grant announcements in the Federal Register. Beginning October 1, 2005, applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: http://www.Grants.gov. Applicants will also be able to find the complete text at http://www.acf.hhs.gov/grants/index.html.

Please reference Section IV.3 for details about acknowledgement of received applications.

Dated: July 13, 2005. 
Josephine B. Robinson, Director, Office of Community Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Quantitative Risk Assessment on the Public Health Impact of Vibrio parahaemolyticus in Raw Oysters; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting to present the “Quantitative Risk Assessment on the Public Health Impact of Vibrio parahaemolyticus in Raw Oysters.” This public meeting is intended to provide clarification about the results of the risk assessment and information on how the risk assessment may be utilized. Stakeholders will have an opportunity to ask questions about the risk assessment. Questions may also be submitted in advance of the public meeting (see Contact section of this document). Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the risk assessment that is being presented at this public meeting.

Date and Time: The meeting will be held on August 15, 2005, from 12 noon to 3 p.m.

Location: The meeting will be held at the Grand Hotel Marriot Resort, One Oysters.

Registration and Requests for Oral Presentation: Send registration information (including name, title, firm name, address, telephone, and fax number), and written materials to the contact person by August 10, 2005. Interested persons may present data, information, or views orally or in writing, on the issue. If you desire to make a formal oral presentation, you should notify the contact person before August 10, 2005, and be prepared to give a brief description of the general nature of the information you wish to present. Time allotted for each presentation may be limited.

If you need special accommodations due to a disability, please contact Melissa Ellwanger at least 7 days in advance of the meeting.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HF1–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: July 8, 2005.

Jeffrey Shuren, Assistant Commissioner for Policy.

Food and Drug Administration


Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus in Raw Oysters; Risk Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a risk assessment entitled “Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus in Raw Oysters.” The quantitative risk assessment will help the agency evaluate risk mitigation strategies and develop effective guidance for the industry. Elsewhere in this issue of the Federal Register, FDA is announcing a public meeting to provide clarification about the results of the risk assessment and information about how the risk assessment may be utilized.

Address: Submit written requests for single copies of the risk assessment document and CD–ROM of the model to Sherri Dennis, Center for Food Safety and Applied Nutrition (see FOR FURTHER INFORMATION CONTACT). Send one self-addressed label to assist that office in processing your request. You also may request a copy of the risk assessment document and model by fayour name and mailing address with the name of the document you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. See the SUPPLEMENTARY INFORMATION section for electronic access to this document.

A copy of the risk assessment document may be reviewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1903.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 19, 2001 (66 FR 5517), FDA announced the availability of a draft risk assessment on the relationship between Vibrio parahaemolyticus in raw molluscan shellfish, specifically raw oysters, and human health. A public meeting was held on March 20, 2001 (66 FR 13544, March 6, 2001), to receive comments on the technical aspects of the draft risk assessment. Interested persons were given until March 20, 2001, with extensions to May 21, 2001 (66 FR 13546, March 6, 2001), and to July 18, 2001 (66 FR 33101, June 20, 2001), to comment on the draft risk assessment. Nine letters, containing one or more comments, were received in response to the draft risk assessment. The risk assessment has been revised in response to the public comments, newly available data, and updated modeling techniques. Elsewhere in this issue of the Federal Register, FDA is announcing a public meeting to provide clarification about the results of the risk assessment and information about how the risk assessment may be utilized.

II. Risk Assessment

The purpose of the quantitative risk assessment is to examine systematically available scientific data and information to estimate the risk of illness associated with consumption of raw oysters that contain pathogenic V. parahaemolyticus. This examination of the current science and the models...
The following steps:

1. Hazard Identification. The review of data and information on health effects (e.g., gastroenteritis and septicemia) associated with consumption of raw oysters containing pathogenic V. parahaemolyticus.
2. Hazard Characterization/Dose-Response. Characterization of the relationship between V. parahaemolyticus exposure level (dose) and probability and severity of illness (response) using data from clinical trials and epidemiological surveys. Anyone exposed to V. parahaemolyticus can become infected and develop gastroenteritis; however, individuals with concurrent underlying chronic medical conditions have a greater probability of developing septicemia.
3. Exposure Assessment. The determination of the likelihood and level of exposure to V. parahaemolyticus from consumption of raw oysters using data on prevalence, water and air temperature, growth and survival of V. parahaemolyticus, oyster landings, and consumption.
4. Risk Characterization. The integration of the exposure and dose-response estimate both the risk to the public health and the uncertainty associated with this estimate. The risk assessment provides estimates of the following: (1) The predicted illness burden as the risk of an individual becoming ill when they consume a single serving of oysters, (2) the predicted number of illnesses (gastroenteritis) in the United States each year, and (3) the predicted number of cases of gastroenteritis that progress to septicemia.

The results of the risk assessment identified the following several significant factors that contribute to the probability of illness: (1) Levels of total V. parahaemolyticus in oysters at time of harvest, (2) harvesting and handling practices that allow growth of V. parahaemolyticus in oysters after harvest, and (3) mitigations that reduce levels of V. parahaemolyticus in oysters post-harvest.

III. Electronic Access

The risk assessment document is available electronically at www.cfsan.fda.gov.

Dated: July 11, 2005.

Jeffrey Shuren, Assistant Commissioner for Policy.