice President, with the Advisors' assistance, may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) Regulatory Working Group. Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Reg-
ulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, the Advisors, and the Vice President. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Vice President on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) Conferences. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Vice President, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

Sec. 6. Centralized Review of Regulations. The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) Agency Responsibilities. (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should,
where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of poten-
tially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C):

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency’s regulatory actions are consistent with applicable law, the President’s priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative
from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(iii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

During the Vice Presidential and Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Vice President shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

At the end of this review process, the President, or the Vice President acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

Sec. 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of
OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Vice President, as provided under section 7 of this order. Upon receipt of this request, the Vice President shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

Sec. 9. Agency Authority. Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law.

Sec. 10. Judicial Review. Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.


William J. Clinton

[Filed with the Office of the Federal Register, 12:12 p.m., October 1, 1993]
Food Safety and Inspection Serv. (Meat, Poultry), USDA § 317.2

317.360 Nutrient content claims for calorie content.
317.361 Nutrient content claims for the sodium content.
317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.
317.363 Nutrient content claims for "healthy".
317.364–317.368 [Reserved]
317.369 Labeling applications for nutrient content claims.
317.370–317.379 [Reserved]
317.380 Label statements relating to usefulness in reducing or maintaining body weight.
317.381–317.399 [Reserved]
317.400 Exemption from nutrition labeling.


SOURCE: 35 FR 15580, Oct. 3, 1970, unless otherwise noted.

Subpart A—General

§ 317.1 Labels required; supervision by Program employee.

(a) When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in § 317.2 except that the following do not have to bear such a label:

1. Wrappings of dressed carcasses and primal parts in an unprocessed state, bearing the official inspection legend, if such wrappings are intended solely to protect the product against soiling or excessive drying during transportation or storage, and the wrappings bear no information except company brand names, trade marks, or code numbers which do not include any information required by § 317.2;

2. Uncolored transparent coverings, such as cellophane, which bear no written, printed, or graphic matter and which enclose any unpackaged or packaged product bearing all markings required by part 316 of this subchapter which are clearly legible through such coverings;

3. Animal and transparent artificial casings bearing only the markings required by part 316 of this subchapter;

4. Stockinettes used as "operative devices", such as those applied to cured meats in preparation for smoking, whether or not such stockinettes are removed following completion of the operations for which they were applied;

5. Containers such as boil-in bags, trays of frozen dinners, and pie pans which bear no information except company brand names, trademarks, code numbers, directions for preparation and serving suggestions, and which are enclosed in a consumer size container that bears a label as described in § 317.2;

6. Containers of products passed for cooking or refrigeration and moved from an official establishment under § 311.1 of this subchapter.

(b) Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear all features required on a label for an immediate container.

(c) No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee.

§ 317.2 Labels: definition; required features.

(a) A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.

(b) Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. In order to meet this requirement, such information must appear on the principal display panel except as otherwise permitted in this part. Except as provided in § 317.7, all words, statements, and other information required
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by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: Provided, however, That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(c) Labels of all products shall show the following information on the principal display panel (except as otherwise permitted in this part), in accordance with the requirements of this part or, if applicable, part 319 of this subchapter:

(1) The name of the product, which in the case of a product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in part 319 of this subchapter, shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation, as prescribed in paragraph (e) of this section;

(2) If the product is fabricated from two or more ingredients, the word “ingredients” followed by a list of the ingredients as prescribed in paragraph (f) of this section;

(3) The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section;

(4) An accurate statement of the net quantity of contents, as prescribed in paragraph (h) of this section;

(5) An official inspection legend and, except as otherwise provided in paragraph (i) of this section, the number of the official establishment, in the form required by part 312 of this subchapter;

(6) Any other information required by the regulations in this part or part 319 of this subchapter.

(d) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part and part 319 of this subchapter with clarity and conspicuousness and without obscuring of such information by designs or vignettes or crowding. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. The principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is at least the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area that is 40 percent of the product of the height of the container times the circumference of the container, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: Provided, however, That if there is immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in paragraphs (c) (2), (3), and (5), such panel shall be known as the “20 percent panel” and such information may be shown on that panel in lieu of showing it on the principal display panel.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

(e) Any descriptive designation used as a product name for a product which has no common or usual name shall clearly and completely identify the product. Product which has been prepared by salting, smoking, drying, cooking, chopping, or otherwise shall be so described on the label unless the name of the product implies, or the manner of packaging shows that the product was subjected to such preparation. The unqualified terms “meat,” “meat byproduct,” “meat food product,” and terms common to the meat industry but not common to consumers such as “picnic,” “butt,” “cala,” “square,” “loaf,” “spread,” “delight,”
“roll,” “plate,” “luncheon,” and “daisy” shall not be used as names of a product unless accompanied with terms descriptive of the product or with a list of ingredients, as deemed necessary in any specific case by the Administrator in order to assure that the label will not be false or misleading.

(f)(1) The list of ingredients shall show the common or usual names of the ingredients arranged in the descending order of predominance, except as otherwise provided in this paragraph.

(i) The terms spice, natural flavor, natural flavoring, flavor and flavoring may be used in the following manner:

(A) The term “spice” means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(B) The term “natural flavor,” “natural flavoring,” “flavor” or “flavoring” means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powered onion, powdered garlic, and powdered celery.

(ii) The term “corn syrup” may be used to designate either corn syrup or corn syrup solids.

(iii) The term “animal and vegetable fats” or “vegetable and animal fats” may be used to designate the ingredients of mixtures of such edible fats in product designated “compound” or “shortening.” “Animal fats” as used herein means fat derived from inspected and passed cattle, sheep, swine, or goats.

(iv) When a product is coated with pork fat, gelatin, or other approved substance and a specific declaration of such coating appears contiguous to the name of the product, the ingredient statement need not make reference to the ingredients of such coating.

(v) When two meat ingredients comprise at least 70 percent of the meat and meat byproduct ingredients of a formula and when neither of the two meat ingredients is less than 30 percent by weight of the total meat and meat byproducts used, such meat ingredients may be interchanged in the formula without a change being made in the ingredients statement on labeling materials: Provided, That the word “and” in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(vi)(A) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: Provided, That the word “and” in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(ii) The term “corn syrup” may be used to designate either corn syrup or corn syrup solids.

(B) The term “natural flavor,” “natural flavoring,” “flavor” or “flavoring” means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powered onion, powdered garlic, and powdered celery.

(iii) The term “animal and vegetable fats” or “vegetable and animal fats” may be used to designate the ingredients of mixtures of such edible fats in product designated “compound” or “shortening.” “Animal fats” as used herein means fat derived from inspected and passed cattle, sheep, swine, or goats.

(iv) When a product is coated with pork fat, gelatin, or other approved substance and a specific declaration of such coating appears contiguous to the name of the product, the ingredient statement need not make reference to the ingredients of such coating.

(v) When two meat ingredients comprise at least 70 percent of the meat and meat byproduct ingredients of a formula and when neither of the two meat ingredients is less than 30 percent by weight of the total meat and meat byproducts used, such meat ingredients may be interchanged in the formula without a change being made in the ingredients statement on labeling materials: Provided, That the word “and” in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(vi)(A) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: Provided, That the word “and” in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.
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amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(2) On containers of frozen dinners, entrees, pizzas, and similar consumer packaged products in cartons the ingredient statement may be placed on the front riser panel: Provided, That the words “see ingredients” followed immediately by an arrow is placed on the principal display panel immediately above the location of such statement without intervening print or designs.

(3) The ingredient statement may be placed on the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container.

(4) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(g)(1) The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as “Prepared for * * *.” The place of business of the manufacturer, packer, or distributor shall be shown on the label by city, State, and postal ZIP code when such business is listed in a telephone or city directory, and if not listed in such directory, then the place of business shall be shown by street address, city, State, and postal ZIP code.

(2) The name and place of business of the manufacturer, packer, or distributor may be shown:

(i) On the principal display panel, or
(ii) On the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container, or
(iii) On the front riser panel of frozen food cartons, or
(iv) On the information panel.

(h)(1) The statement of net quantity of contents shall appear on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph.

(2) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in §317.19. The statement shall not include any term qualifying a unit of weight, measure, or count such as “jumbo quart,” “full gallon,” “giant quart,” “when packed,” “minimum,” or words of similar importance.

(3) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel in lines generally parallel to the base: Provided, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph (h). In any case, the statement may appear in more than one line. The terms “net weight” or “net wt.” shall be used when stating the net quantity of contents in terms of weight, and the term “net contents” or “content” when stating the net quantity of contents in terms of fluid measure.

(4) Except as provided in §317.7, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semisolid viscous or a mixture of solid and liquid. For example, a declaration of ¾-pound avoirdupois weight shall be expressed as “Net Wt. 12 oz.” except as provided for in paragraph (h)(5) of this section for random weight packages; a declaration of 1½ pounds avoirdupois weight shall be expressed as “Net Wt. 24 oz. (1 lb. 8 oz.),” “Net Wt. 24 oz. (1½ lb.),” or “Net Wt. 24 oz. (1.5 lbs.).”

(5) On packages containing 1 pound or 1 pint and less than 4 pounds or 1
gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parentheses) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart, except that on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. Paragraph (h)(9) of this section permits certain exceptions from the provisions of this paragraph for margarine packages, random weight consumer size packages, and packages of less than ½ ounce net weight. Paragraph (h)(12) of this section permits certain exceptions from the provision of this paragraph for multi-unit packages.

(6) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel of the package and shall be uniform of all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on packages, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on packages, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenths inch in height on packages, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on packages, the principal display panel of which has an area of more than 100 but not more than 400 square inches.

(v) Not less than one-half inch in height on packages, the principal display panel of which has an area of more than 400 square inches.

(7) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). Heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter “o” or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(8) The statement shall appear as a distinct item on the principal display panel and shall be separated by a space at least equal to the height of the lettering used in the statement from other printed label information appearing above or below the statement and by a space at least equal to twice the width of the letter “N" of the style of type used in the quantity of contents statement from other printed label information appearing to the left or right of the statement. It shall not include any term qualifying a unit of weight, measure, or count such as, “jumbo quart,” “full gallon,” “giant quart,” “when packed,” “Minimum” or words of similar import.

(9) The following exemptions from the requirements contained in this paragraph (h) are hereby established:

(i) Individually wrapped, random weight consumer size packages shipped in bulk containers (as specified in paragraph (h)(11) of this section) and meat products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined under §317.19 need not bear a net weight statement when shipped from an official establishment, provided that a net weight shipping statement which meets the requirements of paragraph (h)(2) of this section is applied to their shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement on random weight consumer size

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packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (h)(2) of this section;

(iii) Individually wrapped and labeled packages of less than ½ ounce net weight bearing labels declaring net weight, price per pound, and total price shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(iv) Margarine in 1 pound rectangular packages (except packages containing whipped or soft margarine or packages that contain more than four sticks) is exempt from the requirements of paragraphs (h)(3) and (5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel and that the statement be expressed both in ounces and in pounds, if the statement appears as “1 pound” or “one pound” in a conspicuous manner on the principal display panel.

(v) Sliced shingle packed bacon in rectangular packages is exempt from the requirements of paragraphs (h)(3) and (h)(5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel, and that the statement be expressed both in ounces and in pounds, if the statement appears in a conspicuous manner on the principal display panel.

(vi) The official establishment number of the official establishment in which the product was processed under inspection shall be placed as follows:

(1) Within the official inspection legend in the form required by part 312 of this subchapter; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to ensure easy visibility and recognition and accompanied by the prefix “EST”: or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling material in the
container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as “EST. No. on Metal Clip” or “Est. No. on Pan”, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix “EST”.

(j) Labels of any product within any of the following paragraphs shall show the information required by such paragraph for such product:

(1) A label for product which is an imitation of another food shall bear the word “imitation” immediately preceding the name of the food imitated and in the same size and style of lettering as in that name and immediately thereafter the word “ingredients:” and the names of the ingredients arranged in the order of their predominance.

(2) If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR part 125) established pursuant to sections 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

(3) When an artificial smoke flavoring or an smoke flavoring is added as an ingredient in the formula of a meat food product, as permitted in part 318 of this subchapter, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as “Artificial Smoke Flavoring Added” or “Smoke Flavoring Added,” as may be applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring so added as an ingredient in the formula of the meat food product.

(4) When any other artificial flavoring is permitted under part 318 of this subchapter to be added to a product, the ingredient statement shall identify it as “Artificial Flavoring.”

(5) When artificial coloring is added to edible fats as permitted under part 318 of this subchapter such substance shall be declared on the label in a prominent manner and contiguous to the name of the product by the words “Artificially colored” or “Artificial coloring added” or “With added artificial coloring.” When natural coloring such as annatto is added to edible fats as permitted under part 318 of this subchapter, such substance shall be declared on the label in the same manner by a phrase such as “Colored with annatto.”

