Proposed Rules

Federal Register
Vol. 61, No. 227
Friday, November 22, 1996

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 325, 381

[Docket No. 95–049A]

RIN 0583–AC05

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 110

Transportation and Storage Requirements for Potentially Hazardous Foods

AGENCIES: Food Safety and Inspection Service, USDA; Food and Drug Administration, DHHS.

ACTION: Advance notice of proposed rulemaking; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) are seeking information and comments on approaches the two Agencies might take to foster food safety improvements that may be needed in the transportation and storage of potentially hazardous foods. Potentially hazardous foods, including meat, poultry, eggs and egg products, fish, seafood, and dairy products, are those that are capable of supporting the rapid multiplication of microorganisms that cause foodborne illness. This notice seeks comments and information on various issues and alternatives for ensuring the safety of potentially hazardous foods during transportation and storage.

DATES: Comments must be received before: February 20, 1997.

ADDRESSES: Please send an original and two copies of written comments to: FSIS Docket Clerk, DOCKET #95–049A, Room 3806, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. All comments submitted will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 1:00 p.m. and 2:00 p.m. and 4:30 p.m., Monday through Friday. To review the publications and other background information cited in this document, interested persons may visit the Docket Clerk's Office during the times listed above.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Stafko, Office of the Administrator, Room 3835, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, 20250, (202) 720–7773, in regard to meat, poultry, and egg products.

Ms. Shellee Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, U.S. Department of Health and Human Services, 200 C Street SW., Washington, DC 20204, (202) 205–4681, in regard to seafood, whole (shell) eggs, dairy products, and other potentially hazardous foods, other than those listed above for which Mr. Ralph Stafko should be contacted.

SUPPLEMENTARY INFORMATION: FSIS and FDA maintain regulatory programs to help ensure that foods distributed in interstate commerce are not adulterated or misbranded. FSIS's programs, which cover meat, poultry, and egg products, include continuous in-plant inspection of livestock and poultry slaughtering, and processing of products therefrom, and egg product processing activities. FDA, which is responsible for ensuring the safety of foods in most other circumstances, operates a regulatory program that includes unannounced inspection of the domestic food industry and sample analysis. FSIS conducts its inspections at meat, poultry, and egg product processing establishments. FDA inspects establishments that process other types of foods. FSIS and FDA conduct examinations of warehouses and transshipment points, including points of entry of imported foods into the United States. They also conduct Federal-State cooperative programs, and consumer education.

Both FSIS and FDA, in recent rulemakings, have adopted a new food safety regulatory strategy, the framework of which is a science-based system known as the hazard analysis and critical control points (HACCP) system. HACCP is a process control system designed to identify and prevent chemical, physical, and biological hazards in food production. On December 18, 1995, FDA published a final rule, ''Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products'' (60 FR 65096), mandating the development and implementation of HACCP systems to ensure the safe and sanitary processing and importation of fishery products. FSIS promulgated a final rule ''Pathogen Reduction; HACCP Systems'' for meat and poultry on July 25, 1996 (61 FR 38806) mandating implementation of HACCP systems and standard operating procedures (SOP) for sanitation, and pathogen reduction performance standards and testing for meat and poultry.

Both Agencies have come to recognize that, if they are to reduce foodborne illness to the maximum extent possible, they must broadly approach their food safety missions, addressing potential hazards that arise throughout the food production and delivery system. They and the industries they regulate must work toward preventing, minimizing, and eliminating hazards that may arise before raw products or animals enter manufacturing plants or FSIS-inspected establishments and after food products leave those businesses. There is widespread agreement among food safety experts that ensuring food safety requires taking steps to prevent hazards and to reduce the risk of foodborne illness throughout the chain of production, processing, sale, storage, and transportation.

Post-harvest (seafood) and post-processing transporters, storage operators, and retail stores, restaurants, and other food service sectors are important links in the chain of responsibility for food safety. In these areas, FSIS, FDA, and State and local governments share authority and responsibility for oversight of food products. FSIS and FDA do not have programs that address the handling of food by these industry sectors, as they do for federally inspected processing establishments. However, both Agencies have become increasingly concerned about the public health impact of diseases associated with potentially hazardous foods and about what happens to food at the stages through which it passes on the way to consumers.

This notice addresses hazards attributable to the transportation and

storage of potentially hazardous foods outside of the establishments where they are processed.

Transportation and Storage of Potentially Hazardous Foods: Current Regulatory Coverage and Guidance

Foods are susceptible to contamination from a wide variety of agents—physical, microbial, or chemical. Some foods, most notably animal food products like meat, poultry, eggs, seafood, and dairy products are particularly susceptible to microbiological hazards because their moisture, pH levels, and high protein content provide ideal environments for the growth of bacteria. For these reasons, these products must be carefully monitored to prevent their exposure to microbiological, as well as other hazards.

No matter how carefully prepared, however, most any raw food product of animal origin may potentially have some bacteria present, including pathogens, and, thus, must be handled in a manner that minimizes the opportunity for bacteria to multiply. Furthermore, like other foods, these foods may become contaminated through direct abuse such as damaged packaging, exposure to filth or harmful chemicals, or contact with a contaminated surface. Sometimes, contamination is caused by direct or indirect contact with contaminated foods—a process known as cross-contamination. For example, salad components prepared on a cutting board used previously for raw poultry could become contaminated by pathogens that were on the poultry.

Food safety protection can be improved by the control of microbiological and other hazards through the use of preventive methods such as HACCP, good sanitation and manufacturing practices, and food safety performance standards, as appropriate, throughout the food production and distribution chain. Currently, however, most Federal regulatory measures are directed at slaughtering and food processing plants. State and local authorities have also directed their regulatory oversight at certain categories of food processors, generally small firms, as well as retail stores and food service establishments.

Despite increasing concern about the risks that may be created in the transportation and storage of potentially hazardous foods, government agencies at all levels do not have comprehensive regulatory programs for those segments of the farm (or harvest)-to-table food continuum that are comparable to that for slaughtering and processing establishments. Additional information is needed on the extent and severity of food safety problems that may be attributable to the transportation and storage of potentially hazardous food products from harvesting or production to processing plants and from processing plants to the consumer for FSIS and FDA to determine whether there is a need for additional government regulation to address risks that may be created during these stages of food distribution.

1. FSIS

All ingredients used in meat and poultry products prepared in establishments where FSIS maintains inspection (''official establishments'') are subject to examination upon their arrival at the official establishment. Substances and ingredients used in the preparation of egg products at FSIS-inspected plants (''official plants'') are also subject to inspection. Meat and poultry carcasses and parts that enter official establishments are inspected before they may be used in the preparation of meat or poultry food products at such establishments, regardless of whether they previously have been inspected and passed by FSIS, even if returned to the original establishment. Similarly, previously inspected egg products are subject to reinspection upon arrival at an official egg products processing plant.

