Proposed Rules

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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 Chapter III

[Docket No. 95–026N]

Redesigning FSIS for the Future: Roles, Resources, and Structure

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: As part of its overall initiative to improve the safety of meat and poultry products and better protect consumers, the Food Safety and Inspection Service (FSIS) is conducting a ''top-to-bottom'' review of the Agency's regulatory roles, resource allocation, and organizational structure. The review is intended to ensure that the Agency is making the best possible use of its resources to achieve its food safety and consumer protection goals, consistent with its new food safety strategy and budget realities.

ADDRESSES: For comments, send an original and two copies to the FSIS Docket Clerk, Room 4352, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Comments are welcome on a continuing basis.

FOR FURTHER INFORMATION CONTACT: Jeanne Axtell or John McCutcheon, Top-to-Bottom Review Coordinators, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 350–E, Administration Building, Independence Ave., Washington, DC 20250, (202) 720–3521 or (202) 720–2709, respectively.

SUPPLEMENTARY INFORMATION:

Background

FSIS's Food Safety Strategy

FSIS is pursuing a broad, long term science-based strategy to improve the safety of meat and poultry products and better protect public health. The strategy includes proposed requirements for all federally inspected meat and poultry establishments to reduce pathogenic microorganisms that can cause foodborne illness. The proposal, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' (60 FR 6774–6889, published February 3, 1995), would require implementation of mandatory HACCP programs in meat and poultry establishments, would set interim targets for pathogen reduction in slaughter establishments and require microbial testing to meet those targets, and would require establishments to implement three near-term food safety interventions.

The goal of the proposal is to reduce the risk of foodborne illness associated with meat and poultry products to the maximum extent possible. The industry would be required to adopt procedures that systematically prevent food safety hazards and to meet food safety performance standards. The changes would improve FSIS's capacity to hold industry accountable for following preventive procedures and for meeting appropriate food safety standards.

The FSIS food safety strategy will require change in meat and poultry establishments, but it will also require change within FSIS. The Agency is conducting a total review of its food safety regulations to bring them into accord with the HACCP principles reflected in the regulatory proposal. The goal of this review is to eliminate unnecessary ''command and control'' regulations that spell out in minute detail how establishments must operate. FSIS believes it is preferable to set performance standards based on current science and, within the context of HACCP and the philosophy of prevention, allow the industry to decide how it can best meet the standards. This shift will encourage industry innovation to improve food safety and eliminate unnecessary requirements and regulations.

The Agency is also reviewing all of its systems for prior approval, such as those for facilities, equipment, and processing changes, to consider eliminating, streamlining or modifying them. This activity is necessary to ensure that legitimate oversight obligations are met without delaying the introduction of beneficial new technologies or requiring unproductive expenditure of efforts by FSIS or the industry.

Top-to-Bottom Review of Roles, Resources, and Structure

To achieve its food safety and consumer protection goals, FSIS must also ensure it is making the best use of its resources to carry out its responsibilities under a HACCP-based strategy that recognizes food safety must be addressed from farm to table. Less emphasis will be placed on the policing of detailed command and control requirements. More emphasis will be placed on verifying that industry has implemented HACCP and is achieving food safety performance standards. In addition, FSIS regulatory roles outside the currently inspected meat and poultry establishments will expand. The fundamental paradigm shift embodied in this food safety strategy, coupled with the reality of very tight government budgets, compels FSIS to critically review and, where necessary, change its regulatory roles, resource allocation, and organizational structure.

The purpose of the top-to-bottom review is to define for the future the Agency's regulatory roles, resource allocation, and organizational structure in a manner consistent with the goals and strategies of the Pathogen Reduction/HACCP regulation.

For the purposes of the review, FSIS will assume no major change in resources and no major changes in the current statutory mandates under which the Agency operates. FSIS recognizes that these variables are always subject to Congressional review and change, but the Agency also recognizes its urgent obligation, within its current resources and statutory structure, to improve food safety. Improving food safety requires a hard look at how FSIS does its job, and it requires answering three broad questions.

—What should be the Agency's regulatory roles and what are the skills needed to carry out these roles?
—How should the Agency's resources be allocated to best meet its food safety objectives and other responsibilities that fall under FSIS's legislative mandate?
—How should the headquarters and field structures be organized, in light of FSIS's new food safety strategy, to carry out the Agency's mission most effectively and efficiently?

