



5796 '98 OCT 23 P12:39

October 8, 1998

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Drive, Rm. 1-23  
Rockville, MD 20857

Re: Food Safety Initiative Strategic Plan Docket No. 98-045N

To Whom It May Concern:

The American Meat Institute submits for the public record the attached testimony concerning the President's National Food Safety Initiative.

Sincerely,

A handwritten signature in black ink that reads 'James H. Hodges/tr'. The signature is written in a cursive, slightly slanted style.

James H. Hodges  
Senior VP Regulatory Affairs  
American Meat Institute

97N-0074

C68



J. Patrick Boyle  
President and Chief Executive Officer  
American Meat Institute  
to the  
President's Council for Food Safety  
October 2, 1998

The American Meat Institute (AMI) is pleased to have the opportunity to provide our views regarding approaches to food safety regulation. AMI is the national organization representing meat and poultry packers and processors and their suppliers throughout North America. Our members produce the majority of meat and poultry products manufactured in the United States. We have been a presence in Washington since around the turn of the century. My comments today will focus on the meat and poultry industry and the government agencies that intensely regulate our industry.

By way of background, today's meat and poultry inspection program has its origin in the Federal Meat Inspection Act of 1906. At that time, the primary public health concerns were diseased animals and unsanitary conditions in meat packing plants. The law requires all cattle, sheep, swine, goats and equines and their carcasses and parts be inspected and passed as human food for distribution in interstate commerce. The 1957 Poultry Products Inspection Act extended to chickens, turkeys, ducks, geese and guineas many of the same requirements mandated for meat. The Wholesome Meat Act of 1967 further extended inspection programs to the state level by establishing a federal-state cooperative inspection program for plants that produce and distribute meat and poultry products within state boundaries. Twenty-five states currently maintain inspection programs that are required to be at least equal to federal standards. Similar requirements also apply to imports from foreign countries, which must have equivalent inspection systems. The primary goal of these inspection programs is to prevent unwholesome, adulterated or misbranded products from being sold as human food, and to ensure meat and poultry products are slaughtered and processed under sanitary conditions.

The United States Department of Agriculture's (USDA) legal responsibilities are primarily focused on slaughter and processing facilities. It maintains jurisdiction over federally inspected meat and poultry products during storage, distribution and sale, but the federal law exempts retail and restaurant operations from the type of food safety inspection required in federal and state inspected packing and processing plants. Moreover, current meat and poultry inspection statutes give USDA no food safety jurisdiction on farms, ranches, feedlots or other live animal production facilities. No inspection system can eliminate all foodborne illness risks from meat and poultry, but there is a growing consensus that food safety can best be ensured through oversight programs that are coordinated from production through consumption.

USDA's Food Safety and Inspection Service (FSIS) uses significant resources to carry out its responsibilities. FSIS has a total staff approaching 10,000 employees. More than 8,000 field inspectors and supervisors inspect approximately 6,500 plants. The estimated cost to operate this massive, labor-intensive program in fiscal year 1998 is \$675 million, or approximately \$100 thousand per FSIS inspected facility. In contrast, the Food Drug and Administration (FDA) has a budget slightly over \$200 million for food safety activities and approximately 900 employees to regulate an estimated 53,000 establishments that produce, process or store food. That translates to an expenditure of approximately \$4,000 per FDA inspected facility. These statistics demonstrate that meat and poultry manufacturers are the most intensely regulated segment of the U.S. food industry.

Existing governmental resources devoted to food safety are disproportionately directed at meat and poultry manufacturers because federal laws require continuous animal-by-animal inspection and a daily inspection presence in processing facilities. Current statutes coupled with FSIS inspector opposition to change the law and restrict the agency's flexibility to shift its resources in response to changing health risks. FSIS has limited ability to tailor its inspection frequency based on the risks presented by the type of animal, processing technology or other risk factors. FSIS's effectiveness and efficiency could be enhanced if the agency focused its resources on products and processes that present the most significant public health risks.

FSIS has a broad range of enforcement powers to prevent unwholesome, adulterated or mislabeled meat and poultry from reaching the public. Plants are prohibited from operating unless the government provides inspection services. FSIS often exercises its authority to withhold or suspend inspection if plants are not meeting their statutory or regulatory obligations. Such actions shut down plant operations.

It is also illegal to sell or transport adulterated or misbranded products. Unsafe products can be condemned and removed from the market. Violation of the federal meat and poultry laws can result in substantial fines as well as imprisonment.

Over the past two decades, USDA has asked Congress for additional statutory authority to mandate product recalls without obtaining court orders, to summarily withdraw inspection services from companies USDA believes have violated the law and to unilaterally impose civil fines on companies that fail to comply with the laws, regulations, or agency's orders. In light of the scope and breadth of USDA's existing enforcement arsenal, and the absence of any proof that the tools currently available to USDA are inadequate, additional authority is not necessary. Moreover, because of the potential administrative abuse these requested sanctions would present, new enforcement authority would be contrary to sound public policy. More punitive measures will not and cannot make food safer.