The safety and wholesomeness of meat and poultry products being transported in interstate commerce, or being held in storage, are governed by various regulatory and statutory provisions. Certain regulations (9 CFR part 325 and part 381 subpart S) require meat and poultry products being transported to be ''wrapped, packaged, or otherwise enclosed'' so as to prevent their adulteration by air contaminants, unless the means of conveyance in which the product is transported is completely enclosed with tight-fitting doors or other covers for all openings. The means of conveyance must be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues) and free of chemical residues, so that the products placed in it will not become adulterated. Any cleaning compound, lye, soda solution, or other chemical used in cleaning a means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Means of conveyance onto which meat or poultry products are loaded, being loaded, or intended to be loaded are subject to inspection at an official establishment. If a means of conveyance, upon inspection, is found to be in a condition such that meat or poultry products placed in it could become adulterated, it is not to be used until the condition that could cause adulteration is corrected. Meat and poultry products found by an inspector to be in such a condition that they may have become adulterated are subject to inspection.

A guide for inspectors, the FSIS Sanitation Handbook, also presents details on acceptable conditions for transport vehicles and storage facilities of meat and poultry products.

FSIS monitors and enforces compliance with the adulteration and misbranding provisions of the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) during transportation to and among inspected establishments and allied industries, such as renderers, pet food processors, retail stores, and restaurants. Meat and poultry products are considered to be adulterated for various reasons including if they are unsound, unhealthful, unwholesome, or otherwise unfit for human food (21 U.S.C. 453(g), 601(m)). Misbranding of meat and poultry products occurs, if among other reasons, their labeling is false or misleading. (21 U.S.C. 453(h), 601(n).) Similar adulteration and misbranding provisions apply to egg products. (21 U.S.C. 1033(a), 1033(l), 1036.)

FSIS also investigates complaints received from consumers and others alleging that adulterated or misbranded meat, poultry, and egg products have been sold or distributed in commerce.

FSIS has exercised its statutory authority over meat and poultry products outside official establishments in various instances, including in its promulgation of safe-handling labels on raw meat and poultry products (9 CFR 317.2(l) and (m), and 381.125(b)). However, FSIS does not have a comprehensive regulatory program that covers the handling of meat, poultry, and egg products outside of official establishments that is comparable to its program of regulating such products during their production in official establishments. FSIS's regulatory role regarding such products has generally been a reactive one. FSIS generally responds on a case by case basis to instances of adulteration and misbranding of products outside official establishments. FSIS has not focused directly on conditions and practices that occur after meat, poultry, and egg products leave official establishments that contribute to products being exposed to pathogenic contaminants, or that contribute to the multiplication of pathogenic microbes.

FSIS-inspected product that is in distribution channels and is not at an

establishment where FSIS maintains inspection may be examined by FSIS if the product is suspected of being adulterated or misbranded. At this point, the Agency focuses on the condition of the product, not on the conditions under which the product was produced. Product found in distribution channels that is adulterated or misbranded is subject to detention. In certain circumstances, if the product is reprocessed, repackaged, or relabeled under inspection, it may be sold in commerce.

FSIS also checks product for evidence of breaking of bulk packages and repackaging or reshipment without reinspection, for evidence that the product has been processed without inspection, and for spoilage. If such evidence is found, the facility in which the product is found may be subject to a thorough inspection for sanitation, product processing, and storage conditions. For example, discovery of rodent fecal matter in a product could lead to an investigation of the storage warehouse in which the product has been held.

In carrying out its investigations, FSIS does not stop trucks or other transportation vehicles, but rather examines products at key points during distribution. At cold storage warehouses, FSIS examines specific conditions to determine the adequacy of warehouse procedures for preventing the adulteration of meat and poultry products, including the adequacy of sanitation at the warehouse and the other controls utilized to reduce hazards, such as pests, to meat and poultry products.

Post-processing transportation and storage of meat and poultry products was also a subject of concern to commenters on FSIS's February 3, 1995, Pathogen Reduction/HACCP proposal. Various commenters stated that the majority of hazards consumers face from raw meat and poultry products stem from mishandling the products after they have left the official establishments. They stated that to be effective, any regulatory controls contemplated by FSIS must include those industry segments that handle products after they leave official establishments as well as slaughter and processing establishments. Commenters further stated that FSIS should expand its inspection program to include all segments of the food production and transportation industries. Some commenters noted that, although there is not a sufficient number of FSIS (and FDA) employees to inspect businesses outside official establishment on a regular basis, there must be some additional regulatory efforts to ensure proper controls are maintained throughout the food chain.

Other commenters stated that they believed that transportation and storage entities should not be subject to regulatory controls. They stated that warehousing and food distribution operations do not pose the same levels of risk as processing operations. Still others felt that FDA and DOT should develop voluntary guidelines for transport conveyance, not mandatory requirements.

2. FDA

FDA routinely inspects food processing plants and examines food products transported in interstate commerce. The examination and inspectional aspects of FDA's program are carried out by its field force as part of its compliance program for foods. FDA covers the full range of potential food safety problems, including microbial hazards, chemical contaminants, pesticides, filth, and food additives. FDA provides similar coverage for imported foods.

FDA's requirements for the conditions under which food is to be transported and stored are contained in FDA's good manufacturing practice regulations (21 CFR Part 110). The conditions under which food is received, inspected, transported, segregated, prepared, manufactured, packaged, and stored of food must be such as to ensure that the food will not become contaminated with filth or rendered injurious to health. Storage and transportation of finished food must be under conditions that will protect food against physical, chemical, and microbial contamination, as well as against the deterioration of the food and its container (21 CFR 110.93).

FDA's final rule on seafood, which mandates the application of HACCP principles to the processing of seafood, is designed to ensure that the hazards that are presented at all stages of the food processing and distribution chain, including transportation, are identified, and appropriate control measures are put in place to address them. Thus, for example, a processor could require, as part of its HACCP plan, that a certain temperature be maintained during the transport of raw materials to its facility.

FDA is evaluating whether to require a comprehensive preventive regulatory program, similar to its seafood regulatory program, for food products other than seafood in commerce. On August 4, 1994, FDA published an advance notice of proposed rulemaking entitled ''Development of Hazard Analysis Critical Control Points for the Food Industry'' (59 FR 39888), which sought public comment on whether and how FDA should develop regulations to establish requirements for a new, comprehensive, food safety assurance program for both domestically produced and imported foods. Further regulatory action by FDA on this matter is pending.

3. Department of Transportation

The Department of Transportation (DOT) has promulgated a number of regulations affecting the conditions under which edible products can be transported in commerce. For example, a carrier can not transport hazardous material required to be labeled poison in the same motor vehicle with material that is marked or known to be a foodstuff, feed, or any edible material intended for consumption by humans or animals unless packaged in specifically prescribed packages (49 CFR 173.25(c) & 177.841(e).) A rail car that has held poisonous materials in packages showing any evidence of leakage, must be thoroughly cleaned after unloading before the car is returned to service. After any poisonous materials are unloaded from a rail car, that car must be thoroughly cleaned unless that car is used exclusively in the carriage of poisonous materials (49 CFR 174.615(b)).

4. Food Code

Finally, the transportation and storage of food products is dealt with in the model Food Code, which is published by FDA. This model code contains provisions that specifically address the storage and preparation of foods at retail stores, restaurants, and institutions. It also contains recommended holding temperatures for a variety of foods. Most State and local food statutes, regulations, and ordinances are based on some edition of FDA's model food code.