To answer these broad questions and make practical recommendations for change, the review has been organized

around three areas—regulatory roles, resource allocation, and organizational structure—and teams have been formed within each area to achieve the following objectives.

Regulatory Roles

The overall objective is to determine the regulatory roles that should be used in a HACCP environment to hold industry accountable for meeting its food safety and other consumer protection responsibilities.

—Determine the best regulatory approaches, tools, and techniques that could be used to ensure food safety in establishments operating HACCP systems.

—Determine the best regulatory approaches, tools, and techniques that could be used to ensure that products are properly labeled, not misbranded, and not economically adulterated both in establishments and between the establishments and the marketplace.

—Determine strategies to ensure that food safety programs are functioning at points in the farm-to-table continuum other than at the in-plant level.

—Determine what knowledge, skills, abilities, and training are necessary to carry out FSIS roles at the different points along the farm-to-table continuum.

—Determine strategies and techniques to better define the distinct roles and responsibilities of FSIS and industry in ensuring food safety.

Resource Allocation

In light of the Agency's goal to reduce foodborne illness, the overall objective is to determine the optimal allocation of Agency resources.

—Determine the optimal allocation of resources between health and safety activities and economic adulteration, labeling, and misbranding activities.

—Determine how to build flexibility into the resource allocation system.

—Determine what support activities are best performed in the field or at headquarters.

—Determine what level of laboratory activities is necessary for regulatory oversight of industry operations and what testing responsibilities should be best undertaken by the industry and by FSIS.

Organizational Structure

The overall objective is to determine the optimal structure needed for headquarters and the field to carry out the goals and strategies of the pathogen reduction/HACCP regulation and to administer the program of the future.

—Examine options for administrative streamlining in line with the goals set by the Administration and the reinvention objectives outlined in the National Performance Review.

—Determine from what location (field, headquarters, or other central location) various FSIS program and administrative support activities are most likely to be effectively and efficiently carried out.

—Determine how policy and regulation development activities can be better managed within the Agency.

—Determine the nature of supervisory and managerial responsibilities and examine better methods for delivering technical information.

The Top-to-Bottom Review Project

The top-to-bottom review project is designed to determine what changes must be completed within 2 to 4 years to implement the proposed regulation for pathogen reduction and HACCP systems.

Communication will be an integral part of the review process. Information will be provided regularly to employees and constituent groups to let them know what activities are ongoing, why these activities are being carried out, how employees and the various groups will be affected, and how they can become involved in the process. The Agency will ensure that the broadest possible input is received from employees and constituent organizations.

A review group composed of several teams has been assigned to each question above. The teams expect to identify the major issues and potential options related to changes in roles, resources, and structure by late summer. At that time, FSIS plans to solicit feedback from its internal and external constituencies on those issues. The Agency will consider these comments as it decides what changes to make to align itself with its public health, food safety, and consumer protection goals. FSIS expects to make decisions on many of these changes by the end of the calendar year, when the Agency expects to finalize the proposed rule ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems.''

FSIS welcomes any comments on the initiatives announced in this notice (See **FOR FURTHER INFORMATION CONTACT**).

Done at Washington, DC on: June 14, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1270

[Docket No. 93N–0453]

Screening and Testing of Donors of Human Tissue Intended for Transplantation; Draft Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Screening and Testing of Donors of Human Tissue Intended for Transplantation.'' This draft document is intended to provide additional opportunity for individuals to submit comments on screening and testing of donors of human tissue for transplantation. The availability of the draft document is to coincide with the workshop on Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives to be held June 20 and 21, 1995, in Bethesda, MD. The workshop was announced in the **Federal Register** of May 24, 1995.

DATES: Written comments on the draft document should be submitted by July 20, 1995.

ADDRESSES: Single copies of the draft document will be made available to those attending the workshop. Persons not attending the workshop who would like to receive a copy of the draft document should submit a written request for single copies to the Congressional and Consumer Affairs Branch (HFM–12), Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests.

Persons with access to the INTERNET may request the draft document be sent by return E-mail by sending a message to ''TISSUE1@A1.CBER.FDA.GOV''. The draft document may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, ''CDV2.CBER.FDA.GOV''. The ''READ.ME'' file in that subdirectory describes the available documents,