In 1996 the federal government and industry began a several year process to dramatically change the way meat and poultry is inspected. This new regulatory program commonly referred to as Hazard Analysis Critical Control Points, or HACCP, more clearly defines the responsibilities of the regulator and the regulated industry. Meat and poultry companies are required to have a plan

for producing safe food. The government's regulatory role is to set food safety performance standards and to verify through its inspection activities that the company meets those performance standards. Federal inspectors maintain a continuous presence in plants. But where inspectors previously looked for problems that had already occurred, under the new system, they monitor plant activities to be sure appropriate steps are being taken to prevent problems. It is a fundamental shift in the priorities of the federal government.

Substantial progress has been made in recent years by industry and government in identifying and adopting effective food safety standards and procedures. HACCP has become the framework for both industry and government efforts to improve food safety. The adoption of HACCP procedures was mandated in 1995 by the Food and Drug Administration (FDA) for seafood processors and in 1996 by the USDA for meat and poultry slaughterers and processors. Many companies in other segments of the food industry have adopted HACCP on their own, and HACCP is increasingly recognized in other countries and by international organizations as the state of the art in science-based process control for food safety.

An important feature of HACCP is that it provides the basis for clearly defining and modernizing industry and government programs to ensure the safety of food. Government does not produce food. Government action cannot make food safe. At the point of production and processing, only food companies have the capability and responsibility to make food safe. Maintaining food safety requires responsible action at each step of distribution, retail preparation and sale, and subsequent handling by consumers. The government's core regulatory role should be verifying that companies are meeting their food safety responsibilities, establishing food safety performance standards based on the best available science, and providing accountability for companies to meet those standards through appropriate oversight and enforcement.

The transition to this new HACCP-based regulatory program has created several implementation challenges. Many FSIS personnel find it difficult to abandon traditional "command and control" inspection tactics. Many inspectors with no scientific training continue to dictate how a plant's production process is designed and operated. FSIS needs to improve its inspector performance to achieve fair and uniform enforcement of the regulations. A more in-depth understanding of food safety manufacturing principles and the agency's inspection modernization process is needed. USDA's credibility and the ultimate success or failure of its new regulatory program depends on allowing companies to produce products in a manner that results in uncompromising food safety. FSIS should focus on verifying products are safe and abandon the practice of mandating how product safety is achieved.

Regulatory and policy changes are also needed to create an environment that is consistent with HACCP-based inspection. FSIS began a regulatory review process in 1995 to revise or repeal existing regulations that impede implementation of a scientifically designed HACCP program. FSIS has made limited progress in discarding old, outdated regulations. The result is a new HACCP-based inspection program layered over the traditional regulatory compliance program. Inspectors are using new procedures to determine compliance with old regulations. FSIS should complete its regulatory review process as soon as possible. Otherwise, the new HACCP-based

inspection program will be scientifically indefensible and inhibit the adoption of new technologies and innovations that can improve the safety of meat and poultry products.

Industry education is an extremely important element of a production to consumption food safety system. During the past seven years the American Meat Institute Foundation (AMIF) has trained thousands of meat and poultry industry workers in HACCP principles and basic food safety. Joint training in these areas between industry and government employees would be even more beneficial.

AMIF is currently conducting HACCP briefings throughout the United States. The briefings will immediately follow half-day HACCP briefings that FSIS is conducting in twenty U.S. cities. Both the AMIF and the FSIS briefings are designed to help prepare meat and poultry plants for HACCP implementation. The FSIS briefings will focus on the regulatory requirements plants must meet. The AMIF briefings will focus on practical advice for operating under USDA's new Pathogen Reduction/HACCP Rule.

Consumer education is also an important component of a farm to table food safety system. Last year, industry, consumers, and the federal government formed the Partnership for Food Safety Education and launched a consumer education program called Fight BAC!™ It is hoped that this campaign will persuade consumers to improve risky food handling behavior and prevent food borne illnesses.

AMI and the Food Marketing Institute administer the Partnership and own the registered trademarks. The Partnership has raised more than \$580,000 toward a \$1 million goal. Among the accomplishments in 1998 are:

- More than 200,000 Fight BAC!™ Community Action and Supermarket Kits have been distributed in an effort to spread the educational word of the campaign to consumers through community businesses and organizations;
- The Fight BAC!™ television public service announcement has aired on 100 television stations for a total of over 200 million viewer impressions since October 1997;
- A Fight BAC!™ radio public service announcement has been used more than 23,000 times and heard by an estimated 43 million Americans;
- The Fight BAC!™ website has received 1.5 million hits, or nearly 250,000 per month since its launch in 1997.