Risk of Contamination and Disease From Food Transportation

1. Current Transportation Vehicles and Conditions

There are three basic types of transport: air transport; sea transport, including conventional refrigerator ships and container ships; and land transport, which consists of rail cars and trucks. Of the approximately 47 million tons of food shipped between continents each year, about 60 percent goes by sea, 35 percent by land, and 5 percent by air. Approximately 22 million tons of meat and poultry, fish, and dairy products are exported intercontinentally each year, with 40 percent of that total moving by sea transport.

Within a continent, most perishable cargoes are hauled by trucks. A lesser amount is transported by rail. Rail shipments may be by self-contained refrigerated rail cars or by flatcars carrying sea containers known as ''piggyback'' trailers. Over-the-road hauling involves refrigerated trucks or flatbed trailers used to haul sea containers, with most of the refrigerated freight moving in refrigerated trailers. Refrigerated trailers are a necessary method of transportation for the distribution of perishable foods from seaports and rail heads to the ultimate consumer. Thus, it is assumed that most refrigerated food cargo, whether originating overseas or within the U.S., ultimately travels by truck transport.

2. Safeguarding Food Under Conditions of Transport, e.g., the ''Cold Chain''

The logistics of moving perishable, potentially hazardous products generally involves cooling after processing to achieve adequate temperatures before shipping. This means that perishable foods must be refrigerated or frozen after processing and before shipment to inhibit spoilage or growth of pathogens. During transportation and storage, the challenge is to maintain proper refrigeration temperatures and to keep the ''cold chain'' from breaking during steps such as palletization, staging, loading and unloading of containers, movement into storage, and time spent in storage.

For example, post-harvesting temperature control is especially important in preventing illness from consuming certain marine fish and certain raw Gulf-harvested oysters. Improper handling of some marine fish, most notably tuna, mahi mahi, and bluefish can lead to histamine (scombrotoxin) formation, resulting in illness and death. Similarly, the Interstate Shellfish Sanitation Conference has adopted post-harvesting temperature controls to reduce the proliferation of the marine bacterium *Vibrio vulnificus* in oysters harvested from the Gulf of Mexico during warm weather. To date, temperature controls from time of harvest to consumption remain the most practical means of reducing the risk of illness and death for medically compromised consumers of raw Gulf oysters.

3. Technical Analysis Group (TAG) Report on Transportation

When FSIS proposed the Pathogen Reduction/HACCP rule in February 1995 (60 FR 6774), FSIS stated its commitment to develop standards to help ensure the safe handling of meat and poultry products during transportation and storage. FSIS stated it would: (1) Ask a group of experts to provide data on the hazards to food safety and the controls that currently exist in the industry to address such hazards; (2) develop practical standards of performance for establishments and carriers with respect to the transport of food; (3) develop a list of good manufacturing practices and various options for encouraging their use; (4) initiate, where feasible, joint rulemaking with FDA to establish appropriate standards to ensure the safety of meat and poultry products and other foods during transport, and (5) along with FDA, work with the DOT to implement the Sanitary Food Transportation Act of 1990, as revised, and determine whether additional authority is needed to carry out the shared food safety mission of FDA and FSIS. (*Id.*, at p. 6828)

In April 1995, FSIS and DOT contracted with a Transportation Technical Analysis Group (TAG) to identify the primary hazards associated with the transport of perishable foods and recommend reasonable controls that might be employed by industry to ensure food safety. The 10-member TAG was composed of representatives from academia, the transportation and food industries, and DOT. The TAG's tasks were to identify hazards associated with the transportation of perishable foods; identify practical controls to prevent, reduce, or eliminate the risks involved; and outline the cost implications and desired results of applying the controls. The TAG's analysis was intended to provide basic information FSIS could use in formulating good manufacturing practices (industry guidance) or regulations, or both, dealing with the transportation of meat, poultry, and egg products.

Tasks of the TAG for meat, poultry, and egg products included: (1) Identifying and describing the steps comprising the transportation of these foods, from the live animal to the consumer; (2) identifying all hazards to these foods that can pose a risk to public health; (3) estimating the potential impact of each hazard by considering its prevalence in these foods, and the severity of the adverse effect of the hazard; (4) identifying practical controls to prevent, eliminate, or reduce each hazard to an acceptable level; (5) noting any scientifically valid procedures for verifying the effectiveness of each control; (6) identifying the desired results of applying the controls; and (7) identifying any research and development activities needed to better define the hazards or improve on the identified controls. The TAG identified hazards associated with the transportation and storage of potentially hazardous foods, control points for addressing such hazards, and procedures needed to eliminate, minimize, or reduce the hazards.

Because its members considered trucks to be the predominant mode of transportation for potentially hazardous foods, the TAG focused its initial attention on this mode of transportation. Limitations of time and money kept the TAG from inquiring much into the state of perishable food transport by air, sea, or rail. Therefore, FSIS would appreciate having information and comments from those who are familiar with transport operations in these industries on factors that affect the safety and wholesomeness of perishable foods shipped by plane, rail, or ocean or freshwater vessel.

The TAG found that how trucks are loaded has a very direct relation to the likelihood of food contamination and abuse. A less-than-full-load (LTL) is a truck that has available space as it begins its journey, and to which additional freight may be loaded during the journey. A mixed load is a truck that is fully loaded at the time it begins its journey, but whose load consists of different types of freight. According to available information, a disproportionate number of product handling problems, resulting in claims for product losses, are associated with LTL's and mixed loads. In addition, TAG members believed that LTL product handling problems are more likely to occur among smaller carriers which are more likely to haul smaller, mixed cargoes.

LTL and mixed loads may be troublesome from the food safety standpoint for several reasons. First, such a load may consist of foods with different holding temperature requirements. The temperature of the trailer or container with the load may be suitable for one food but not for another. An extreme example of this problem would be an LTL or mixed load maintained at a refrigeration temperature but in which part of the food cargo must be kept frozen. Some freight companies have solved this problem by using partitioned trailers; each storage space between the partitions can be maintained at a different temperature, so the LTL holding temperature problem does not arise.

Another hazard to which food carried in LTL containers may be exposed is the failure to maintain the proper storage temperature throughout the transit. Because LTL or mixed load carriers tend to be loaded and unloaded more frequently during a trip, it is

technologically more difficult to consistently maintain food cargo at the correct temperature than it is for uniform food cargo carried to a single destination. Each time freight is loaded or unloaded, the opportunity exists, even under the best of handling conditions, for a temperature fluctuation that may cause food safety problems.

A further problem that can arise is potential adulteration of food cargoes by incompatible food or non-food cargoes. For example, some cargoes may release gases or odors that are absorbed by other cargoes.

The TAG identified other concerns involving the transportation of perishable foods by truck. These included the cleaning and precooling of trucks, proper packaging of foods, loading patterns and partial loading or unloading of trucks, adequacy of refrigeration units, air circulation, humidity, insulation of trucks, and the time taken to transport the food.