(6) When product is placed in a casing to which artificial coloring is applied as permitted under part 318 of this subchapter, there shall appear on the label, in a prominent manner and contiguous to the name of the product, the words “Artificially colored.”

(7) If a casing is removed from product at an official establishment and there is evidence of artificial coloring on the surface of the product, there shall appear on the label, in a prominent manner and contiguous to the name of product, the words “Artificially colored.”

(8) When a casing is colored prior to its use as a covering for product and the color is not transferred to the product enclosed in the casing, no reference to color need appear on the label but no such casing may be used if it is misleading or deceptive with respect to color, quality, or kind of product, or otherwise.

(9) Product which bears or contains any other artificial coloring, as permitted under part 318 of this subchapter, shall bear a label stating that fact on the immediate container or if there is none, on the product.

(10) When an antioxidant is added to product as permitted under part 318 of this subchapter, there shall appear on the label a statement identifying the officially approved specific antioxidant by its common name or abbreviation thereof and the purpose for which it is added, such as, “BHA, BHT, and Propylgallate added to help protect flavor.”

(11) Containers of meat packed in borax or other preservative for export to a foreign country which permits the use of such preservative shall, at the
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time of packing, be marked “for export,” followed on the next line by the words “packed in preservative,” or such equivalent statement as may be approved for this purpose by the Administrator and directly beneath this there shall appear the word “establishment” or abbreviation thereof, followed by the number of the establishment at which the product is packed. The complete statement shall be applied in a conspicuous location and in letters not less than 1 inch in height.

(12) Containers of other product packed in, bearing, or containing any chemical preservative shall bear a label stating that fact.

(13)(i) On the label of any “Mechanically Separated (Species)” described in §319.5(b)(1) of this subchapter, the name of such product shall be followed immediately by the phrase “for processing” unless such product has a protein content of not less than 14 percent and a fat content of not more than 30 percent.

(ii) When any “Mechanically Separated (Species)” described in §319.5(a) of this subchapter is used as an ingredient in the preparation of a meat food product and such “Mechanically Separated (Species)” contributes 20 mg or more of calcium to a serving of such meat food product, the label of such meat food product shall state the calcium content of such meat food product, determined and expressed as the percentage of the U.S. Recommended Daily Allowance (U.S. RDA) in a serving in accordance with 21 CFR 101.9(b)(1), (c)(7)(i) and (iv), and (e), as part of any nutrition information included on such label, or if such meat food product does not bear nutrition labeling information, as part of a prominent statement in immediate conjunction with the list of ingredients, as follows: “A ______ serving contains ———% of the U.S. RDA of calcium”, with the blanks to be filled in, respectively, with the quantity of such product that constitutes a serving and the amount of calcium provided by such serving: Provided, That, calcium content need not be stated where (a) the percent of the U.S. RDA of calcium to be declared would not differ from the percent of the U.S. RDA that would be declared if the meat food product contained only hand deboned ingredients or (b) the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more if the meat food product contained only hand deboned ingredients.

(k) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: “Keep Refrigerated,” “Keep Frozen,” “Perishable Keep Under Refrigeration,” or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution and thawed prior to or during display for sale at retail shall bear the statement on the shipping container: “Keep Frozen.” The consumer-size containers for such products shall bear the statement “Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.” For all perishable canned products the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be in upper case letters at least one-half inch in height.

(l) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, or other equine not heat processed in a manner that conforms to the time and temperature combinations in the Table for Time/Temperature Combination For Cooked Beef, Roast Beef, and Cooked Corned Beef in §318.17, or that have not undergone other further processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations For Fully-Cooked Patties in §318.23; except as exempted under paragraph (l)(4) of this section.

(1)(i) Safe handling instructions shall accompany every meat or meat product, specified in this paragraph (l) destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller
than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading “Safe Handling Instructions” which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (1)(2) and (1)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) The labels of the meat and meat products specified in this paragraph (l) shall include the following rationale statement as part of the safe handling instructions, “This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.” This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Meat and meat products, specified in this paragraph (l), shall bear the labeling statements:

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product’s specific handling instructions, may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Meat or meat products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (1)(1) through (1)(3) of this section.

(m)(1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without
§ 317.3 Approval of abbreviations of marks of inspection; preparation of marking devices bearing inspection legend without advance approval prohibited; exception.

(a) The Administrator may approve and authorize the use of abbreviations of marks of inspection under the regulations in this subchapter. Such abbreviations shall have the same force and effect as the respective marks for which they are authorized abbreviations.

(b) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label, or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph apply only to labels, or other marking devices, bearing or containing a food safety and inspection service form for signature by a Program employee and the official establishment ordering the brand or other marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the brands or other marking devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the brand or other marking device manufacturer.

(3) The manufacturer of the brands or other marking devices shall engrave or otherwise mark each brand or other marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each brand or other marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the brands or other marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such brands or other marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such brand or other marking device which does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such brand or other marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)


§ 317.4 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling...
Food Safety and Inspection Serv. (Meat, Poultry), USDA § 317.20

5.7. Pressed and Blown Glass Tumblers and Stemware

APPENDIX D: PACKAGE NET CONTENTS REGULATIONS

D.1.1. U.S. Department of Health and Human Services, Food and Drug Administration
D.1.2. Department of Agriculture, Food Safety and Inspection Service
D.1.3. Federal Trade Commission
D.1.4. Environmental Protection Agency
D.1.5. U.S. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms


Supplement 3

Chapter 2 General Considerations

2.13.1. Polyethylene Sheeting and Film
2.13.2. Textiles
2.13.3. Mulch

Chapter 3 Methods of Test for Packages Labeled by Weight

3.11.4. Exhausting the Aerosol Container
3.11.5. The Determination of Net Contents: Part 2

Appendix A. Report Forms

[55 FR 49834, Nov. 30, 1990, as amended at 60 FR 12884, March 9, 1995]

§ 317.20 Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.

(a) All scales used to weigh meat products sold or otherwise distributed in commerce in federally inspected meat establishments shall be installed, maintained and operated to insure accurate weights. Such scales shall meet the applicable requirements contained in National Institute of Standards and Technology Handbook 44, “Specifications, Tolerances and Other Technical Requirements for Weighing and Measuring Devices,” 1994 Edition, October 1993, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., Suite 700, Washington, DC 20408.

(b) All scales used to weigh meat products sold or otherwise distributed in commerce or in States designated under section 301(c) of the Federal Meat Inspection Act, shall be of sufficient capacity to weigh the entire unit and/or package.

(c) No scale shall be used at a federally inspected establishment to weigh meat products unless it has been found upon test and inspection, as specified in NIST Handbook 44, to provide accurate weight. If a scale is reinspected or retested and found to be inaccurate, or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been inspected and tested by a USDA official, or a State or local government weights and measures official, or State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook.
§ 317.21  Scales: testing of.

(a) The operator of each official establishment that weighs meat food products shall cause such scales to be tested for accuracy, in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more frequent tests may be required and monitored by an authorized USDA program official.

(b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures authority or from a State registered or licensed scale repair firm or person, or shall have a net weight program under a Total Quality Control System or Partial Quality Control Program in accordance with §318.4 of this subchapter.


§ 317.22  Handling of failed product.

Any lot of product which is found to be out of compliance with net weight requirements upon testing in accordance with §317.19 shall be handled as follows:

(a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section and be reinspected, in accordance with the requirements of this part.

(b) A lot tested outside of an official establishment and found not to comply with net weight requirements must be reweighed and remarked with a proper net weight statement, provided that such reweighing and remarking shall not deface, cover, or destroy any other marking or labeling required under this subchapter and the net quantity of contents is shown with the same prominence as the most conspicuous feature of a label.

[55 FR 49834, Nov. 30, 1990]

§ 317.23  [Reserved]

§ 317.24  Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for their intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and any other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty must include the conditions of use, in accordance with 21 CFR 7.12 and 7.13. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department...
EXECUTIVE SUMMARY

This is the Food Safety and Inspection Service’s (FSIS) Quarterly Regulatory and Enforcement Report. Although this report focuses on regulatory and enforcement actions taken, it is important to recognize that this is only one aspect of the Agency's work. The Agency's main purpose is to protect public health by achieving compliance with laws and regulations. For example, the data indicate that plants operating under Hazard Analysis and Critical Control Point (HACCP) Systems have a 92 percent compliance rate for this reporting period.

The report provides a summary of the regulatory and enforcement actions, including those under the Pathogen Reduction/HACCP regulations, FSIS has taken to ensure that products that reach consumers are safe, wholesome, and properly labeled. FSIS inspects products produced in over 6,000 meat, poultry, and egg product plants. Since January 1998, approximately 300 large plants (those employing 500 or more employees) have been operating HACCP Systems with FSIS regulatory oversight. On January 25, 1999, approximately 2,300 small plants (those employing 10 or more, but fewer than 500 employees) began HACCP implementation. Very small plants (those employing fewer than 10 employees or with annual sales of less than $2.5 million) will phase in HACCP in January 2000.
Publication of this information is another step in the Agency's commitment to openness and transparency in its work to protect the public from adulterated or misbranded meat, poultry, and egg products.

The report is presented in sections that correspond with the category of action. Activities reported within the categories are either pending or experienced new activity during the reporting period. For example, during this quarter, FSIS detained nearly 10 million pounds of product and issued 641 warning letters for violations of law. FSIS also coordinated administrative actions, where regulatory or other authorities were applied in inspected plants, and managed USDA participation in criminal cases pending in Federal courts. These actions, along with the thousands of inspections made each day in plants throughout the country, form strong underpinnings for promoting compliance with food safety laws. Each section of this report is described and reported in more detail as follows:

FSIS ENFORCEMENT PROCESSES
NONCOMPLIANCE REPORTS AND APPEALS
PRODUCT CONTROL ACTIONS
LETTERS OF WARNING
ADMINISTRATIVE ACTIONS
CRIMINAL ACTIONS
CIVIL ACTIONS
FSIS ENFORCEMENT PROCESSES

USDA’s Food Safety and Inspection Service (FSIS) is charged with ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled. FSIS, in cooperation with state counterparts, inspects, monitors, and verifies the proper processing, handling, and labeling of meat and poultry products from the delivery of animals to the slaughterhouse to when the products reach consumers. FSIS, in cooperation with FDA and the states, provides similar coverage for egg products – the processed whole egg ingredients used in manufacturing other foods. (More information concerning egg products inspection and enforcement is provided in the FSIS publication "Focus on Egg Products" which can be accessed at: http://www.fsis.usda.gov/OA/pubs/eggprod.htm). This regulatory oversight generally reflects compliance by the large majority of businesses. However, if FSIS detects problems at any step along the way, it can use a number of product control and enforcement measures to protect consumers.

USDA has traditionally focused much of its effort on the plants that slaughter food animals and process products. USDA ensures that products at these establishments are produced in a sanitary environment in which inspectors or plant employees identify and eliminate potential food safety hazards. These establishments must apply for a grant of inspection from FSIS and demonstrate the ability to meet certain requirements for producing safe, wholesome, and accurately labeled food products. Requirements include meeting sanitation, facility, and operational standards and, through new requirements now being implemented, having preventive systems in place to ensure the production of safe and unadulterated food. Products from official establishments are labeled
with the mark of inspection, indicating that they have been inspected and passed by USDA and can be sold in interstate commerce.

FSIS uses Compliance Officers throughout the chain of distribution to detect and detain potentially hazardous foods in commerce to prevent their consumption and to investigate violations of law. Even if products are produced under conditions that are safe and sanitary, abuse on the way to the consumer, for example, if transported in trucks that are too warm or if exposed to contamination, can result in product that can cause illness or injury. FSIS has recognized a need to spend increasing amounts of its energy on activities to promote safe transporting, warehousing, and retailing of meat, poultry, and egg products, and is moving forward on these efforts.

FSIS also works closely with USDA’s Office of Inspector General, which assists FSIS in pursuing complex criminal cases. In addition, many state and local jurisdictions have enforcement authorities that apply to USDA regulated products. FSIS cooperates with these other jurisdictions in investigations and case presentations. FSIS also participates with OIG and the U.S. Department of Justice in monitoring conditions of probation orders and pretrial diversion agreements developed to resolve cases.

