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,