The TAG concluded that good controls are essential to ensuring safe transportation of perishable foods. They noted that ''The focus needs to be on establishing control points that will monitor temperatures and times en route and at the loading and storage facilities. Time, temperature, and sanitation are the three elements of any control plan.'' (Transportation TAG Report, at p. 14)

The TAG identified six critical control points, points at which loss of control may result in an unacceptable health risk. They are: (1) Inspecting the truck trailer before loading; (2) ensuring that the temperature of the product intended to be loaded is not above 40 °F; (3) proper configuration of the load; (4) maintenance of a 40 °F temperature while awaiting additional product to be loaded; (5) maintaining the temperature of the food during transit; and (6) maintaining the inside temperature of the food during unloading and movement to storage. For each of these critical control points, the TAG identified interventions that would address the hazards at each critical control point, the frequency of monitoring needed to ensure the interventions are carried out, who should monitor the critical control points, actions to be taken if deficiencies or deviations are noted, how corrective actions should be documented, and who should verify the corrective actions taken.

4. FSIS and FDA Concerns: Evidence of a Problem

FSIS and FDA are concerned about whether reliable procedures are being used by all sectors of the food production and delivery chain to combat the invisible threats to safety and health posed by microbial pathogens. Control of microbial pathogens is difficult even in those areas where inspection and other regulatory and public health measures are applied most intensively, as in slaughterhouses, and food processing facilities.

Agencies concerned with food safety have devoted relatively few resources to the transportation and storage sectors of the food chain. There is an absence of data and information about whether adequate and appropriate food safety controls are being employed while food is being transported and stored. This lack of information does not by itself indicate the existence of a problem warranting regulatory intervention. However, FSIS and FDA need information about the transportation and storage of food if they are going to assure that the food safety risks associated with transportation and storage are properly identified and adequately addressed.

The United States annually experiences an estimated 6.5 to 33 million foodborne illness cases. These are largely associated with potentially hazardous foods that have become contaminated. In most cases of foodborne illness, post-processing temperature abuse or other mishandling contributed to the food hazard implicated in the illness. Such mishandling of potentially hazardous foods frequently occurs in food-service establishments and homes. However, food product abuse also may occur at earlier stages. In processing establishments, for example, equipment breakdowns, failure to adhere to appropriate time and temperature requirements, cross-contamination between raw and cooked product, and physical contamination by chemicals or foreign matter may render foods unsafe.

Although there is little empirical data on the extent to which conditions under which food is transported and stored contribute to safety hazards, there is anecdotal evidence. For example, a 1994 salmonellosis outbreak reported to have affected 224,000 people is believed by public health authorities to have been caused by cross-contamination of a pasteurized ice cream premix during transportation in tanker trailers that had previously hauled nonpasteurized liquid eggs.[1]

[1] Thomas W. Hennessy, M.D., et al. 1996. A National Outbreak of *Salmonella enteritidis* Infections from Ice Cream. *N. Engl. J. Med.* 334:1281–1286.

FSIS, in its continuous inspection of meat and poultry establishments, has found that some food spoilage can be attributed to mishandling during transportation, based on examination by inspectors of meat and poultry products returned to official establishments (''returned product'') that have been refused by a buyer or consignee. The amount of returned product may serve as an index of the amount of spoiled foods that may be in transportation channels, but the Agencies do not know how much potentially hazardous food that is spoiled is returned or otherwise handled.

Only a very small percentage of meat or poultry product that is shipped from a federally inspected establishment is returned to the establishment. FSIS staff officers estimate that perhaps one-tenth of this returned product was returned because of a problem that developed during transportation. This seems generally true for imported meat and poultry products, as well as domestically produced products. In 1994, FSIS rejected nearly 14 million pounds (0.5 percent) of imported meat and poultry products, most commonly for processing defects, contamination, unsound condition, and transportation damage. This rejection rate is roughly equivalent to the rejection rate of product produced in the United States.

Returned product must go back to the establishment where it was prepared and must be received in a designated area for reinspection. Although many plants are permitted to handle such products under their own quality-control program, inspectors routinely evaluate establishment records on returned product to ensure they are complete and accurate, and show that the establishment has sorted and otherwise taken all corrective action necessary to ensure proper disposition of the product. The inspectors also supervise condemnation of unwholesome or misbranded product.

From time to time, foreign countries to which U.S. meat and poultry exports are sent have rejected U.S. product that has become spoiled because of transportation or storage failures. Such problems have the potential to cause, or contribute to, serious trade disruptions. In 1994, Russia refused to accept shipments of United States-produced poultry alleged to be ''off-condition'' and unfit for food purposes. The poultry had apparently been allowed to thaw at some point between shipment from the processing plant and receipt by the importer. Similar cold storage problems involving pork shipments to the same country had occurred some years earlier.

Similarly, there have been occasional, documented instances of careless handling and transportation of meat and poultry within the U.S. These generally involve inadequate refrigeration or exposure to physical hazards.

There appears to be increasing public awareness of the possibility that food might become contaminated during shipment. From time to time, Congress has expressed concern that gaps in the regulatory coverage of food during transportation in commerce ought to be filled. For example, in 1990 Congress passed the ''Sanitary Food Transportation Act'' that required the Secretary of Transportation, in consultation with the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency, to issue regulations with respect to the transportation of food products in motor vehicles or rail vehicles that are also used to transport nonfood products that could make food subsequently shipped in the vehicles unsafe.[2] (Pub. L. 101–500; 49 U.S.C. app. section 2801 *et seq.*) Although information on the extent of the practice was scarce, there were press accounts of trucks carrying food from the Midwest to both the East and the West Coasts and returning with garbage for Midwest landfills. It was feared that food products could become contaminated and unfit for human consumption if irresponsible vehicle operators failed to prevent contamination of food products in vehicles that had been previously used to haul waste or other non-food materials.

On May 21, 1993, DOT proposed regulations to implement the new law. The proposal addressed the safe transportation of food products during highway and rail transportation (58 FR 29698). Further action on the proposal is pending.

5. Data and Information Needed

FSIS and FDA are now attempting to develop better information on the nature and scope of food safety risks posed by transportation and storage practices. The Agencies would like, among other things, to develop reliable estimates of the number of cases of foodborne illness that are attributable to the abuse of potentially hazardous foods during transportation. Also needed are better data to determine whether current estimates of the annual number of shipments of potentially hazardous foods are accurate and to determine what types and amounts of such foods are transported by truck, rail car, airplane, or ship. FSIS and FDA would also like to obtain information about what controls are currently being used to ensure the safety of potentially hazardous food during transportation, for truck, rail car, airplane, or ship transports.

Additionally, the Agencies would like to know whether there are any special concerns relating to transportation of imported products. Further, the Agencies seek information from owners or operators of cold storage facilities, warehouses, depots, and similar kinds of businesses regarding the types and volumes of potentially hazardous foods that they handle and the controls that they use to ensure the safe storage of foods.

The Agencies have addressed some of these matters in the preliminary work on which this ANPR is based, but more precise information is needed.

Information and Accountability; Failure of the Market

Most large food companies conduct rigorous quality control operations to ensure, among other things, that the foods and food ingredients they purchase match contract specifications and will be suitable for use in the manufacture of their products. Many companies already operate HACCP systems to ensure the safety of the food products that they deliver to consumers.

Such companies enforce their own criteria for foods and food ingredients delivered to them. If refrigerated or frozen foods arrive at the receiving departments of these companies in an ''off'' condition, if they are spoiled or damaged, or if they fail lot acceptance inspections, the companies will not accept delivery. The company that shipped the product or the transporter may be liable for the costs of the unaccepted product, or the company that insured the shipment may be called upon to satisfy a claim.