In January 1997, FSIS began implementing new requirements in plants that produce meat and poultry. New regulations, entitled “Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,” require that federally inspected meat and poultry plants: (1) develop and implement a preventive HACCP plan; (2) develop and implement Sanitation Standard
Operating Procedures (SSOP’s); (3) collect and analyze samples for the presence of generic *E. coli*, and record results; and (4) meet *Salmonella* performance standard requirements. These new requirements are designed to help target and reduce foodborne pathogens. All plants have already implemented SSOP’s and, as appropriate, are phasing in the other requirements. All large plants—accounting for most federally inspected meat and poultry sold—must now meet the requirements for HACCP Systems. Approximately 2,300 additional plants began implementing HACCP in January 1999. By the year 2000, HACCP implementation will be complete, even in the smallest plants.

The new prevention-oriented meat and poultry inspection system is showing positive results. New data from the first year of testing in large plants show that the *Salmonella* in broilers, swine, and ground beef was substantially lower after HACCP implementation. Also, 88 percent of large plants with completed sample sets are meeting the *Salmonella* standard. Of approximately 2,300 small plants required to have HACCP in place by January 25, 1999, only about 20 plants received notices of suspension for failure to comply with the regulation during this quarter.

This report provides a summary of the regulatory and enforcement actions, including actions that address the Pathogen Reduction/HACCP regulatory requirements, FSIS has taken to ensure that products that reach consumers are safe, wholesome, and properly labeled. The Agency recognizes that this report is a snapshot in time of a dynamic process. Some information will be out-of-date by the time this report is published (approximately one month after close of reporting period), and more current information will not be included. For example, many matters shown as under appeal will have been resolved by the time this report is published. Other actions could
be appealed or closed after this reporting period. This information will be updated on a quarterly basis and made available to the public through future reports.

**NONCOMPLIANCE REPORTS AND APPEALS**

FSIS inspection program personnel perform thousands of inspection tasks and procedures each day to determine whether or not inspected plants are in compliance with regulatory requirements. Each time inspection program personnel make a non-compliance determination they complete a report explaining the nature of the regulatory action. They notify plant managers of problems by a written Noncompliance Report (NR) or, in plants that have not yet implemented HACCP, a Process Deficiency Record (PDR). NRs and PDRs document noncompliance determinations that occur in the plant’s sanitation and other controls and notify the plant that it must take action to remedy a problem and prevent its recurrence. If this is done, the plant will continue to operate without interruption. Problems reported on NRs and PDRs vary from minor labeling discrepancies to serious breakdowns in food safety controls. When deficiencies occur repeatedly or when the plant fails to prevent adulterated product from being shipped, FSIS takes action to control products and may take an action to withhold or suspend inspection.

As of March 31, 1999, approximately 300 large plants (plants with 500 or more employees) and approximately 2,300 small plants (plants employing 10 or more, but fewer than 500 employees) operated under HACCP-based inspection. Approximately 3,400 very small plants operated under traditional inspection. Because monitoring and documentation requirements in the two systems differ, the number and type of NRs and related appeals for HACCP plants cannot be accurately compared to the number and type of PDRs and related appeals for traditional plants. Plants can appeal NRs, PDRs, and other inspection decisions at various levels in the Office of
Field Operations, within FSIS. FSIS has emphasized that appeals are both expected and appropriate to resolve legitimate disagreements. FSIS encourages plants to make their appeals in a timely manner. A tracking system for monitoring industry appeals became operational on May 11, 1998.

Table 1a provides numbers of NRs and PDRs issued by FSIS inspection personnel. The PDR’s referenced in Table 1a were issued between January 1, 1999 and March 31, 1999. The NR’s referenced in the table were issued between January 3, 1999 and April 4, 1999. During this period, FSIS performed 1,458,132 inspection tasks at non-HACCP plants and 769,181 at HACCP plants. Table 1b shows the number of appeals and the dispositions of the appeals filed at traditional (non-HACCP) plants and at HACCP plants, from January 1 to March 31, 1999.

### Table 1a. Process Deficiency Record and Noncompliance Report Totals

<table>
<thead>
<tr>
<th>PDR/NR Totals</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PDRs Issued (1/1/99-3/31/99)</td>
<td>15,512</td>
</tr>
<tr>
<td>NRs Issued (1/3/99-4/4/99)</td>
<td>28,995</td>
</tr>
</tbody>
</table>
Table 1b. Appeals of PDRs and NRs (1/1/99 – 3/31/99)

<table>
<thead>
<tr>
<th>Number of Non-HACCP Plants Filing Appeals</th>
<th>36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appeal of PDR Granted</td>
<td>16</td>
</tr>
<tr>
<td>Appeal of PDR Denied</td>
<td>33</td>
</tr>
<tr>
<td>Appeal of PDR Pending</td>
<td>2</td>
</tr>
<tr>
<td>Total PDRs Appealed</td>
<td>51</td>
</tr>
</tbody>
</table>

(Total exceeds 36 because some plants filed multiple appeals.)

<table>
<thead>
<tr>
<th>Number of HACCP Plants Filing Appeals</th>
<th>73</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appeal of NR Granted</td>
<td>80</td>
</tr>
<tr>
<td>Appeal of NR Denied</td>
<td>142</td>
</tr>
<tr>
<td>Appeal of NR Pending</td>
<td>21</td>
</tr>
<tr>
<td>Total NRs Appealed</td>
<td>243</td>
</tr>
</tbody>
</table>

(Total exceeds 73 because some plants filed multiple appeals.)

PRODUCT CONTROL ACTIONS

FSIS takes product control actions to gain physical control over products when there is reason to believe they are adulterated or misbranded. The actions ensure that those products do not enter commerce or, if they are already in commerce, that they do not reach consumers.

In official establishments, FSIS inspectors may retain products whenever there is evidence of unwholesomeness, or if products are adulterated or mislabeled. FSIS inspectors condemn animals for disease, contamination, or adulteration to prevent their use as human food. Figures for condemnations for livestock for the reporting period are as follows: FSIS inspected 33,707,115 livestock carcasses, of which 65,395 carcasses were condemned. FSIS inspected 1,845,733,710 poultry carcasses of which 21,627,281 carcasses were condemned. Statistics regarding the number of poultry carcasses inspected and condemned for the reporting period, October 1, 1998 through December 31, 1998, were unavailable when the previous report was...
issued. It is now possible to report that for the period October 1, 1998 through December 31, 1998, FSIS inspected 2,022,334,385 poultry carcasses of which 20,577,049 were condemned.

**Detentions**

After products are distributed from plants, FSIS Compliance Officers detain any that may be adulterated or misbranded. FSIS then has 20 days to request a Federal court to seize the product (see Civil Actions). **Table 2** provides the number of detentions and the pounds of product involved in these actions for meat and poultry, reported in total and by FSIS District Office, for this quarterly reporting period. Most detentions result in voluntary disposal of the product and do not require court seizures.

**Table 2. Detention Summary**  
(1/1/99 — 3/31/99)

<table>
<thead>
<tr>
<th>District</th>
<th>Detentions</th>
<th>Pounds Detained</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALAMEDA, CA</td>
<td>45</td>
<td>113,002</td>
</tr>
<tr>
<td>ALBANY, NY</td>
<td>15</td>
<td>5,832</td>
</tr>
<tr>
<td>ATLANTA, GA</td>
<td>22</td>
<td>141,577</td>
</tr>
<tr>
<td>BELTSVILLE, MD</td>
<td>8</td>
<td>216,829</td>
</tr>
<tr>
<td>BOSTON, MA</td>
<td>7</td>
<td>98,285</td>
</tr>
<tr>
<td>BOULDER, CO</td>
<td>5</td>
<td>30,490</td>
</tr>
<tr>
<td>CHICAGO, IL</td>
<td>12</td>
<td>10,260</td>
</tr>
<tr>
<td>DALLAS, TX</td>
<td>16</td>
<td>633,315</td>
</tr>
<tr>
<td>DES MOINES, IA</td>
<td>22</td>
<td>996,037</td>
</tr>
<tr>
<td>JACKSON, MS</td>
<td>12</td>
<td>2,678</td>
</tr>
<tr>
<td>LAWRENCE, KS</td>
<td>9</td>
<td>12,814</td>
</tr>
<tr>
<td>MADISON, WI</td>
<td>7</td>
<td>83,479</td>
</tr>
<tr>
<td>MINNEAPOLIS, MN</td>
<td>1</td>
<td>2,550</td>
</tr>
<tr>
<td>PHILADELPHIA, PA</td>
<td>6</td>
<td>7,972</td>
</tr>
<tr>
<td>PICKERINGTON, OH</td>
<td>6</td>
<td>35,733</td>
</tr>
<tr>
<td>RALEIGH, NC</td>
<td>9</td>
<td>57,826</td>
</tr>
<tr>
<td>SALEM, OR</td>
<td>21</td>
<td>12,909</td>
</tr>
<tr>
<td>SPRINGDALE, AR</td>
<td>29</td>
<td>7,534,267</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>252</td>
<td>9,995,855</td>
</tr>
</tbody>
</table>
Recalls

A recall is a voluntary action by a firm to remove adulterated, misbranded, or suspect products from distribution. FSIS cannot require recalls but can recommend and monitor those that occur. Class I recalls involve a health hazard when there is a reasonable possibility that the use of the product will cause serious adverse health consequences or death. Class II recalls involve a health hazard when there is a remote probability of adverse health consequences from use of the product. Class III recalls involve a situation in which use of the product is not likely to cause adverse health consequences. For current information on recalls, go to the FSIS recalls web page at:  http://www.fsis.usda.gov/OA/news/xrecalls.htm

Import Inspections

FSIS maintains a comprehensive system of import controls to carry out the requirements of the Federal meat, poultry, and egg products inspection laws to ensure the wholesomeness of imported products. The system of import controls involves two major components: oversight and reinspection. FSIS conducts a rigorous review of an exporting country’s controls to ensure they are equivalent to those of the United States, prior to the country’s eligibility to export to the United States. Reinspection of meat, poultry and egg products that enter the U.S. is based on statistical sampling and verifies the country’s inspection system is working. A product that fails to meet U.S. requirements is refused entry into this country. The product must be re-exported, destroyed or, in some cases, converted to animal food. Table 3 provides the total number of presented lots and pounds of imported meat and poultry products presented, reinspected, and refused entry during the period from January 1 to March 31, 1999.
Table 3. Imported Meat, Poultry and Egg Products  
(1/1/99 — 3/31/99)

<table>
<thead>
<tr>
<th>Presented, Reinspected and Refused Entry</th>
</tr>
</thead>
</table>

**Meat and Poultry**

<table>
<thead>
<tr>
<th>Number of Presented Lots</th>
<th>Number of Reinspected Lots</th>
<th>Number of Refused Entry Lots</th>
</tr>
</thead>
<tbody>
<tr>
<td>35,255</td>
<td>7,301</td>
<td>2,884</td>
</tr>
<tr>
<td>768,028,232</td>
<td>174,404,804</td>
<td>3,204,101</td>
</tr>
</tbody>
</table>

**Egg Products**

<table>
<thead>
<tr>
<th>Number of Presented Lots</th>
<th>Number of Refused Entry Lots</th>
</tr>
</thead>
<tbody>
<tr>
<td>90</td>
<td>0</td>
</tr>
<tr>
<td>926,263</td>
<td>0,000</td>
</tr>
</tbody>
</table>

**LETTERS OF WARNING**

FSIS issues letters of warning (LOW) for minor violations of law that are not referred to United States Attorneys for prosecution. FSIS may also issue these warnings when a United States Attorney declines to prosecute a case or bring action against a specific business or person. These letters warn that FSIS may seek criminal action based on continued violations. Letters of warning may be issued to any individual or business, including Federal plants, wholesalers, distributors, restaurants, retail stores and other entities that process, store, or distribute meat and poultry products. **Table 4** shows letters of warning issued by headquarters and by each of the eighteen FSIS District Offices during the reporting period.
Table 4. Letters of Warning for Criminal Actions
(1/1/99 — 3/31/99)

Letters of Warning for Criminal Violations

<table>
<thead>
<tr>
<th>District</th>
<th>Number of LOWs Issued by Districts</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALAMEDA, CA</td>
<td>55</td>
</tr>
<tr>
<td>ALBANY, NY</td>
<td>75</td>
</tr>
<tr>
<td>ATLANTA, GA</td>
<td>29</td>
</tr>
<tr>
<td>BELTSVILLE, MD</td>
<td>30</td>
</tr>
<tr>
<td>BOSTON, MA</td>
<td>88</td>
</tr>
<tr>
<td>BOULDER, CO</td>
<td>26</td>
</tr>
<tr>
<td>CHICAGO, IL</td>
<td>29</td>
</tr>
<tr>
<td>DALLAS, TX</td>
<td>31</td>
</tr>
<tr>
<td>DES MOINES, IA</td>
<td>17</td>
</tr>
<tr>
<td>JACKSON, MS</td>
<td>14</td>
</tr>
<tr>
<td>LAWRENCE, KS</td>
<td>14</td>
</tr>
<tr>
<td>MADISON, WI</td>
<td>54</td>
</tr>
<tr>
<td>MINNEAPOLIS, MN</td>
<td>13</td>
</tr>
<tr>
<td>PHILADELPHIA, PA</td>
<td>53</td>
</tr>
<tr>
<td>PICKERINGTON, OH</td>
<td>6</td>
</tr>
<tr>
<td>RALEIGH, NC</td>
<td>8</td>
</tr>
<tr>
<td>SALEM, OR</td>
<td>71</td>
</tr>
<tr>
<td>SPRINGDALE, AR</td>
<td>20</td>
</tr>
</tbody>
</table>

Total number issued by Districts 633

ADMINISTRATIVE ACTIONS

FSIS inspects meat and poultry products and applies the marks of inspection when inspectors are able to determine that products are not adulterated. FSIS may temporarily withhold the marks of inspection from specific products, suspend inspection, or withdraw a grant of inspection if a plant is not meeting crucial requirements.

