

**Location:** The meeting and the technical workshop will be held at the University of Maryland, Stamp Student Union Building "Atrium," College Park, MD.

**Contact:** Roberta Morales, VA—MD Regional College of Veterinary Medicine, University of Maryland, College Park, MD 20742-3711, 301-935-6083, ext. 158, FAX 301-935-0149.

**Registration:** Send registration information for both the meeting and the workshop (name, title, firm name, address, telephone and fax numbers) to Jacqueline M. Williams, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4224, FAX 202-205-4422, or register on-line at "<http://www.foodsafety.gov/~mow/jifsan.html>". There is no registration fee.

If you need special accommodations due to a disability, please contact Roberta Morales at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** On January 25, 1997, the President announced the National Food Safety Initiative. As a part of this initiative, the development of methods and models directed for enhanced food safety risk assessment, particularly for microbiological pathogens and their toxins were identified as priority needs.

Risk assessment characterizes the nature and magnitude of the risks to human health associated with hazards, and makes clear the assumptions and degree of scientific certainty of the data associated with risk estimates. Risk assessments require specific information on the hazard and on the exposed population to provide meaningful information for those making risk-management decisions. Although risk assessment methods are fairly well established for evaluating chemicals and contaminants in food, risk assessment is far less developed for foodborne pathogens. The May 1997 National Food Safety Report to the President noted that intensive commitment is necessary to develop critically needed methods for analyzing food safety data and addressing its uncertainty, and that methods that account for variability of living microbial pathogens are essential to focus public resources on risks that have the greatest consequences for human health.

A component of this effort has been the establishment of a joint Risk Assessment Consortium of Federal agencies with food safety risk-management responsibilities. The purposes of the consortium are: To advance the science of microbial food safety risk assessment; to serve as

advisors for direction and review of Risk Assessment Clearinghouse activities; and to assist agencies in fulfilling their specific food safety mandates. The consortium seeks to comprehensively cover risk assessment activities including solicitation of expertise from risk assessment professionals, scientists, and interested parties from government, industry, consumer organizations, and academia. As a means of assuring that the Risk Assessment Clearinghouse will meet the needs of the diverse clientele it is intended to serve, JIFSAN will take the lead role in the development of the clearinghouse and is seeking comments from interested parties at an open meeting and an open technical workshop. This input will be used to construct a draft framework document that will define the users and their needs, the scope, objectives, mechanisms, and output of the clearinghouse.

JIFSAN is a multi-disciplinary research and education program established by FDA and the University of Maryland in 1996. JIFSAN is a major component of the FDA food safety program's integration with academic institutions to create intellectual partnerships. The JIFSAN includes research and outreach components from the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the University of Maryland. JIFSAN combines resources from the primary Federal public health agency responsible for assuring the safety of the nation's food supply, a research university, and public and private partnerships to provide the scientific basis for assuring a safe, wholesome food supply. JIFSAN provides a neutral environment in which experts from industry, consumer and trade groups, international organizations, government, and academia can pool their resources and ideas to provide the scientific base for the development of sound public health policy.

The meeting and 2-day technical workshop are intended to ensure a wide cross-section of input. The August 7, 1998, meeting will share information on risk assessment applications in relation to food safety concerns by providing an overview of risk assessment and risk analysis, including an historical perspective, terminology, and approaches. Examples of current and potential applications in relation to food uses will be discussed. Through an open forum, input into the needs and expectations of clearinghouse users will be sought. The information obtained at this meeting will be used to help

develop a framework for the scope of clearinghouse activities.

At the October 5 and 6, 1998, 2-day technical workshop, an in-depth evaluation by food safety and risk assessment experts and the public of the adequacy of the overall draft framework will be addressed. The workshop will include breakout sessions on topics such as: Systems for cataloguing information; criteria for transparent evaluation of risk assessments; strategies to promote public involvement; solicitation and receipt of voluntary data from industry, government, and other interested parties; systems for protection of the anonymity of proprietary data; user access; information dissemination and output formats; infrastructure needs; implementation priorities; and customer service.

The outcome of the workshop will be a refined framework draft that will be used to guide further development of the clearinghouse. Further opportunities for comment and refinement will be provided.

Final program agendas will be posted on the JIFSAN web page at "<http://www.foodsafety.gov/~mow/jifsan.html>".

Dated: July 24, 1998.

**William K. Hubbard,**  
*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-20300 Filed 7-27-98; 4:44 pm]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Relating Numbers of Foodborne Pathogens to Human Illness; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing a public workshop sponsored by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). This public workshop is being held to explore issues essential to better the general understanding of the risk of illness associated with foodborne microorganisms. The workshop is intended to facilitate a scientific discussion that will serve as a basis for further dialogue with the greater scientific community in structuring approaches to dose-response modeling of foodborne pathogens.

**Date and Time:** The public workshop will be held on August 4, 1998, 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the University of Maryland, Stamp Student Union Building "Atrium," College Park, MD.