However, to the extent that firms do not take actions that provide consumers with products of the level of safety that they desire, there exists a market failure. The most significant element of this market failure is lack of information for purchasers. Purchasers of potentially hazardous food products may lack information about products other than their appearance. Signs of spoilage, such as unpleasant odor or discoloration, may not be present to warn of possible safety concerns.

When foodborne illness does occur, it may often be difficult or impossible to trace the cause back to a specific source because some pathogens do not cause illness until several days or weeks after exposure. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of food. This information deficit also applies to wholesalers and retailers who generally rely on sensory tests—sight and smell—to determine whether a food is safe to sell or serve. Therefore, if food became contaminated because of a problem in transportation or storage, the receivers of the food might not know about it and might not be able to relate a resultant outbreak of foodborne illness to the problem.

Applicable Legal Authorities

Both the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) give the Secretary of Agriculture authority to regulate meat and poultry products in commerce. Specifically, the FMIA and PPIA authorize the Secretary to prescribe regulations covering the storage or other handling of meat or poultry products whenever the Secretary determines that regulations are necessary to assure that meat or poultry products are not adulterated or misbranded when they are delivered to the consumer (21 U.S.C. 624, 463). The statutes further state that no person may ''sell, transport, offer for sale or transportation, or receive for transportation'' in commerce any meat or poultry product that is capable of use as human food and is ''adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation * * *'' (21 U.S.C. 610(c), 661(c) and 454(c), 458(a)(2).) The statutes also prohibit any act with respect to such products, while they are being transported in commerce or held for sale after such transportation, ''which is intended to cause or has the effect of causing such articles to be adulterated or misbranded.'' (21 U.S.C. 610(d), 661(c) and 454(c), 458(a)(3).) These prohibitions, and Federal regulation and inspection generally, are applicable to operations and transactions conducted in commerce and to those conducted wholly within a state in those states that have been ''designated'' by the Secretary. See 21 U.S.C. 454(c) and 661(c). For a list of such states, see 9 CFR 331.2, 381.221. The Egg Products Inspection Act also has provisions concerning the sale and transportation in commerce of adulterated or misbranded eggs or egg products (21 U.S.C. 1037).

The Federal Food, Drug, and Cosmetic Act (FFD&C Act), administered by FDA,

[2] In July 1994, Congress passed Public Law 103–272, which revised Title 49 of the U.S. Code, including provisions for Sanitary Food Transportation (Chapter 57—Sanitary Food Transportation. (49 U.S.C. 5701 to 5714.)

prohibits the adulteration or misbranding of food in interstate commerce (21 U.S.C. 331(b)). The FFD&C Act also prohibits the introduction or delivery for introduction into interstate commerce, and the receipt in interstate commerce, of adulterated or misbranded food (21 U.S.C. 331(a) and (c)). Section 402(a)(4) provides that a food is deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (21 U.S.C. 342(a)). Section 701(a) authorizes FDA to promulgate regulations for the efficient enforcement of the FFD&C Act (21 U.S.C. 371(a)).

The Public Health Service Act (PHSA) authorizes the Secretary of Health and Human Services and, by delegation, FDA, to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State.'' (42 U.S.C. 264(a).) Communicable diseases are defined by FDA as illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment (21 CFR 1240.3(b)). With respect to food as a vector (carrier), infectious agents include *Listeria monocytogenes, Salmonella enteritidis, Vibrio vulnificus,* and similar pathogens. Moreover, FDA may take such measures as may be necessary to prevent the spread of communicable diseases, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection (42 U.S.C. 264(a)).

These statutes give FDA the authority to establish regulations concerning foods in interstate commerce, including regulations governing the transportation and storage of such foods.

The Sanitary Food Transportation provision also provides authority to regulate the transportation of food (49 U.S.C. 5701 to 5714). However, FSIS and FDA regard some of the potential food safety issues associated with previous cargoes as involving more than just nonfood products regulated by DOT. It seems clear that all types of prior cargoes need to be addressed, not just nonfood products. Thus, this ANPR seeks information on the appropriate mechanism for addressing prior food cargoes. FSIS and FDA seek comment on how DOT requirements for food transportation conveyances that also haul nonfood items, under its Sanitary Food Transportation statutory provisions, might be complemented by additional FSIS/FDA requirements.

FSIS and FDA believe existing statutory authorities are ample to support the regulatory initiative being considered to regulate the safe and sanitary transportation of potentially hazardous foods.

Alternatives Considered

Because transportation and storage are vital links in the farm (or seafood harvest)-to-table food chain, the success of a comprehensive, farm (or harvest)-to-table food protection strategy requires that effective preventive measures be taken to ensure the safe transportation and storage of food. FSIS and FDA are considering several alternatives for addressing the safety of potentially hazardous foods during transportation and storage. These alternatives include specific requirements, such as temperature standards, performance standards, recordkeeping to ensure that food safety controls are maintained, mandatory HACCP-type systems, voluntary guidelines, and combined approaches.

Regardless of the alternative, one constant is the need for personnel who understand the importance of handling food cargoes safely and who know how to do it. All persons involved in transporting and storing foods need to recognize that contaminated foods can cause illness and that microbes can spoil or poison foods. It is important that they recognize that vehicles must be adequately cleaned, and they should know how to accomplish this task. They should understand the influence of temperature on product quality and microbial growth and the importance of controlling insects and rodents. Government and industry can both play a role in ensuring that essential knowledge is provided to those who need it.

1. Temperature Performance Standards

One approach is the promulgation of a performance standard that would require that potentially hazardous foods be cooled to and maintained at or below a specific temperature during transportation and storage from the food processing plant to the retail outlet, restaurant, or other establishment serving the consumer. If this approach is adopted, all potentially hazardous foods being transported to retail or food service establishments would have to be maintained at or below such a maximum temperature.

In its February 1995 Pathogen Reduction/HACCP proposal, FSIS proposed various requirements for chilling and cooling meat and poultry products. The proposal included specific time and temperature parameters for the rate of cooling meat and poultry carcasses in slaughtering establishments and a maximum shipping temperature of 40 °F for raw meat and poultry products leaving FSIS-inspected establishments. FSIS agreed with commenters that keeping raw products cooled after they leave the establishment and during transportation, storage, distribution, and sale to consumers is essential to prevent growth of pathogenic microorganisms on raw products.

The Agencies have considered at least two possible maximum temperatures as appropriate for this kind of performance standard. The first is 41 °F. This standard is consistent with the temperature recommended by the 1995 Food Code for cooling and holding (including during transportation) potentially hazardous food. It would provide a margin of safety to prevent the multiplication of pathogenic bacteria, which generally will not proliferate at temperatures below 50 °F.

A second temperature limit being considered is 45 °F. This temperature would provide a smaller margin of safety but would comport with the temperature established by the European Union [3] for the transportation, in commerce, of raw meat products. This temperature is increasingly accepted as a standard for potentially hazardous foods during storage and transportation by other countries and appears to be an emerging standard for international trade. Comments are invited on these potential performance standards and on any other appropriate temperature standard applicable to specific commodities.