Additionally, the Partnership will concentrate this year on developing educational materials for children. Recent, unpublished research conducted by USDA and FDA shows that the best way to reach children with safe food handling messages in schools is through the science curriculum; and the best grades for learning this information are three, four, five and six. The Partnership is developing a classroom teaching guide for grades kindergarten through three. The guide uses a

BAC™ puppet, songs and games to teach safe food handling to very young children. A consulting firm has been selected to create a science class teaching guide for grades five through eight.

The meat and poultry industry is committed to doing everything within its powers to ensure that the food it processes, distributes and serves to American consumers is the safest and most wholesome in the world. Companies strive every day to make their food safety systems better. Manufacturers of meat and poultry products routinely employ many state-of-the-art practices to minimize the risks of foods causing human illness, but we cannot guarantee all food products are free from all risks. By the same token, no food inspection system or testing program can guarantee zero risks.

One central question facing the federal government is the organizational structure of the U.S. food safety regulatory system. Most organizations representing the food industry believe the current organizational structure is adequate to maintain the safety of the food supply. Most organizations are far more concerned about having a scientifically supportable inspection program than where it is located within the federal bureaucracy. However, a serious debate is emerging about the establishment of a single food safety agency to regulate all foods.

On August 20, 1998 the National Academy of Science (NAS) released the report of the Committee to Ensure Safe Food from Production to Consumption. This congressionally mandated study examined the scientific and organizational needs for an effective food safety system. The committee concluded outdated food safety laws and a fragmented federal structure serve as barriers to improving protection of the nation's food supply. The report came to three primary conclusions:

- An effective and efficient food safety system must be science based;
- Current statutes governing food safety regulation and management must be revised;
- Reorganization of federal food safety efforts is required.

The committee recommended several measures regarding the scientific and organizational changes needed to improve the US food safety system, including the establishment of a unified, central framework, headed by one official, for managing all federal food safety programs. Specifically of interest to the meat and poultry industry is a recommendation that congress no longer mandate government employees inspect each animal carcass. The committee said outmoded safety statutes, such as the visual inspection system for meat and poultry may detract from protection efforts by diverting resources from implementation of science-based inspection reforms. Instead, the committee recommended congress mandate a single set of regulations for all foods.

The report does not recommend a specific organizational structure, such as a single food agency, but clearly moves the debate in that direction. AMI agrees in principle that consolidating

resources and expertise can help harmonize the varying degrees of regulatory oversight that federal, state and local governments exercise over different segments of the food industry; but specific proposals will need careful evaluation before proceeding to change the existing food safety regulatory system that has served the American public well.

In response to the NAS report, President Clinton issued an executive order on August 25, 1998 that would create a President's Council on Food Safety. The council would be composed of cabinet and White House officials and jointly chaired by Agriculture Secretary Glickman, Health and Human Services Secretary Shalala and Neal Lane, the assistant to the President for Science and Technology.

The Council will have three primary functions, including: (1) developing a comprehensive strategic federal food safety plan; (2) advising agencies of priority areas for investment in food safety and ensuring that federal agencies annually develop coordinated food safety budgets; and (3) overseeing the recently established Joint Institute for Food Safety Research and ensuring that it addresses the highest priority research needs. We are hopeful this council will provide more effective leadership for a scientifically sound, risk based federal food safety program.

Most Americans have a relatively high degree of confidence in the safety of the food supply, based on a combination of experience and belief that a system is in place to ensure food is safe. People react strongly, however, when a food safety problem arises or when the system seems to have failed. Such real or perceived failures in the food safety system capture media attention, which in turn influence public opinion and reaction.

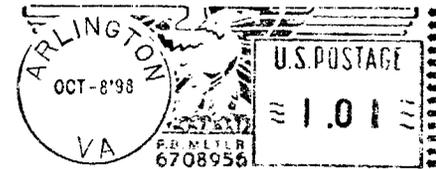
Outbreaks of foodborne illness or other food safety problems will never be totally eliminated. The food production and distribution system is too complex. Maintaining public confidence in the safety of food depends on providing consumers the safest food possible and educating consumers on how to protect themselves from food safety hazards by proper food handling and preparation.

The fundamental elements of a sound food safety system are in place today. Food manufacturers and distributors willingly accept their responsibilities to produce safe food. Government has a valuable regulatory role, but it must expand its leadership and investment in other areas such as food safety research, education and technology development. Food safety is a shared responsibility. Maintaining the safety of the U. S. food supply depends on all participants in the food chain--from producers to consumers--taking appropriate measures to prevent foodborne diseases.



Post Office Box 3556, Washington, DC 20007

**ADDRESS CORRECTION REQUESTED**



Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Drive, Rm. 1-23  
Rockville, MD 20857