**Contact:** June A. Bradlaw, Center for Food Safety and Applied Nutrition (HFS-508), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 301-594-5883, FAX 301-594-0517.

**Registration:** Send registration information (name, title, firm name, address, telephone and fax numbers) to Jacqueline M. Williams, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4224, FAX 202-205-4422. Registration should be sent by August 3, 1998, or register on-line at "<http://www.foodsafety.gov/~mow/jifsan.html>". There is no registration fee for this workshop.

If you need special accommodations due to a disability contact June A. Bradlaw at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** On January 25, 1997, the President announced the National Food Safety Initiative. As a part of this initiative, a need was recognized for the development of methods and models for enhanced food safety risk assessment, particularly for microbiological pathogens and their toxins.

Risk assessment generally characterizes the nature and magnitude of the risks associated with hazards to human health, and helps to clarify the assumptions and degree of scientific certainty of the data associated with risk estimates. Risk assessments require specific information on the hazard and on the exposed populations to provide meaningful information to public health officials to develop and arrive at risk-management decisions. Although risk assessment methods are fairly well established for evaluating chemicals and contaminants in food, risk assessment is far less developed for foodborne pathogens. The May 1997 National Food Safety report to the President noted that an intensive commitment is necessary to fill this gap and develop critically needed methods for analyzing food safety data and addressing its uncertainty.

A component of this effort has been the establishment of a joint Risk Assessment Consortium of Federal agencies with food safety risk-management responsibilities. The role of the consortium is: To advance the science of microbial food safety risk assessment; to serve as advisors for direction and review of Risk Assessment Clearinghouse activities; and to assist

agencies in fulfilling their specific food safety regulatory mandates. Consistent with these goals, JIFSAN will host an open workshop that will explore issues requisite to quantifying the risk of illness associated with foodborne pathogenic microorganisms. Guidance in the development of this workshop has been provided by the Risk Assessment Consortium.

JIFSAN is a multi-disciplinary research and education program established by FDA and the University of Maryland in 1996. JIFSAN is a major component of the FDA's integration with academic institutions to create intellectual partnerships. JIFSAN includes research and outreach components from the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the University of Maryland. JIFSAN combines resources from FDA, the primary Federal public health agency responsible for the safety of the nation's food supply, an established research university, and public and private partnerships to provide the scientific basis for assuring a safe, wholesome food supply. JIFSAN provides a neutral environment in which experts from industry, consumer and trade groups, international organizations, government, and academia can pool their resources and ideas to provide the scientific base for the development of sound public health policy.

The goal of this workshop is to evaluate the current state of science for quantifying dose-response relations for foodborne pathogens and to identify opportunities and alternative sources of information that can be used to develop enhanced dose-response models for conducting microbial risk assessments. Broad areas to be discussed will include: (1) Current modeling of foodborne pathogenic microorganisms, (2) how traditional dose-response models can be adapted to provide better estimates of the severity and likelihood of illness due to foodborne pathogens, and (3) alternative approaches and sources of information for elucidating dose-response relations.

Speakers will consider scientific principles and methods that can be used or adapted to elucidate dose-response relations for microorganisms that are pathogenic in humans. This will include detailed discussion concerning how these relations can be modeled for use in microbial risk assessment. Discussions will focus on how these data, which are often developed for other purposes, can be useful for dose-response models. Emphasis will be placed on modeling susceptible

populations, use of animal models and improvement of methods of data collection.

The draft scientific agenda includes the following presentations: Classical and Modern Chemical Dose-Response Models—Concepts and Applications in Risk Assessment; Limitations of Current Dose-Response Models for use in Modeling Dose-Response for Pathogenic Microorganisms; Linking In Vitro, Animal and Human Studies Through Mechanisms of Pathogenesis; Correlating Host Resistance and Susceptibility With Biomarkers From In Vitro, Ex Vivo and Animal Models; Use of Epidemiological Data in Dose-Response Models; Estimation of Infective Dose Based on an Actual Outbreak Investigation; and Suitability of Small Human Clinical Studies to Measure Pathogenesis of Foodborne Pathogens. The agenda also includes open discussion periods during which participants will be encouraged to discuss the merits of different approaches for developing microbial risk assessment dose-response models and to identify additional approaches not identified in the formal presentations.

The workshop will serve as an initial foray into issues and questions surrounding the relationship between the numbers of pathogenic microorganisms consumed and the resultant illness. The workshop is intended to facilitate a scientific discussion that will serve as a basis for further dialogue with the greater scientific community in structuring approaches to dose-response modeling of foodborne pathogens.

The program agenda and workshop abstracts will be posted on the world wide web (WWW) at "<http://www.foodsafety.gov/~mow/jifsan.html>". Verbatim transcripts will also be posted on the WWW after the workshop.

Dated: July 24, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-20299 Filed 7-24-98; 4:44 pm]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0548]

### Draft Guidances for Industry on the Development of Antimicrobial Drug Products; Availability

**AGENCY:** Food and Drug Administration, HHS.