Relevant to this discussion is the 1991 Farm Bill legislation that provided for a 45 °F ambient air shipping and storage temperature requirement for shell eggs. USDA proposed, but has not promulgated, regulations to implement that requirement. FSIS is concerned that the rule as proposed could impose significant costs, especially on small business entities, but achieve no clear public gains in food safety protection. Available evidence indicates that the key factor in determining bacterial

[3] ''Agreement on International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for Such Carriage (ATP)'' (Geneva, September 1, 1970) (Annex III).

growth in shell eggs is how long eggs leaving laying farms stay warm. The effect of cool ambient air temperatures on packed and crated shell eggs during transport and distribution is difficult to ascertain, even if the ambient temperature is 45 °F (however measured). FSIS's approach to temperature requirements for shell eggs is similar to its approach to the cooling of red meat carcasses. FSIS has decided that before it can impose temperature requirements, it must have better data and information on the food safety effects of temperature controls at all phases of production and distribution.

Temperature-based performance standards might include the use of a recording thermometer or other means to ensure compliance with the standard. A temperature performance standard might be complemented by some requirement that would permit processors to determine the acceptability of a food transport vehicle for the transport of bulk foods that pose a risk of communicable disease, as discussed below. This might be based on a review of transporters' prior cargo records.

FSIS and FDA anticipate that Federal standards governing proper transportation and storage for potentially hazardous foods and other food safety practices would be, to some extent, self-enforcing. In the view of FSIS and FDA, large commercial purchasers of such foods, such as retail grocery store chains, are likely to incorporate such standards in their purchasing specifications and would enforce them through routine quality assurance and product acceptance procedures. The Agencies request comment on the extent to which such Federal standards are likely to achieve and safeguard public food safety objectives with a minimal enforcement effort.

The merits of any temperature standards, and alternative approaches for preventing temperature abuse and achieving appropriate product temperature controls during transportation and storage of all potentially hazardous foods, are topics for discussion at the joint FSIS–FDA technical conference held November 18–20, 1996, in Washington, D.C.

2. Shipper Recordkeeping

The Agencies might also consider recordkeeping requirements with respect to the conditions under which foods that pose a risk of being vectors for the spread of communicable disease are transported interstate, to help prevent contamination and cross-contamination of certain food cargoes. Relying on the relevant statutory authorities, the Agencies may consider requiring carriers of potentially hazardous foods that are shipped in bulk (foods which directly contact a food conveyance) to provide food shippers with records that identify the last three cargoes for any conveyance being offered to the food shipper for use in transporting the food and that disclose the data of the most recent cleaning of the conveyance.

FDA and FSIS request comments on the feasibility and effectiveness of this approach for ensuring the availability of information needed to assess potential contamination from prior cargoes in a transportation vehicle.

3. Mandatory HACCP-type Systems

Another approach that could be taken would be to require that a HACCP system be established specifically with respect to the transportation and storage of potentially hazardous foods to prevent the contamination of these foods, although, as noted earlier, comments on the FDA and FSIS HACCP rulemakings were negative on requiring HACCP for transportation and storage. Such requirements could be modeled on the regulations recently adopted by FSIS and FDA that apply to establishments that process meat, poultry, and seafood.

Such HACCP-type systems would probably be relatively simple. Essentially, they would likely require that potentially hazardous foods be maintained at a particular refrigeration temperature or frozen temperature, and that the temperature be recorded using a recording thermometer. The use of a temperature performance standard would allow processors to determine the acceptability of a food transport vehicle for the transport of certain bulk foods, i.e., those that pose a risk of communicable disease, based on cargo records.

Personnel involved in the implementation of the HACCP-type systems would have to be knowledgeable about product vulnerabilities and be trained in HACCP principles, the development, reassessment, and modification of HACCP plans, and record review. If this option were pursued, the Agencies would consider the development of model HACCP plans or other guidelines that could be used by transportation and storage companies in developing their own HACCP plans.

4. Voluntary Guidelines

Another approach under consideration is to make more use of voluntary guidelines. FSIS and FDA are aware that some government agencies, industry groups, and other organizations have published guidelines or recommended practices that address the transportation and storage of potentially hazardous foods, whether fresh or frozen. Such guidelines could serve as the basis for developing joint Government-industry guidelines for food transportation and storage.

For example, the Association of Food and Drug Officials (AFDO), a voluntary organization of State and local food regulatory officials, in its publication entitled ''Guideline for the Transportation of Food,'' states that during transportation, potentially hazardous food should be maintained at 45 °F or below. The AFDO guideline states that frozen food should be held at an air temperature of 0 °F or below and should not exceed a product temperature of 10 °F for more than a short period of time during transportation. The use of an easily accessible temperature-recording device is recommended for measuring air temperature in the transportation vehicle. Maintaining the proper food temperature is one of AFDO's four major food transportation measures for ensuring food safety. The remaining measures cover the use of good sanitation practices, good personal hygiene of food employees, and adequate transportation equipment.

The Frozen Food Round Table, a trade organization, in its publication entitled ''Frozen Food Handling and Merchandizing'' presents several recommended practices for transporting and storing frozen foods. These practices include maintaining product temperature at 0 °F or colder and use of a recording device to accurately measure the air temperature inside the transportation vehicle.

In September 1995, USDA's Agricultural Marketing Service (AMS) published a revised version of its handbook ''Protecting Perishable Foods During Transport by Truck.'' The handbook contains recommendations for loading and transporting various food commodities. In the handbook, AMS states that maintaining the desired or ideal holding temperature is a major factor in protecting perishable foods against quality loss during transportation and storage. The handbook also presents recommended temperatures for holding meat, poultry, fresh fish, and other commodities during transportation.

The Interstate Shellfish Sanitation Commission also has published a manual that provides appropriate temperatures for shipping shellfish.

The International Dairy Foods Association (IDFA) is carrying out a

long-term strategy for ensuring product safety that focuses primarily on HACCP but that also depends for its effectiveness on a series of prerequisite good manufacturing practices (GMP's). The association has developed a manual that is product-oriented and product-specific and contains model HACCP programs for such product categories as fluid milk, ice cream, cheese, and yogurt.

Finally, the HACCP systems that have been implemented voluntarily by some major food service companies provide time, temperature, sanitation, and contamination critical limits to be applied at critical control points such as at shipping and receiving locations and aboard transport vehicles. For example, there are temperature critical limits for trailers that haul refrigerated and frozen foods, procedures for daily monitoring of compliance with these criteria, and documentation of findings and any necessary corrective action.

All these organizations could participate in the development of guidelines for various products. The Federal Government, possibly in cooperation with the States, could provide technical advice and assistance in the development of such guidelines. Since the transportation and storage ''gap'' in regulatory coverage is similar at the Federal and the State levels, such an approach might be useful.

5. Combination of Approaches

The Agencies intend also to consider some combination of the above-discussed approaches. For example, time/temperature performance standards could be required along with mandatory HACCP-type systems. By specifying critical limits—such as the maximum temperature—to be met in handling, storage, and shipping potentially hazardous foods, there would be some degree of uniformity among processors in measures that they take to ensure the safety and quality of that food while it is being transported and stored.