Withholding the Marks of Inspection

If a plant fails to prevent preparation and shipment of adulterated products or develops a pattern of noncompliance showing the plant’s sanitation or process control systems have failed, the
Inspector-in-Charge notifies plant managers that the USDA mark of inspection is being withheld from some or all of the products in the plant. This action effectively shuts down affected operations, because it is illegal to sell products in interstate commerce that do not bear the USDA mark of inspection. Other non-affected parts of the plant, if any, may still operate.

**Suspension of Inspection**

FSIS may temporarily suspend inspection if a plant fails to present a corrective action plan to bring the plant sanitation or process control systems into compliance. As with withholding actions, a suspension shuts down all or part of the plant’s operations. USDA may hold in abeyance the suspension action if corrections are presented, put into effect, and effectively prevent additional problems. FSIS District Offices have established procedures to monitor and verify activities in plants where the suspension is being held in abeyance.

**Notification to Establishments of Intended Enforcement Actions**

In April 1998, FSIS established a procedure for notifying establishments of intended enforcement actions related to certain HACCP System inadequacies that have not resulted in actual shipment of adulterated products. Under this procedure, a notice will be issued to an establishment when the Inspector-in-Charge determines that a HACCP System inadequacy has occurred because the establishment has experienced multiple, recurring noncompliances and has failed to implement corrective and preventive measures to prevent a HACCP System inadequacy. The “Notice” informs the establishment that the nature and scope of the noncompliances indicate that their HACCP System is inadequate and, because of the trend of noncompliances, FSIS intends to withhold the marks of inspection and suspend inspection. The
“Notice” explains the basis and references documentation for the intended enforcement action, and provides the establishment an opportunity to demonstrate why a HACCP System inadequacy determination should not be made or that the plant has achieved regulatory compliance.

**Withdrawal of Inspection**

In some situations, FSIS may decide that it is necessary to withdraw inspection from a plant. In these cases, FSIS withdraws inspection from a Federal plant by filing a complaint with the USDA Hearing Clerk. The plant may request a hearing before an Administrative Law Judge. If the action is based on insanitation, the plant will remain closed while proceedings go forward. In other cases that do not involve a threat to public health, operations may continue. These actions are often resolved by FSIS and the plant entering into a consent decision, which allows the plant to operate under certain specified conditions. Once inspection is withdrawn, a closed plant must reapply to receive Federal inspection.

USDA may initiate withholding, suspension, or withdrawal actions to limit a plant’s slaughtering or processing, or prevent the plant from operating altogether, based on any of the following reasons related to the PR/HACCP regulations:

- failure to collect and analyze samples for the presence of generic *E. coli* and record test results,
- failure to develop or implement Sanitation Standard Operating Procedures,
- failure to develop or implement a required HACCP plan, or
- failure to meet applicable *Salmonella* performance standard requirements.

In addition, USDA may initiate a withholding, suspension, or withdrawal action for any of these other reasons:
• insanitary conditions,
• inhumane slaughtering of livestock,
• failure to destroy condemned product, or
• interference with inspection personnel.

Tables 5, 6, and 7 list administrative actions (other than actions based on convictions) by establishment, initiated, pending, or closed, for the quarter, along with whether the action is based on an SSOP or HACCP Systems failure, or for some other reason, such as inhumane slaughter. In some plants, FSIS may find more than one basis for taking enforcement action or may take more than one action. For example, the plant has sanitation problems and is not conducting *E. coli* testing, or a sanitation problem occurs more than once. Tables 5 and 6 list these actions taken at large and small plants now operating under HACCP. Table 7 lists actions at plants still operating under traditional inspection. A plant is placed in a table dependent upon its size and whether HACCP is implemented. The enforcement action can be for any of the identified reasons. During this period, activity is reported concerning 72 plants. Thirty-four of the actions in these plants were initiated during this reporting period. Twenty-two actions were also closed by letter of warning or other means during this period.

With regard to suspensions taken at small HACCP plants, Table 6 also identifies plants where suspension action was taken, but held in abeyance for a 90 day period. Certain small plants failed to fully meet basic regulatory requirements for HACCP implementation, in January, but had demonstrated positive efforts to do so. Given these efforts to comply with the regulations, FSIS allowed plants to complete their HACCP implementation and held the suspension action in abeyance.
Tables 5, 6, and 7 also identify those cases in which an appeal of the withholding or suspension action has been made, along with whether the appeal was granted or the administrative action was sustained (appeal denied). When decisions on appeals have not been made during the period of this report, the appeal is shown as pending and will be reported in the next quarterly report. During this period, a decision was reached concerning one appeal and one appeal decision remained pending.
<p>| Establishment/ Establishment/ | Withholding | Suspension In Suspension In Basis for Action Appeals and Actions |</p>
<table>
<thead>
<tr>
<th>Estab. Number/ Location</th>
<th>Effect</th>
<th>Abeyance</th>
<th>E.Coli</th>
<th>SSOP</th>
<th>HACCP</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carolina Golden/ Gold Kist Inc.</td>
<td>2/12/98</td>
<td>2/13/98</td>
<td>X</td>
<td></td>
<td></td>
<td>On 1/5/99 suspension case closed with a letter of warning.</td>
</tr>
<tr>
<td>P-17980 Sumter, SC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1415M/P6655 Madison, FL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>364 West Fargo, ND</td>
<td>10/22/98</td>
<td>10/28/98</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foster Food Products P-6137 Livingston, CA</td>
<td>12/1/98</td>
<td>12/8/98</td>
<td>12/9/98</td>
<td>X</td>
<td></td>
<td>Remains in abeyance.</td>
</tr>
<tr>
<td>GFI American Inc. 2368/P-2368 Minneapolis, MN</td>
<td>1/5/99</td>
<td>1/7/99</td>
<td>1/11/99</td>
<td>X</td>
<td></td>
<td>On 3/26/99 suspension case was closed with a letter of warning.</td>
</tr>
<tr>
<td>GoldKist Poultry P-1277 Athens, GA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>On 1/13/99 suspension held in abeyance following a notice of intended enforcement issued to the plant. Remains in abeyance.</td>
</tr>
<tr>
<td>Gold Kist P-40 Ellijay, GA</td>
<td>1/13/99</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBP Inc. 9268 Wallula, WA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>On 2/18/99 notice of intended enforcement issued. On 2/26/99 suspension held in abeyance after corrective and preventive measures received from plant officials. Remains in abeyance.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>On 11/9/98 a notice of intended enforcement action issued. On 11/6/98 withholding held in abeyance after corrective and preventive measures were received from plant officials. Remains in abeyance.</td>
</tr>
</tbody>
</table>
Table 6. Administrative Actions: Small HACCP Plants  
(1/1/99 - 3/31/99)

<table>
<thead>
<tr>
<th>Establishment/Estab. Number/Location</th>
<th>Withholding</th>
<th>Suspension In Effect</th>
<th>Suspension In Abeyance</th>
<th>Basis for Action</th>
<th>Appeals and Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Foodservice Corp 2069/P712 King of Prussia, PA</td>
<td>1/28/99</td>
<td>1/28/99</td>
<td>X</td>
<td></td>
<td>90 day notice of abeyance for “basic” noncompliance. Remains in abeyance.</td>
</tr>
<tr>
<td>Case Farms of Ohio P-15724 Winesburg, OH</td>
<td>10/15/98</td>
<td>10/18/98</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carlton Food Products 1943 Dallas, TX</td>
<td>2/26/99</td>
<td>3/2/99</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 7. Administrative Actions: Non-HACCP Plants
(1/1/99 - 3/31/99)

<table>
<thead>
<tr>
<th>Establishment/Estab. Number/Location</th>
<th>Withholding</th>
<th>Suspension In Effect</th>
<th>Suspension In Abeyance</th>
<th>Basis for Action</th>
<th>Appeals and Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottisti's Pizzeria 4362/P-4362 Amsterdam, NY</td>
<td>12/4/97</td>
<td>12/5/97</td>
<td>12/31/97</td>
<td>X</td>
<td>On 1/10/99 plant requested a 120 day voluntary suspension.</td>
</tr>
<tr>
<td>Dos Banderas 9269/P9269 Maywood, CA</td>
<td>8/24/98</td>
<td>8/28/98</td>
<td>9/17/98</td>
<td>X</td>
<td>Remains in abeyance.</td>
</tr>
<tr>
<td>Feldman Veal Corp. 4419 Watertown, NY</td>
<td>1/20/98</td>
<td>1/20/98</td>
<td>X</td>
<td></td>
<td>On 2/8/99 suspension case closed with a letter of warning.</td>
</tr>
<tr>
<td>Grand Champion Foods Inc. 466/P-8884 Norwich, CT</td>
<td>7/21/98</td>
<td>7/29/98</td>
<td>X</td>
<td></td>
<td>Remains in abeyance. Suspension based on adulterated and misbranded meat food products found in plant.</td>
</tr>
</tbody>
</table>
Withdrawal for Unfitness

Under the statutes it administers, FSIS also can move to withdraw inspection, after opportunity for a hearing, based on the unfitness of an applicant for, or a recipient of inspection, because of a felony conviction or more than one violation involving food. Table 8 identifies actions pending or taken (other than outstanding consent decisions) on this basis for this reporting period.
<table>
<thead>
<tr>
<th>Establishment</th>
<th>Location</th>
<th>Complaint to Deny/Withdraw Inspection</th>
<th>Consent Decision</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allens Mills Meat Market</td>
<td>Reynoldsville, PA</td>
<td>2/16/99</td>
<td></td>
<td>Complaint to withdraw inspection based on owner's conviction of two misdemeanors for allowing uninspected cattle and swine to enter a federally inspected slaughtering facility and slaughtering and preparing cattle and swine not in compliance with FMIA.</td>
</tr>
<tr>
<td>Brestensky Meat Market Inc.</td>
<td>Freeport, PA</td>
<td>1/27/98</td>
<td></td>
<td>Complaint to withdraw inspection based on firm's felony conviction for selling, with intent to defraud, adulterated meat products within the State of Pennsylvania. Administrative hearing scheduled for June 30, and July 1, 1999.</td>
</tr>
<tr>
<td>Thomas Beaver and T&amp;D Meats Lockers, Inc.</td>
<td>Sioux Center, IA</td>
<td>6/1/98</td>
<td></td>
<td>Complaint to withdraw inspection based on multiple misdemeanor convictions of plant president for selling, transporting, offering for sale or transportation, or receiving for transportation an article produced from livestock which was both capable of human consumption as human food and adulterated or misbranded at the time. Administrative hearing scheduled for April 7, 1999.</td>
</tr>
</tbody>
</table>
Table 9. Custom Exempt Actions  
(1/1/99 – 3/31/99)

Administrative Actions Taken at Custom Exempt Facilities

<table>
<thead>
<tr>
<th>Name</th>
<th>Location</th>
<th>Complaint</th>
<th>Consent</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martin’s Mountain</td>
<td>Harrison, AK</td>
<td>1/14/99</td>
<td>2/11/99</td>
<td>Stipulation and Consent agreement in lieu of removing custom exempt</td>
</tr>
<tr>
<td>Processors</td>
<td></td>
<td></td>
<td></td>
<td>privileges because of insanitary conditions.</td>
</tr>
</tbody>
</table>

CRIMINAL ACTIONS

If evidence is found that a person or business has engaged in violations of the Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act, USDA may refer the case to the appropriate United States Attorney to pursue criminal prosecution. Conviction for a criminal offense can result in a fine, imprisonment, or both. Table 10 lists criminal actions and criminal cases in categories according to the status of the case, which may be indictment or information issued; pleas, convictions, or acquittals, and sentences rendered during this reporting period.
### Table 10. Criminal Actions  
(1/1/99 – 3/31/99)