The combination of a performance standard, such as a time-temperature standard, with voluntary transport and storage ''good practice'' guidelines on how to achieve that standard would probably be regarded as the most flexible option, though not necessarily the least burdensome of the approaches that involve regulation. Some of the voluntary guidelines mentioned above, such as the IDFA and the AFDO guidelines, make specific time/temperature recommendations or cargo handling procedures intended to prevent physical, biological, or chemical contamination. Some involve the voluntary implementation of HACCP systems. The voluntary guidelines therefore cover many of the recommendations considered in this ANPR as possible regulatory requirements.

Thus, the use of voluntary guidelines would not necessarily be less burdensome to the industry than regulation-based alternatives. The major disadvantage is the reduced ability of the agencies to assure uniformly effective adoption of the guidelines by transportation and storage facilities and the consequent achievement of food safety goals.

6. Alternative of No Federal Regulatory Initiative

This alternative would mean that the Agencies would rely only on enforcement of current laws and regulations. Both Agencies have the authority to detain or seize adulterated and misbranded food products that are in interstate commerce. The Agencies could, for example, take action on a cargo of potentially hazardous food that is found to be in an off-condition, that is contaminated with some deleterious substance, or that is being held at too high a temperature. Depending on the type of cargo, the food could be detained based on evidence of adulteration and be allowed to be returned to the establishment that produced it, or it could be subject to Government seizure. However, actions of this sort are inefficient ways to encourage safe food handling practices and can involve the Agencies and food companies in costly court actions. Worse, they are merely reactive. Although they may have some deterrent effect on the mishandling of foods, they do not address the underlying causes of the problem.

The Agencies could, and would, continue to promote food safety practices through public information and consumer education, directing their efforts, to the extent possible and appropriate, to food transporters and storage facility operators. The effectiveness of these efforts, however, would depend on the industry also being an advocate for good food storage and handling practices and comprehensive preventive approaches.

Comparison of Alternatives

FSIS and FDA would appreciate comments on the following: Which of the alternatives presented seem most likely to contribute to achieving the goal of reducing the risk of foodborne illness associated with the consumption of potentially hazardous foods? Which of the alternatives is both feasible and is most likely to prevent food safety hazards from arising during transportation and storage? Which would be most effective and which least? Which would allow industry the greatest flexibility in adopting technologies or developing other means to prevent food safety hazards or reduce the likelihood they will occur? Which would be most likely to encourage the adoption of new technologies, such as improved refrigeration methods, more efficient insulated trailers, more accurate thermography, and state-of-the art vehicle tracking and communications?

1. Approach to Regulatory Compliance

FSIS and FDA also seek comments on what roles the Federal, State, and local jurisdictions should play in regulating the transportation and storage of potentially hazardous foods. This is particularly important in light of increasingly tight budgets affecting FSIS, FDA, the States, and local jurisdictions, and the consequent need to ensure that all public resources devoted to the common goal of food safety are used in a coordinated way that maximizes public health protection while minimizing public costs.

2. Balancing of Interests and Limitations

Any option involving additional regulation of the conditions under which potentially hazardous foods are transported and stored will necessarily involve investment of a larger proportion of the Agencies' resources to monitoring the transportation and storage of food, compared with resources presently allocated to those activities. Assuming at best no real growth in the Agencies' budgets, it may be necessary to shift resources from in-plant inspection and other activities to the examination of food transportation and storage. Reallocations of personnel would entail judgments on the benefits of making new assignments. Ideally, the Agencies believe, judgments on how best to allocate static or declining resources would be based primarily on assessments of relative risks to public health. Therefore, any such shift of resources would require careful analysis of relative risks to consumers that derive from transportation and storage operations, compared with the risks that derive from food processing and other activities.

Thus, for example, new information may dictate that FDA and FSIS inspectors and FSIS compliance officers be assigned to new tasks to verify compliance with any requirements that apply to the conditions under which potentially hazardous food is

transported by land, air, or sea, or is stored.

Therefore, the agencies would appreciate comments on how best to balance competing demands on Government resources. That is, assuming that the general goal of the Agencies is to achieve maximum food safety protections throughout the farm (pre-harvest)-to-table continuum, is it reasonable for the Agencies to redeploy their personnel and other resources to achieve such additional coverage?

Alternatively, if an option not involving regulation were chosen, such as industry agreements to abide by voluntary guidelines, should the Agencies nonetheless redeploy resources to increase the monitoring of potentially hazardous foods during transportation and storage under their existing authorities to prevent the distribution in commerce of adulterated or misbranded foods?

Of course, Government regulation is rarely more than a part of the solution. The primary responsibility for protecting the safety of food products in distribution channels rests with those in that business—in this case, those who buy and sell, handle, and store, and are responsible for the shipment of potentially hazardous foods.

This responsibility argues for an alternative that involves a strengthening, by industry itself, of the control systems that they utilize. An alternative that induced a more widespread application of available technologies, such as improved refrigeration, thermography, and vehicle tracking and communication systems, could result in efficiency gains to industry and reduced risk to consumers.

3. Costs and Benefits

Companies that institute a HACCP-type system or other control system where such systems are not already in operation would incur one-time direct costs to implement a control system. These costs would include those of setting up the needed documentation, tracking, inventory control, or other systems, and one-time costs of training personnel to operate them. For temperature monitoring, the cost of acquisition of thermometric equipment and temperature recording devices could also occur.

For any alternative that might involve the application of new technologies, the cost to industry of implementing the technologies would have to be considered. Such direct costs could be offset by the benefits of such technology gains as those from: improved thermography, improved temperature control; trailers made with lighter and more effective insulating materials, more fuel-efficient refrigeration; improved thermographic equipment, more accurate temperature monitoring and control; and from improved vehicle tracking and communication, more efficient and effective delivery with less product loss. The benefits of these technologies can reduce transit time and risk and provide shippers, receivers, and consumers with fresher, higher quality products.

Because of the Agencies' interest in reducing foodborne illness, the Agencies would appreciate data or information on the control or reduction in microbial populations that the application of new technologies could produce. Of special value would be information relating to predictive modeling of time, temperature, and microbial growth under conditions in which the technologies might be applied.

The costs to the Agencies of increased oversight over food transportation and storage would include costs associated with increases in personnel travel, costs for training of personnel in oversight techniques, and costs (mostly one-time) related to personnel reassignments.

The ultimate beneficiaries of a regulatory or non-regulatory initiative in the transportation and storage area would be the general public, to the extent that the initiative resulted in a reduction of foodborne illness. There would be additional tangible and intangible benefits. For some companies, increased reliance on quality control or HACCP-type systems could result in improved product tracking and inventory control, reduction in product loss, and overall efficiency gains. An intangible benefit, increased confidence in the food supply among both domestic and foreign purchasers, could lead to indirect tangible benefits for processors, distributors, and producers, in the form of increased sales.

Information Needed for Regulatory Analyses

As a general matter, when developing new regulations, regulatory agencies take into consideration many factors. FDA and FSIS consider, among other things, the costs of enforcement and compliance (to the Government, regulated entities, and the public) of new regulations. FSIS and FDA also consider, where appropriate, alternative ways of achieving an objective and where applicable, the risks addressed by an intended regulation. The factors the Agencies consider are set forth in statutes and other authorities.