<table>
<thead>
<tr>
<th>Name</th>
<th>Location</th>
<th>Indictment</th>
<th>Information</th>
<th>Plea</th>
<th>Sentencing</th>
<th>Action Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charles W. Cripps, Owner C &amp; B Foods, Inc.</td>
<td>Ft. Smith, AR</td>
<td>02/18/99</td>
<td>2 misdemeanor counts for causing poultry products to become adulterated and preparing poultry products not in compliance with the requirements of the Poultry Products Inspection Act.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Custom Cold Storage and Services Inc., and Jacob Fleishman and Sons, Inc.</td>
<td>Miami, FL</td>
<td>10/19/98 01/07/99</td>
<td>2 felony counts for causing, offering for transportation and distribution meat and poultry products adulterated by rodent gnawing and feces. Fined $40,000, $200 special assessment fee, placed on probation for 3 years, and required to adhere to a specific compliance program aimed at eradicating health, sanitation, maintenance problems.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donald M. Johnson, Plant Superintendent C &amp; B Foods, Inc.</td>
<td>Ft. Smith, AR</td>
<td>02/18/99</td>
<td>2 misdemeanor counts for causing poultry products to become adulterated and preparing poultry products not in compliance with the requirements of the Poultry Products Inspection Act.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HP Food Supply Chi La, Co-owner, and Huong Ho, Manager</td>
<td>San Jose, CA</td>
<td>01/29/99</td>
<td>5 felony counts for processing poultry products without federal inspection, sale and transportation of adulterated and misbranded poultry products, caused poultry products to become adulterated, and caused meat products to become adulterated and misbranded.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marco A. Trejo, Owner A&amp;T Baja Export, Inc.</td>
<td>Calexico, CA</td>
<td>01/26/99</td>
<td>2 felony counts for use of simulated certificates with intent to defraud the United States. Fined $10,000, $300 special assessment fee, and placed on probation for 3 years.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palmetto Institutional Foods, Inc.</td>
<td>Columbia, SC</td>
<td>02/05/99</td>
<td>1 misdemeanor count for causing poultry products to become adulterated by rodent gnawing and feces. Fined $5,000, $125 special assessment fee, and placed on probation for 3 years.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred Freezer Services, Miami, Inc.</td>
<td>Miami, FL</td>
<td>10/26/98 01/13/99</td>
<td>2 misdemeanor counts for causing meat and poultry products to become adulterated by rodents and 1 felony count for distribution of said products. Fined $50,000, $450 special assessment fee, and placed on probation for 4 years.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotunda Packing Company, former President Ronald T. Kuhn</td>
<td>Dearborn, MI</td>
<td>12/16/98</td>
<td>6 felony counts for selling and transporting spoiled, sour meat and poultry products to retail stores, restaurants, and a correctional facility.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CIVIL ACTIONS

FSIS also has authority to seek a variety of civil actions in Federal Court.

Seizures

When FSIS has reason to believe distributed products are adulterated or misbranded, the Agency will, through the U.S. Attorney, institute a seizure action against the product. The product is held pending an adjudication of its status. If the court finds that the product is adulterated or misbranded, it will condemn the product. Condemned product is destroyed, sold, or, upon posting of an appropriate bond, returned to its owner to be brought into compliance with the law. Condemned product cannot be further processed to be used for human food. There were no new actions during this reporting period.

Injunctions

FSIS, through the U.S. Attorney, may request a U.S. District Court to enjoin repetitive violators of the FMIA, PPIA, or EPIA. The Agency seeks injunctions to stop uninspected retail stores from processing products without required inspection for wholesale business or to prevent or restrain other violations of law. There were no injunctions entered during the reporting period. Currently 29 firms are under injunctions.
False Claims Act Violations

The Department of Justice Affirmative Civil Enforcement (ACE) program is used by U.S. Attorneys to recover damages when a violation of law involves fraud against the Federal government. Under the False Claims Act, the government may recover three times its estimated losses. FSIS typically seeks action under this program for cases involving products, not in compliance, sold to the military, to public schools engaged in the school lunch program, or to other Federal institutions. ACE program actions are generally in lieu of criminal prosecution.

There are no new actions to report this reporting period.

FOR MORE INFORMATION:

Media Inquiries: (202) 720-9113
Freedom of Information Act Requests: (202) 720-2109
Congressional Inquiries: (202) 720-3897
Constituent Inquiries: (202) 720-8594

Consumer Inquiries: Call USDA’s Meat and Poultry Hotline at 1-800-535-4555, 10 a.m. to 4 p.m., Eastern Time. In the Washington, DC area, call (202) 720-3333.

FSIS Web site: www.usda.gov.fsis
CLEAN WATER ACT COMPLIANCE AUDIT PROGRAM FOR PORK PRODUCERS

Fact Sheet

Background

The U.S. Environmental Protection Agency (EPA) and the National Pork Producers Council (NPPC) have agreed to a comprehensive Clean Water Act Compliance Audit Program (CAP). The NPPC, which represents pork producers nationally, plans to have independent auditors conduct more than 10,000 of the audits nationwide to improve environmental management practices and assure compliance with the Clean Water Act. The Clean Water Act CAP provides incentives for pork producers to undertake voluntary comprehensive on-farm environment assessments by greatly reducing penalties for any Clean Water Act violations that are promptly disclosed and corrected under this program.

This program was developed after the NPPC approached EPA to propose an environmental assessment program for the industry. The NPPC developed a comprehensive and rigorous evaluation process for reviewing pork production facilities that is designed to assure the protection of our nation's waterways by improving environmental protection controls at pork farms throughout the United States.

This compliance audit program is the result of an agreement between EPA and the NPPC that provides reasonable incentives for pork producers without compromising EPA's and the States' ability to enforce the law consistently and appropriately. The program demonstrates how
government and industry can come together to find practical and resourceful solutions for reducing waste runoff into our nation’s rivers, lakes and streams.

**Voluntary Compliance Audit Program**

- The CAP program is open to all pork producers in the country, but excludes slaughterhouses, pork processing and packing facilities, or areas of ancillary operations such as equipment or feed storage or cropland—other than cropland used for land application of swine waste. Participation in either the NPPC audits or the CAP program itself is voluntary.

- Producers with existing pork production facilities must register for the voluntary CAP Agreement by Sept. 30, 2001. For facilities that are completed after Sept. 30, 2001, producers must register by Sept. 30, 2003. Pork producers who want to register for the program can contact their local pork producers’ organization or the National Pork Producers Council, at (515) 223-2600.

- These audits will be conducted by trained and certified independent inspectors at no cost to producers, and according to a comprehensive and public protocol. The program was developed by NPPC at a cost of $1.5 million with millions more to be spent on training assessors and overseeing the program. EPA has provided a $5 million grant to America’s Clean Water Foundation to assist with the voluntary assessments.

- Participating pork producers must identify and report Clean Water Act violations within 120 days of the start of an assessment, and complete corrective action within specified timetables. For example, the CAP Agreement provides for 60-90 days for correcting operating and maintenance violations, and one year where additional waste storage or disposal capacity is needed.

- For a pork producer to be eligible for the CAP Agreement, the auditor must report that the audit was conducted properly according to the protocol. Producers must certify that the report to EPA is complete and accurate, and an auditor or licensed engineer must certify that the correction is complete.

- Producers that report and correct violations within the timetable and otherwise comply with the CAP Agreement are eligible for reduced penalties. Penalties are based on economic benefit, range from $1,000 to $10,000 for violations resulting in a discharged, and are capped at no more than $40,000 per facility. These penalties can be reduced further for early correction, and EPA retains flexibility under existing policies to waive them where circumstances require it.

- EPA will consult with any State to assure participating pork
producers have complied with the terms of the CAP Agreement. A State may elect to administer the CAP Agreement; in those cases, EPA would refer any CWA violation disclosures to the State for consideration and response under the terms of the CAP Agreement.

NPPC Seal

● The NPPC will award special seals to pork producers who have the voluntary environmental assessment performed, and promptly report and correct any CWA violations discovered. The seal may be withdrawn if a pork producer is found to be in violation of the CWA.

Limitations

● This CAP is limited to Clean Water Act violations, although States may wish to adapt it for other requirements.

● The CAP Agreement would not apply to violations already discovered by EPA or a State, or which are the subject of a citizen suit action.

● Reduced penalties are available only for those violations that are reported and corrected under the CAP Agreement. The program reserves EPA's ability to pursue injunctive relief when there is a discharge and where there is an "imminent and substantial" endangerment under section 504 of the Clean Water Act, and reserves EPA's ability to recommend prosecution for criminal conduct. EPA may impose penalties and seek all other available remedies where a pork producer fails to comply with the CAP Agreement. The program does not relieve the producer from its obligations to comply with all CWA permits, regulations and other applicable environmental laws and regulations.

Environmental Benefits

● This environmental auditing and enforcement program will help protect the public health and the nation's rivers from waste runoff. Corrective measures will be taken to address discharges and other National Pollution Discharge Elimination System (NPDES) permit violations.

● More than 10,000 pork production facilities, including most of the large pork farms in the U.S., are planned to have on-farm assessments. Audited farms are likely to account for about 80 percent of U.S. pork production.

● The CAP program potentially exceeds what EPA has the resources to do otherwise, and will disclose violations that EPA may not have discovered otherwise.

● The program brings facilities within the regulatory system and
potentially provides important information on facilities. The program will educate pork producers about corrective measures to address violations and prevent future violations.

***


Last Updated: November 25, 1998
The following services are financed by fees and miscellaneous contributions advanced by importers, manufacturers, States, local organizations, individuals, and others:

Miscellaneous contributed funds.—Funds are received from States, local organizations, individuals, and others and are available for plant and animal quarantine inspection and cooperative plant and animal disease and pest control activities (7 U.S.C. 450b, 2220). Commencing in 1979, fees were collected for the importation of commercial birds.

### Program and Financing (in millions of dollars)

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<thead>
<tr>
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<tr>
<td>11.5 Other personnel compensation</td>
<td>1111</td>
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<tr>
<td>Provided fees collected for the cost of laboratory accreditation as authorized and in addition, $1,000,000 may be credited to this account from the Egg Products Inspection Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Animal and Plant Health Inspection Service, and the Egg Products Inspection Act, (7 U.S.C. 450b, 2220). (in millions of dollars)</td>
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<tr>
<td>Total:</td>
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### Object Classification (in millions of dollars)

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<tr>
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<tbody>
<tr>
<td>11.1 Full-time permanent compensation:</td>
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<tr>
<td>11.3 Other than full-time permanent compensation:</td>
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<td>11.5 Other personnel compensation:</td>
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<td>11.9 Total personnel compensation:</td>
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<td>12.1 Civilian personnel benefits:</td>
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<td>21.0 Travel and transportation of persons:</td>
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<td>25.2 Other services:</td>
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<td>44.0 Refunds:</td>
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<td>99.9 Total new obligations:</td>
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### Summary of Budget Authority and Outlays (in millions of dollars)

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<tr>
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<tr>
<td>Obligations by program activity:</td>
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<td>00.01 Direct program:</td>
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<tr>
<td>09.01 Reimbursable program:</td>
<td>85 85 85</td>
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<td>10.00 Total new obligations:</td>
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<td>Budgetary resources available for obligation:</td>
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<tr>
<td>21.00 Unobligated balance available, start of year:</td>
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<tr>
<td>22.00 New budget authority (gross):</td>
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<td>23.90 Total budgetary resources available for obligation:</td>
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<td>40.00 Appropriation:</td>
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<td>40.36 Unobligated balance rescinded:</td>
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<td>43.00 Appropriation (total):</td>
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<td>68.00 Spending authority from offsetting collections: Offsetting collections (cash):</td>
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<td>70.00 Total new budget authority (gross):</td>
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<td>73.10 Total new obligations:</td>
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<td>73.20 Total obligations (gross):</td>
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<td>73.40 Adjustments in expired accounts:</td>
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<td>74.40 Unpaid obligations, end of year: Obligated balance, end of year:</td>
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<td>Outlays (gross), detail:</td>
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<td>86.90 Outlay from new current authority:</td>
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<td>86.93 Outlays from current balances:</td>
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<td>86.97 Outlays from new permanent authority:</td>
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<tr>
<td>87.00 Total outlays (gross):</td>
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<td>Offsets:</td>
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<td>88.40 Offsetting collections (cash) from: Non-Federal sources:</td>
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<td>Net budget authority and outlays:</td>
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<td>89.00 Budget authority:</td>
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<td>90.00 Outlays:</td>
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<td>Summary of Budget Authority and Outlays:</td>
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<td>Enacted/requested:</td>
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<td>Outlays</td>
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<td>Legislative proposal, not subject to PAYGO:</td>
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<td>Outlays</td>
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</tr>
<tr>
<td>Total:</td>
<td>589 617 653</td>
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</table>
The primary objectives of the Food Safety and Inspection Service are to ensure that meat, poultry, and egg products are wholesome, unadulterated, and properly labeled and packaged, as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. Providing adequate resources for Federal food safety agencies continues to be a priority of the Administration, and the 2000 budget proposes a $36 million increase for inspection of meat, poultry, and egg products. This increase will cover pay cost increases for Federal and State inspection programs, and initiatives for: redeployment of inspection workforce; validation of State HACCP requirements; improved emergency response coordination with States; and civil rights training and program improvements.