Executive Order 12866 provides that to the extent permitted by law and where applicable, agencies should adhere to certain principles of regulation. These principles include considering to the extent reasonable, in setting regulatory priorities, the degree and nature of the risks posed by various activities within an Agency's jurisdiction. Under the Executive Order, agencies also examine whether an intended regulatory action would be significant. A regulatory action could be considered to be significant for a number of reasons, including if it were determined to have an annual effect on the economy of $100 million or more.

The Regulatory Flexibility Act (RFA), recently amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA, PL 104–121; 5 U.S.C. 601 *et seq.*), requires assessment of a proposed regulation's economic impact on small entities, which includes small businesses and other small entities, including local governmental units. Agencies are required under the RFA to determine whether a proposed regulatory action would have a significant economic effect on a substantial number of small entities. If it is determined that it would have such an impact, an initial regulatory flexibility analysis is published that discusses various issues including an estimate of the number of small entities to which the proposed rule will apply, the rule's projected reporting, recordkeeping, and compliance requirements, and significant alternatives that would accomplish the stated objectives of an applicable statute which minimize any significant economic impact of the proposed rule on small entities. At the final rule stage, a final regulatory flexibility analysis is published.

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1531 *et seq.*) requires consideration of the possibility that regulatory or other resource-intensive burdens are being imposed by the Federal government without providing for funding to accomplish the mandated function.

FSIS also is required to conduct a risk analysis under the Federal Crop Insurance Reform Act and Department of Agriculture Reorganization Act of 1994 (Pub. L. 103–354, 7 U.S.C. 2204e) to ensure adequate risk assessment and cost benefit analysis for major proposed regulations whose primary purpose is to regulate issues of human health, human safety, or the environment. Under this Act, a major rule is defined as a rule that is likely to have an annual impact on the economy of the United States of $100 million.

Therefore, the Agencies would also use the information requested earlier in this document to help them conduct any risk assessment that may be needed. Especially useful would be information on the following for potentially hazardous foods: (1) The probability of occurrence of hazards in potentially hazardous foods at the beginning of transportation; (2) the hazards that could be introduced or spread during transportation, and the magnitude of these hazards; (3) the occurrence of factors such as improper cooling and temperature maintenance that could increase the probability and/or magnitude of microbial hazards; (4) the probability of occurrence of hazards in potentially hazardous foods at the end of the transportation segment; and (5) the probability of occurrence and magnitude of human foodborne illnesses that can be directly or indirectly attributed to the transportation of potentially hazardous food.

The Agencies also need information about the businesses that may be affected by any of the alternatives being considered in order to assess their potential costs and benefits on small entities under the RFA. Businesses of concern would include establishments that process and ship meat, poultry, eggs, seafood, and other potentially hazardous foods, motor freight companies, food storage warehousing operations, air freight companies, and water transport firms.

Under the Small Business Administration regulations, a small entity in the motor freight and warehousing category is one whose annual receipts are no greater than $18.5 million. A small entity in the category that includes air freight or railroad transportation is one with no more than 1,500 employees. A small entity in the categories of water transportation or food processing is one that employs no more than 500 people.

Finally, the agencies are requesting relevant environmental information because under the National Environmental Policy Act (42 U.S.C. 4332), the individual or cumulative effect of regulations on the human environment needs to be considered. The agencies do not now possess the data that would permit detailed analysis of any environmental impacts of the alternatives described in this document. Therefore, information on potential environmental impacts is also requested, including: (1) the potential for increased energy consumption that may result either from the need to increase refrigeration during transportation of food or from the use of more trucks to avoid transporting food in trucks that had previously held cargoes that could affect food safety, (2) increased disposal of defective foods, (3) new or increased use and disposal of sanitizing products, and (4) a description of measures that could be taken to avoid or mitigate adverse environmental impacts that might result from this action.

Done at Washington, DC, on: November 18, 1996.

Thomas J. Billy,

Administrator, Food Safety and Inspection Service.

William B. Schultz,

Deputy Commissioner for Policy, Food and Drug Administration.

[FR Doc. 96–29837 Filed 11–18–96; 5:08 pm]

BILLING CODE 3410–DM–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Small Business Size Standards; Waiver of the Nonmanufacturer Rule

AGENCY: Small Business Administration.

ACTION: Notice of intent to waive the Nonmanufacturer Rule for Routers and Switches.

SUMMARY: The Small Business Administration (SBA) is considering granting a waiver of the Nonmanufacturer Rule for Routers and Switches. The basis for a waiver of the Nonmanufacturer Rule for this product is that there are no small business manufacturers or processors available to supply these products to the Federal Government. The effect of a waiver would be to allow an otherwise qualified Nonmanufacturer to supply other than the product of a domestic small business manufacturer or processor on a Federal contract set aside for small businesses or awarded through the SBA 8(a) Program. The purpose of this notice is to solicit comments and potential source information from interested parties.

DATES: Comments and sources must be submitted on or before November 29, 1996.

ADDRESSES: David Wm. Loines, Procurement Analyst, U.S. Small Business Administration, 409 3rd Street S.W., Washington, DC 20416, Tel: (202) 205–6475.

FOR FURTHER INFORMATION CONTACT: David Wm. Loines, tel: (202) 205–6475.

SUPPLEMENTARY INFORMATION: Public law 100–656, enacted on November 15, 1988, incorporated into the Small Business Act the previously existing regulation that recipients of Federal contracts set-aside for small businesses or the SBA 8(a) Program procurement must provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor. This requirement is commonly referred to as the Nonmanufacturer Rule. The SBA regulations imposing this requirement are found at 13 CFR 121.406(b). Section 303(h) of the law provides for waiver of this requirement by SBA for any ''class of products'' for which there are no small business manufacturers or processors in the Federal market. To be considered available to participate in the Federal market on these classes of products, a small business manufacturer must have submitted a proposal for a contract solicitation or received a contract from the Federal Government within the last 24 months. The SBA defines ''class of products'' based on two coding systems. The first is the Office of Management and Budget Standard Industrial Classification Manual (SIC). The second is the Product and Service Code (PSC) established by the Federal Procurement Data System.

The Small Business Administration is currently processing a request for a waiver of the Nonmanufacturer Rule for Routers and Switches (SIC 3661, PSC 5805) and invites the public to comment or provide information on potential small business manufacturers for this product.

In an effort to identify potential small business manufacturers, the SBA has searched the Procurement Automated Source System (PASS) and *Thomas Register,* and the SBA will publish a notice in the Commerce Business Daily. The public is invited to comment or provide source information to SBA on the proposed waiver of the Nonmanufacturer Rule for this class of products.

Dated: November 4, 1996.

Judith A. Roussel,

Associate Administrator for Government Contracting.

[FR Doc. 96–29879 Filed 11–21–96; 8:45 am]

BILLING CODE 8025–01–P

13 CFR Part 121

Small Business Size Standards; Waiver of the Nonmanufacturer Rule

AGENCY: Small Business Administration.

ACTION: Notice of intent to waive the Nonmanufacturer Rule for 8mm Tri-Deck Airborne Recorder (ruggedized).

SUMMARY: The Small Business Administration (SBA) is considering