The meat, poultry, and egg products inspection program of the Food Safety and Inspection Service provides in-plant inspection of all domestic plants preparing meat, poultry, or egg products for sale or distribution; reviews foreign inspection systems and establishments that prepare meat, poultry, or egg products for export to the United States; and provides technical and financial assistance to States which maintain meat and poultry inspection programs.

In 2000, the Administration is proposing a new user fee to offset Federal cost of meat, poultry, and egg products inspection. The proposal would require industry to reimburse the government for all Federal services. This proposal would ensure that sufficient resources are available to provide the level of in-plant inspection necessary to meet the demands of the industry.

On January 25, 1997, the President announced the 1998 President’s National Food Safety Initiative. The initiatives for 1998 and 1999 have laid the foundation for building a strong, scientific base for a farm-to-table food safety system that protects public health by monitoring and addressing a broad range of food safety hazards. The 2000 Food Safety Initiative builds on this foundation and will increase department-wide by $32 million over the 1999 level of $119 million. Resources are targeted to: (1) further develop a nationally integrated food safety system by expanding and strengthening the partnership between Federal, State, and local agencies; (2) continue enhancing surveillance of foodborne diseases and increasing the speed and efficiency of responses to outbreaks of foodborne illness; and (3) put greater emphasis on the control of foodborne hazards in the pre-harvest phase of the farm-to-table continuum. Continued investment is required to realize the President’s goal of establishing a seamless, science-based food safety system.

In 1998 the President’s Council on Food Safety was established to develop a comprehensive strategy for food safety activities, including coordinating research efforts and budget submissions among the food safety agencies.

### FEDERALLY FUNDED INSPECTION ACTIVITIES

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<tr>
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<tbody>
<tr>
<td>Slaughter plants</td>
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<td>245</td>
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<tr>
<td>Processing plants</td>
<td>4,297</td>
<td>4,270</td>
<td>4,255</td>
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<tr>
<td>Combination slaughter and processing plants</td>
<td>985</td>
<td>970</td>
<td>960</td>
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<tr>
<td>Talmadge-Aiken plants</td>
<td>256</td>
<td>250</td>
<td>245</td>
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<tr>
<td>Import establishments</td>
<td>135</td>
<td>130</td>
<td>120</td>
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<tr>
<td>Egg plants</td>
<td>78</td>
<td>78</td>
<td>76</td>
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### Compliance activities:

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<td>Corrective action reviews</td>
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<td>Food testing (samples analyzed)</td>
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<td>Food chemistry</td>
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<td>Antibiogram</td>
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<td>Egg Products</td>
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<td>Food chemistry</td>
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<td>Food microbiology</td>
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<tr>
<td>Chemical residues</td>
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<tr>
<td>Consumer Education and public outreach</td>
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<td>Meat and Poultry Hotline Calls received</td>
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<td>115,000</td>
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<td>Epidemiological Investigations</td>
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<td>Cooperative efforts with State and public health offices</td>
<td>24</td>
<td>30</td>
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<td>Illnesses reported and treated</td>
<td>8,051</td>
<td>8,100</td>
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<tr>
<td>Field Automation and Information Management Project (cumulative)</td>
<td>3,779</td>
<td>3,539</td>
<td>4,249</td>
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<tr>
<td>Number of computers to be provided to federal field inspection staff</td>
<td>916</td>
<td>1,832</td>
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### Object Classification (in millions of dollars)

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<tr>
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<tbody>
<tr>
<td>Direct obligations</td>
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<tr>
<td>Personal compensation</td>
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<tr>
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<td>Other personal compensation</td>
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<td>Communications, utilities, and miscellaneous charges</td>
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<td>Advisory and assistance services</td>
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<td>Purchases of goods and services from Government accounts</td>
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<td>Subtotal, direct obligations</td>
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<td>Below reporting threshold</td>
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<td>Total new obligations</td>
<td>674</td>
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### Personnel Summary

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<tbody>
<tr>
<td>Direct</td>
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<tr>
<td>Honorably discharged veterans</td>
<td>9,403</td>
<td>9,407</td>
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<td>Reimbursable</td>
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<tr>
<td>Total compensable workyears</td>
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<tr>
<td>Full-time equivalent employment</td>
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<tr>
<td>Part-time equivalent employment</td>
<td>2,500</td>
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### Field Automation and Information Management Project (cumulative)
General and special funds—Continued

Salaries and Expenses

(Legislative proposal, not subject to PAYGO)

Program and Financing (in millions of dollars)

Identification code 12-3700-2-1-554

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Obligations by program activity:</td>
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<tr>
<td>00.01 Direct program</td>
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<tr>
<td>09.01 Reimbursable program</td>
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</tr>
<tr>
<td>10.00 Total new obligations</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>New budget authority (gross), detail:</td>
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<td></td>
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<tr>
<td>Current:</td>
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<tr>
<td>40.00 Appropriation</td>
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<tr>
<td>Permanent:</td>
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<td>68.00 Spending authority from offsetting collections: Offsetting collections (cash)</td>
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<td>Outlays (gross), detail:</td>
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</tr>
<tr>
<td>86.90 Outlays from new current authority</td>
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<td></td>
<td>504</td>
</tr>
<tr>
<td>86.97 Outlays from new permanent authority</td>
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<td></td>
<td>504</td>
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<tr>
<td>87.00 Total outlays (gross)</td>
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<td></td>
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<tr>
<td>Offsets:</td>
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<td></td>
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<tr>
<td>88.40 Offsetting collections (cash) from: Non-Federal sources</td>
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<td>504</td>
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<td>Net budget authority and outlays:</td>
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<tr>
<td>89.00 Budget authority</td>
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<td></td>
<td>504</td>
</tr>
<tr>
<td>90.00 Outlays</td>
<td></td>
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<td>504</td>
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</tbody>
</table>

Legislation will be proposed to charge fees for the cost of all Federal inspection of meat, poultry, and egg products at all establishments inspected by the Food Safety and Inspection Service (FSIS). Currently, fees to reimburse the cost of overtime inspection are required at some FSIS-inspected establishments, but not at others. Requiring the payment of user fees for inspection services would not only result in savings to the taxpayer, but would also ensure that sufficient resources are available to provide the mandatory inspection services needed to meet increasing industry demand. These fees would result in a cost of less than one cent per pound of product to consumers, but would allow the government to maintain its level of inspection effort to ensure a safe supply of meat, poultry, and egg products. The implementation of the user fee authority would be designed to be fair and equitable; promote accountability and efficiency; and minimize any impact on the competitive balance among affected industries.

This is one of several proposals in the budget to charge fees to users directly availing themselves of, or subject to, a government service, program, or activity, in order to cover the government’s costs.

Object Classification (in millions of dollars)

Identification code 12-3700-2-1-554

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Direct obligations:</td>
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</tr>
<tr>
<td>Personnel compensation:</td>
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</tr>
<tr>
<td>11.1 Full-time permanent</td>
<td></td>
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<td>304</td>
</tr>
<tr>
<td>11.3 Other than full-time permanent</td>
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</tr>
<tr>
<td>11.5 Other personnel compensation</td>
<td></td>
<td></td>
<td>–16</td>
</tr>
<tr>
<td>11.9 Total personal compensation</td>
<td></td>
<td></td>
<td>–334</td>
</tr>
<tr>
<td>12.1 Civilian personnel benefits</td>
<td></td>
<td></td>
<td>–94</td>
</tr>
<tr>
<td>13.0 Benefits for former personnel</td>
<td></td>
<td></td>
<td>–1</td>
</tr>
<tr>
<td>21.0 Travel and transportation of persons</td>
<td></td>
<td></td>
<td>–22</td>
</tr>
<tr>
<td>22.0 Transportation of things</td>
<td></td>
<td></td>
<td>–5</td>
</tr>
<tr>
<td>23.2 Rental payments to others</td>
<td></td>
<td></td>
<td>–1</td>
</tr>
<tr>
<td>23.3 Communications, utilities, and miscellaneous charges</td>
<td></td>
<td></td>
<td>–5</td>
</tr>
<tr>
<td>24.0 Printing and reproduction</td>
<td></td>
<td></td>
<td>–1</td>
</tr>
</tbody>
</table>

Under authority of the Agricultural Marketing Act of 1946, Federal meat and poultry inspection services are provided upon request and for a fee in cases where inspection is not mandated by statute. This service includes: certifying products for export beyond the requirements of export certificates; inspecting certain animals and poultry intended for human food where inspection is not required by statute, such as buffalo, rabbit, and quail; and inspecting products intended for animal consumption.
NOTIFICATION TO ESTABLISHMENTS OF INTENDED ENFORCEMENT ACTIONS

This notice explains FSIS’s process for notifying establishments of intended enforcement actions related to HACCP system inadequacy determinations.

If the Inspector-in-Charge (IIC) determines that there may be a HACCP system inadequacy because an establishment has multiple, recurring noncompliances as specified in 9 CFR 417.6 and has failed to adequately implement immediate and further planned actions as documented on the Noncompliance Record (NR) (FSIS Form 5400-4), the IIC should discuss this developing trend at the weekly meetings held with establishment management. If the IIC subsequently determines that the trend of multiple, recurring noncompliances without successful interventions has led to a HACCP system inadequacy and that the marks of inspection should be withheld, he or she shall contact the District Office (DO) and provide all the relevant information for the DO to prepare a “Notice of Intent to Suspend Inspection.” The Notice shall:

1. inform the establishment that the nature and scope of the noncompliances indicate that the HACCP system is inadequate as specified in 417.6 of the regulations;

2. state that, because of the trend, FSIS intends to withhold the marks of inspection and suspend inspection;

3. explain the reason for the determination;

4. reference each pertinent NR by number;

5. inform the establishment that it is being afforded the opportunity to demonstrate why a HACCP system inadequacy determination should not be made or that it has achieved regulatory compliance; and

6. provide the establishment 3 business days from the date of the letter to provide its response to the DO.

Based on the establishment’s response, FSIS will determine further actions.

If at any time inspection personnel determine that adulterated product was shipped, they should proceed in accordance with FSIS Directive 5000.1 part II. paragraph III. C.

/sig/
Margaret O’K. Glavin

Deputy Administrator
Office of Policy, Program Development and Evaluation
INSPECTION DECISION APPEALS

This notice explains FSIS policy regarding the appeal of inspection findings and decisions. It also establishes the Inspection Appeals Tracking System (IATS) report. This notice supersedes any other correspondence related to the appeals of inspection findings and decisions.

FSIS regulations provide establishments with the opportunity to appeal, orally or in writing, an inspection finding or decision made by any program employee. Such appeals should be directed to the immediate supervisor. The following outlines the chain-of-command for inspection decisions:

1. Program employee, including the Inspector-in-Charge (IIC), who made the determination
2. Circuit Supervisor
3. District Manager
4. Assistant Deputy Administrator for District Inspection Operations
5. Deputy Administrator for Office of Field Operations

Prior to appealing, the establishment may request that the program employee or IIC reconsider his or her finding or decision. The program employee or IIC who made the finding or decision should evaluate and consider any factual information the establishment provides. Program employees should encourage establishment management officials who indicate that they may appeal a decision or finding to do so as soon as possible. Timely appeals will help ensure that the relevant information is provided to subsequent decision makers promptly and that facts and observations can be verified. Timely appeals also avoid the implication that the establishment does not contest the inspection finding or decision.

When an appeal reaches any FSIS program employee, there are several points to keep in mind in order to address it in the most appropriate manner:

1) Act on each appeal promptly and professionally,

2) Obtain all relevant factual information,
3) Objectively evaluate the inspection findings and decisions made by inspection personnel and the information provided by the establishment,

4) Thoroughly analyze all supporting documentation, including Program Deficiency Reports (PDR), Noncompliance Records (NR), and the establishment’s written or oral statements in support of its appeal,

5) Contact the Technical Service Center for scientific or technical advice (if necessary),

6) Make a decision regarding the appeal, document your determination, and provide necessary information for the IATS report (described below). If modifying or reversing a previous appeal decision, document the change and attach it to the subject PDR or NR,

and

7) Communicate the decision orally or in writing to establishment management officials and other FSIS program employees involved with that appeal.

The IATS report is being established to track appeals and ensure that they are processed in a timely and effective manner. The IATS report includes the name and address of the establishment and establishment management official making the appeal, the level and status of the appeal in FSIS, the date the appeal was made, and the related PDR or NR number and description of the finding or decision. Attachment 1 describes what each block of the IATS report should contain and Attachment 2 is a sample IATS report. The District Offices will submit the report to headquarters on a weekly basis. Until it is automated, the IATS report should be faxed to (202) 720-6050, Office of the Deputy Administrator for District Inspection Operations.

An FSIS program employee making decisions concerning appeals should recognize that his or her decision may also be appealed. Some appeals will be sustained and some will be modified or reversed, by supervisory personnel. A modification or reversal by a supervisor should not be seen as a lack of support by the supervisor.

/sig/
Margaret O’K. Glavin
Deputy Administrator
Office Policy, Program Development and Evaluation
## INSTRUCTIONS FOR COMPLETING THE INSPECTION APPEALS TRACKING SYSTEM (IATS) REPORT

<table>
<thead>
<tr>
<th>Block</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishment Name and Number</td>
<td>Establishment name, address, and establishment number.</td>
</tr>
<tr>
<td>Person Making Appeal</td>
<td>The name and title of the establishment official making the appeal.</td>
</tr>
<tr>
<td>Level and Status</td>
<td>The level of the appeal (i.e., IIC, CS or DM.)  The status of the appeal.</td>
</tr>
<tr>
<td>Date Appeal Made</td>
<td>The date the appeal was made to each level.</td>
</tr>
<tr>
<td>PDR/NR Number and Description</td>
<td>First, the PDR and NR number. Second, a statement describing exactly what decision or action the establishment is appealing.</td>
</tr>
<tr>
<td>Closure</td>
<td>The closure date, explanation of the resolution, and the disposition of the appeal as either “denied” or “granted.”</td>
</tr>
</tbody>
</table>

See Attachment 2 for an example.
## THE INSPECTION APPEALS TRACKING SYSTEM (IATS) REPORT

<table>
<thead>
<tr>
<th>Establishment</th>
<th>Person Making Appeal</th>
<th>Level and Status</th>
<th>Date Appeal Made</th>
<th>PDR/NR Number and Description</th>
<th>Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Packing Co. 123 Main Street Any town, USA xxxx Est No. xxxxxx</td>
<td>Bob Jones, VP</td>
<td>Circuit Level -- Securing a copy of the PDR in question.</td>
<td>3/25/98 -- IIC level. 3/30/98 -- Circuit level.</td>
<td>PDR # 47568 -- Plant does not believe the deficiency classification made by the inspector should have been marked as “critical.”</td>
<td>Closed at the circuit level on 4/2/98 after providing explanation to Mr. Jones. Appeal denied.</td>
</tr>
<tr>
<td>ABC Packing Co. 123 Main Street Any town, USA xxxx Est No. xxxxxx</td>
<td>Bob Jones, VP</td>
<td>District Level --- In the progress of evaluating the appeal.</td>
<td>3/26/98 -- IIC level. 3/30/98 -- Circuit level. 4/3/98 -- District level.</td>
<td>NR #98876 -- Plant disagrees with the description of the noncompliance and believes that the inspector failed to consider all relevant information.</td>
<td>Closed at the district level on 4/6/98 after reviewing the specifics of the appeal and evaluating the facts. Spoke to Mr. Jones and advised him as to why the description was correct. Appeal denied.</td>
</tr>
</tbody>
</table>

Note: List establishments in alphabetical order. This table was preparing using the WordPerfect table feature. Preparers may use another format, but each of the above elements must be included and presented as described in Attachment 1.
FSIS Customer Service Standards

You Can Expect FSIS to:

- Be innovative, forward-thinking, and continue to look for ways to improve how we inspect meat, poultry, and egg products and protect the public health.
- Provide you with up-to-date information on food safety issues through the USDA Meat and Poultry Hotline.
- Solicit and consider your ideas to assist us in making policy and program improvements.
- Provide uniform inspection in meat and poultry plants across the United States and hold them all to the same high standards.
- Ensure that the meat and poultry products you buy have safe-handling instructions on them.
- Investigate and prosecute people and businesses that violate meat and poultry laws.
- Continue to improve our current inspection system using new science and technological advances.

Customer Service Results

Innovation

On July 25, 1996, FSIS completed the regulation which will change the way meat and poultry is inspected from a sensory system started in 1906 to a science-based system. The new rule was in response to foodborne illness outbreaks and requires meat, poultry and egg product plants to implement Hazard Analysis and Critical Control Points (HACCP) systems as a means of controlling their processes to prevent microbial contamination. This regulation represents a significant step in modernizing federal meat and poultry inspection. The Agency developed extensive and innovative methods for ensuring public involvement in the rulemaking process and reopened the comment period on two occasions to allow for additional interactive meetings with constituents on significant issues.

The first milestone in implementing the new regulation came on January 27, 1997, when all inspected establishments were required to develop and to start using Sanitation Standard Operating Procedures (SOPs). The Sanitation SOPs describe all procedures an establishment conducts daily to prevent direct product contamination or adulteration of product(s). To promote uniform inspection and implementation, FSIS developed a reference guide for inspectors and industry, trained federal inspectors, provided a special telephone "hotline" staffed by individuals who could answer technical questions, and held public meetings before and after to provide information and listen to concerns. Overall, the inspection workforce, consumer advocates, and industry representatives all stated that implementation of the Sanitation SOPs had gone remarkably well.

FSIS conducted a top-to-bottom review of FSIS resource allocations and organization. The Agency issued a report for public comment and conducted public meetings and employee call-ins to ensure
full participation in the process. This review, which was the basis for a comprehensive reorganization of the Agency, is also being used to enhance the overall performance of the Agency in fulfilling its public health and consumer protection mission, and to create a more focused and customer-driven organization.

FSIS began the process of restructuring both headquarters and field offices. The new structure has eliminated one layer of management at the Agency’s headquarters level, reduced the number of supervisory positions, centralized management of all policy, rulemaking and development activities, and improved the Agency’s ability to make effective and efficient program changes.

The Agency expanded its partnerships with the Food and Drug Administration and the Centers for Disease Control and Prevention of the Department of Health and Human Services and State and local health departments to determine the frequency of foodborne illnesses caused by consuming meat and poultry products and prevent future illnesses.

The Agency also reviewed performance standards, personnel regulations, policies, and procedures to ensure standards adequately measure Agency functions.

**Food Safety Information**

In 1994, FSIS conducted a survey to test consumer satisfaction with the Meat and Poultry Hotline which provides consumers with information on the safe handling, storage, and preparation of meat and poultry products. Eighty-two percent of the respondents said that they were very satisfied with the information provided, ease of use, and service delivery. Ninety-nine percent stated that they would call the Hotline again and gave Hotline representatives high marks for their courteous and helpful manner. Consumers also suggested additional food safety topics on which advice should be offered.

**Public Outreach**

In 1995 and 1996, the Agency held more than two dozen public meetings, informational briefings, conferences, and hearings on the Pathogen Reduction/HACCP regulation with its constituent groups. These meetings with consumers, industry, academicians, state and local officials, union members, and public health officials were held to gain input from Agency customers on the new rule, program improvements, and other elements of the Agency’s strategy for change. The Agency intends to continue to review how well its customers are being served by its programs through frequent contact with its constituent groups.

FSIS also developed an Agency-wide document tracking system to capture customer concerns and distribute the information to top decision makers.

The Agency, in conjunction with the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and other Agencies within the Department of Agriculture is undertaking a new initiative to educate consumers on proper food handling. In June, the Agency is co-sponsoring the first national conference devoted to adopting new strategies in this area. In addition, there will be a video teleconference with State, county and regional health regulatory officials to discuss activity and strategy coordination to better serve the public.

**Consistency of Inspection**

FSIS launched substantial regulatory reform by conducting a page-by-page review of all FSIS regulations and targeted close to 33% for elimination. The remaining regulations will be revised to simplify use, clarify industry responsibilities, and encourage innovation. The Agency published
seven documents outlining specific regulatory reform actions in 1995 and 1996.

In March 1997, FSIS sent a letter to all meat and poultry industry establishment owners and operators announcing a Plant Communication Initiative to improve two-way communication between FSIS and Plants. As part of this initiative, a series of meetings will be held around the country to discuss the kind of information establishments need from FSIS so that they can successfully implement HACCP, the best ways FSIS can meet their informational needs including working with new technologies, and the options for FSIS to get a consistent inspection message to all plants.

Labeling Activity

As a service to consumers, the Agency reviewed industry’s labeling of food products for both nutritional content and safe handling instructions.

Enforcement

FSIS continued to work on uniformity in enforcement. All firms and individuals that process, store, or distribute meat and poultry products are subject to random reviews.

FSIS is amending its regulations to clarify and strengthen enforcement of its zero-tolerance policy regarding visible fecal material on poultry carcasses. The final rule formalizes what has been a longstanding policy of the Agency. The zero tolerance policy for visible fecal contamination is an important food safety standard because fecal contamination is a major vehicle for spreading disease-causing microorganisms, such as Salmonella, to raw poultry.

New Technologies

FSIS is exploring new technologies and methods for microbial testing to improve how it inspects meat, poultry and egg products and protects the public health. In addition, FSIS sought and received additional funding from Congress to extend data automation to inplant inspectors. When fully implemented this will improve communications with laboratories and other internal sources, provide training, transfer documents, connect various application systems, improve the productivity of the inspection workforce.

FSIS is working with the CDC and the FDA to monitor five foodborne illness "sentinel sites." These sites were established to estimate the national incidence of the major foodborne diseases and to explore what relationships may exist between specific pathogens and the types of meat, poultry, and other food products associated with them. On January 25, 1997, the President announced the Administrations’s Food Safety Initiative, which includes an expansion of the sentinel site project into the Nation’s Early Warning System. The current sentinel sites are an integral part of the Early Warning System, and the President has requested funding for FSIS, FDA and CDC to increase the number of sites from five to eight, better equip and link the sites, and make available state of the art laboratory and electronic technology. With sentinel site information, FSIS can review HACCP programs and, where appropriate, trigger changes to prevent future outbreaks of foodborne illness.

For Further Information Contact:
FSIS Planning Staff
Phone: (202) 501-7138
Fax: (202) 501-7642

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

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

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

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

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

As of January 2000, 100% of cattle, swine, and chicken are subject to testing for Salmonella incidence at the slaughter plant. Data from a year of testing in small plants show a decline in the prevalence of Salmonella from the pre-HACCP baseline studies. Of broiler carcasses, 20% tested positive for Salmonella before HACCP implementation, compared to 16.3% since implementation; a decline of 18.5% to date. In ground beef, 7.5% of the national baseline samples tested positive for Salmonella prior to HACCP implementation versus 4.3% since HACCP implementation; a 42.6% decline. Of cow and bull carcasses, 2.7% tested positive before HACCP implementation while 2.3% tested positive after HACCP implementation; a 15% decline.

FSIS has prepared a white paper on E. coli:O157:H7 that was a major topic at the May 2000 meeting of the National Advisory Committee on Meat and Poultry Inspection. In the next few months, FSIS will publish notices in the Federal Register calling for all establishments that process beef to reassess their HACCP plans for control of E. coli O157:H7. The Agency will also announce that copies of the risk assessment for O157:H7 will be available.

President Clinton, in his May 6th radio address, said that the Administration's goal is to cut the number of illnesses caused by Listeria in half by the year 2005. FSIS held a public meeting in May 2000 to discuss the issue. The Agency has also advised manufacturers of ready-to-eat meat and poultry products to reassess their HACCP plans to ensure that they adequately address this pathogen. In November 1999, FSIS released a refined laboratory methodology that reduces the analytical time required for detecting and identifying potentially contaminated products by at least two days. FSIS has made significant progress in implementing action items in a plan issued last year.

In 1998, FSIS and the Food and Drug Administration (FDA) jointly developed a risk assessment model for shell eggs and egg products to address the risks of foodborne illness caused by Salmonella enteritidis.

In December 1999, the President's Council on Food Safety released the Egg Safety Action Plan. It was based on the results of the joint risk assessment mentioned above. Under the Plan, FSIS will develop HACCP-based standards for shell egg packers and egg products processors, as well as be responsible for providing inspection and enforcement for both. FSIS is also developing a rule in conjunction with the Egg Safety Action Plan. This rule, expected to be published in late 2000, will
establish HACCP-based systems for shell eggs as well as for processed egg products. The rule will include components such as basic facility sanitation, biosecurity, and Sanitation Standard Operating Procedures (SSOPs).

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

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

Status:

- FSIS continues to actively participate in the Partnership for Food Safety Education, the President's Council for Food Safety, the National Partnership for Reinventing Government, and other intra- and inter-agency food safety task forces. FSIS and FDA worked together to establish the National Food Safety Information Network, part of the Food Safety Initiative, that maintains a database of educational materials. In addition, the Agency continues to produce educational materials for a wide audience.

- Under the Food Safety Initiative, FSIS contributes to the Foodborne Disease Active Surveillance Network (FoodNet) which currently contains nine sites. For 2000, FoodNet now encompasses approximately 29 million Americans, nearly 11% of the population. In addition to new data on the burden of foodborne illness in general, FoodNet found Campylobacter to be the leading cause of sporadic cases of foodborne illness from 1996 through 1998.

- FSIS also contributes to the PulseNet, a computerized database that matches the DNA fingerprint of foodborne diseases, and accelerates the traceback process to the source of the contamination. PulseNet is especially successful in identifying dispersed illnesses with potentially common sources of implicated product and in alerting the appropriate regulatory agencies so they can take action. Recently, Harvard University and the Ford Foundation selected the interagency PulseNet effort to receive the prestigious "Innovations in American Government Award."

- Under the Food Safety Initiative, U.S. Department of Agriculture (USDA), Health and Human Services (HHS), and the Environmental Protection Agency (EPA) created the Foodborne Outbreak Response Coordinating Group (FORCG) to bring together Federal, State and local agencies to develop a comprehensive, coordinated, national foodborne illness outbreak response system.

- During 1999, FSIS hosted the first-ever joint meeting of State Secretaries of Health and Agriculture with federal food safety officials on improving cooperation and working towards a seamless national food safety system.

- In February 1999, FSIS and FDA signed a Memorandum of Understanding to facilitate an exchange of information between the Agencies about establishments and operations that are subject to the jurisdiction of both Agencies. This exchange of information permits resources to be used more efficiently, and will improve public health protection.

- On December 23, 1999, FSIS published a final rule to streamline the approval process for food
ingredients and additives by ending the requirement that they be approved separately by both FDA and FSIS. Previously, once FDA approved a food ingredient, FSIS had to conduct separate rulemaking in order for it to be approved for use in meat or poultry. The new rule became effective January 24, 2000.

- In November 1999, FSIS and the U.S. Public Health Service (PHS), Commissioned Corps, signed a Memorandum of Understanding assigning Commissioned Corps officers to FSIS to assist in reducing the incidence of foodborne illness.

3. Promote food safety from farm to table.

- Cooperate with States and producers to expand knowledge and use of public health-based on-farm practices.
- Improve food safety during transportation and distribution.
- By 2000, communicate food safety information to 158 million people a year through partnerships between FSIS and industry, academics and educational institutions, scientists, and consumers.
- Promote the nationwide adoption of the Food Code.

Status:

- Through FSIS efforts, state veterinarians, and other officials responsible for the production of food animals are incorporating food safety responsibilities into their practices. Producers and veterinarians are becoming more aware of the impact of the HACCP rule. State partnerships to foster producer education continue to encourage small packer-producer information sharing, and efforts to strengthen relationships between and among public health and animal health officials are increasing. FSIS entered into several new state partnerships; producers from these states represent 32% of all producers. FSIS continues its leadership role by cooperatively organizing a national conference on the role of animal production in food safety. The conference is scheduled for September 6 and 7, 2000 in St. Louis, Missouri.

- FSIS continues to be actively involved in the Partnership for Food Safety Education. The "Fight BAC" campaign began in October 1997 as a unique partnership of industry, government, and consumer groups dedicated to reducing the incidence of foodborne illness. The partnership, which was originally kicked off by Vice President Gore, has grown from 10 founding members to 18 active organizations. Hundreds of grassroots organizations are now "BAC Fighters" helping to spread the consumer education messages designed to reduce foodborne illness. Tens of thousands of publications, curricula packages, and fact sheets from the Web-based Virtual Tool Box have been distributed throughout the U.S. and the Fight BAC! Web sites had 3 million hits in 1999. Additionally, Canada became the first international affiliate.

- On May 25, 2000, FSIS launched a new food safety education campaign to promote the use of food thermometers in the home. The campaign theme is: "It's Safe to Bite When The Temperature Is Right!" FSIS introduced its new messenger, Thermy™, after focus group testing confirmed consumer acceptance of the character and the message. The campaign was created as a result of USDA research that indicated that 1 out of 4 hamburgers turned brown before reaching a safe internal temperature--high enough to destroy harmful bacteria. Color can be misleading and a food thermometer is the only safe way to be sure meat, poultry, and egg dishes are safely cooked.

- USDA and FSIS support adoption of the Food Code by all jurisdictions because it promotes uniformity in the nation's laws on food safety. This uniformity in turn promotes commerce, fosters cooperation among jurisdictions on a problem that is inherently multi-jurisdictional, and enhances
public health for all Americans. Senior USDA officials have shown support through numerous public remarks, direct communications to State governors and other officials, and agency support of various intergovernmental initiatives. The Secretary of Health and Human Services and the Secretary of Agriculture signed a joint letter to state governors promoting the Food Code. In good measure due to federal prompting, the Food Code has been adopted by increasing numbers of jurisdictions. As of December 1999, 27 State agencies in 19 states, and many federal, local, and tribal agencies have done so. Another 25 State agencies, and the Puerto Rican Department of Health, among others, are in some stage of the adoption process.

- To better inform consumers, FSIS recently adopted a policy to issue a press release for each recall. The policy went into effect February 2000, and serves to alert consumers of all recalls conducted. It also serves to remind consumers to always follow safe handling practices with meat, poultry, and egg products.

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

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

**Status:**

- FSIS completed training 100% of the meat and poultry inspectors responsible for HACCP implementation to ensure a smooth transition to HACCP. Inspection personnel were provided with resource materials and participated in work unit meetings. FSIS maintained a HACCP hotline at the FSIS Technical Services Center in Omaha for additional information as needed.
- FSIS implemented the Management Leadership Development Program (Management Academy) both in headquarters and in the field. The Agency plans to phase it in over the next few years.
- In 1997, FSIS and Texas A&M began collaborating on the Food Safety Education Program designed to educate FSIS employees in the scientific foundation for HACCP and related issues. By the end of fiscal year 2000, approximately 1,175 individuals will have graduated and received five college credits for their efforts.
- Management of all policy, rulemaking, and program development activities to reform existing regulations and to eliminate layering is now centralized under the Office of Policy, Program Development and Evaluation.
- FSIS is significantly reforming its regulations, and putting them into plain language that can be understood by plant personnel, FSIS employees, and the public. Traditionally, Agency regulations were very long, detailed, prescriptive, and not easily-understood. FSIS has been converting these command-and-control regulations to performance standards, to clarify responsibilities and allow flexibility for industry innovation. Examples of regulatory reform include: eliminating prior approval for certain types of product labels; eliminating prior approval requirements for equipment; converting highly prescriptive sanitation requirements to performance standards; harmonizing and streamlining FSIS and FDA procedures to review and approve use of food ingredients and sources.
On December 23, 1999, FSIS published a final rule, previously discussed in this document, to streamline the approval process for food ingredients and additives. On May 30, 2000, FSIS published a final rule removing requirements for partial quality control (PQC) programs in meat and poultry processing plants. This followed previous rulemakings that eliminated many PQC program requirements. This new rule is the latest in a series of regulatory reform initiatives published by the Agency to improve food safety. Simultaneously, FSIS is making regulations less burdensome, easier to use, and more consistent with HACCP systems.

In FY1999, FSIS created new job descriptions defining the more science-based inspection role we will play under HACCP. Although we received OPM approval for Consumer Safety Officers (CSOs), Congress raised concerns about our plans to implement conversion to and hiring of CSOs. FSIS reported to Congress that we intend to minimize costs by advertising vacancies only in local commuting areas where there is an adequate number of qualified candidates. FSIS still hopes to hire 50 to 75 CSOs during FY 2000. In the future, we will need a mix of technical, professional, and administrative employees. However, within that mix FSIS must increase the proportion of scientific professionals in frontline occupations. The CSO, a scientific generalist, will be the journeyman FSIS employee of tomorrow.

FSIS will soon issue the report entitled The Future of FSIS Veterinarians: Public Health Professionals For the 21st Century. To develop this report, in 1999, FSIS convened a select panel of veterinarians from inside and outside of FSIS, a variety of FSIS management personnel, and individuals affiliated with academe, non-government organizations, and foreign governments. This task force met numerous times during 1999. In February 2000, FSIS held a public meeting and solicited comments on the draft report. Recommendations cover five major issues: Defining the role of the FSIS veterinarian; Education, training, recognition and recruitment; Development and refinement of partnerships; Information management centered around animal identification; and Veterinary contributions to international credibility. Upon receipt of the final report in the next few weeks, FSIS intends to implement most of the recommendations which will positively impact our approximately 1,200 veterinarians.

5. Promote international cooperation on food safety.

- Assure the safety of the domestic food supply through the application of appropriate domestic food safety standards to imported products.

- Participate in Codex Alimentarius to improve the Codex system and to develop and adopt international food safety standards that promote fair trade.

Status:

- All plants exporting meat and poultry products to the U.S. must now meet the new requirements of our HACCP system. To ensure the safety of imported meat and poultry products, FSIS developed and applied a process to assess the equivalency of eligible foreign inspection programs relative to the requirements of the HACCP rule. Although foreign food regulatory systems need not be identical to the U.S. system, they must employ equivalent sanitary measures that provide the same level of protection against food safety hazards as is achieved domestically.

- FSIS houses the U.S. Codex Office and maintains an active role in all Codex activities. These activities include restructuring the interagency policy steering committee to ensure focus on policy development and coordination; training of delegates; conducting foreign outreach efforts; hosting
Codex sessions on food hygiene, processed fruits and vegetables, and residues of veterinary drugs in foods.

During the 23rd session of the Codex Alimentarius Commission, FSIS Administrator, Thomas J. Billy, was elected to a two-year term as Chairperson of this United Nations Commission. His role as Chair helps to ensure that the processes used by Codex to develop food standards are based on sound science and have integrity. Under his leadership, the Codex priorities will include: 1) continuing support of science-based decision making; 2) obtaining support from WHO and FAO; 3) increasing and strengthening participation of developing countries; 4) ensuring greater participation of non-governmental organizations and addressing the need for transparency; and 5) improving efficiency and speed of the Codex process and consensus building.

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Discussion Questions

1. Consider food safety as an issue of public policy (A2). Why is this an issue at this point in time? What is the basis for a federal regulatory role? Why does this deserve presidential attention (A1)?

2. Consider the current approach to regulating the safety of meat products as evidenced by legislative provisions (B1) and relevant administrative regulations (B2). How would you characterize the use of the tool of social regulation in this case? How coercive is the approach? How "automatic" is the approach? How intrusive is the approach? [For additional information see B3 and E1.]

3. Consider the administration (B3) and funding (F1) for regulating the safety of meat products. What are the central issues that the Food Safety and Inspection Service faces in managing the regulatory function? How are resources allocated among different agency functions?

4. The existence of "red tape," consisting of unnecessary or overly cumbersome requirements, is a common complaint about regulations. Consider the examples of substantive (C1) and procedural requirements (C2) along with the examples of design (D1) and performance standards (D2). Which of these, or which aspects, do you think constitute red tape? Why do you think these take the form that they do? How could these provisions be revised to reduce or eliminate the red tape?

5. Consider exemptions to the meat inspection requirements illustrated by C3. How do these exemptions affect the overall safety of meat products? What reasons can you offer for these exemptions? Do these seem like reasonable exemptions?

6. Consider the regulatory rulemaking procedures under Executive Order 12866 (C4). What is the intent of this regulatory review process? What criteria are to be used to justify new regulations? How workable are these criteria and the review process?

7. Consider the due process aspects of notification (F2) and appeal (F3) procedures for the enforcement of requirements for the safety of meat products. How do these procedures protect regulated entities from overly zealous enforcement? How cumbersome are these procedures from the perspective of the regulatory agency? How would you modify these procedures?

8. Consider the criticisms of traditional approaches to ensuring the safety of meat products (A2) and the use of "voluntary" audit programs in other settings (E2). What are the criticisms of the traditional approach? How could voluntary regulation be applied to the safety of meat products (also see G2)?

9. A key issue in the regulation of food safety is inspiring public and elected officials' confidence in the regulatory system. How has the Food Safety and Inspection Service attempted to inspire this confidence (G1 and G2)? Which actions do you think would be the most effective in this regard? What would you do?