

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1999N–1075] (formerly 99N–1075)

### 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.

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**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.

**ADDRESSES:** 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 faxing your 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 developed from it are among the tools available to FDA to aid in the evaluation of risk mitigation strategies and in the formulation of effective guidance for the industry. The risk assessment focused on raw oysters because that is the food in the United States predominately linked to illness from *V. parahaemolyticus* outbreaks since 1997. This risk assessment is a quantitative analysis in which the levels of pathogen in oysters were estimated beginning with harvest of the oysters through post-harvest handling, processing, and storage to predict exposure from consumption of raw oysters. The likelihood of illness following exposure to pathogenic *V. parahaemolyticus* from consumption of raw oysters was determined for different geographical areas and for various times of the year. The baseline model was used to develop “what-if” scenarios to evaluate the likely impact of potential intervention scenarios on the exposure to pathogenic *V. parahaemolyticus*. 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.

The risk assessment follows the framework recommended both by the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

- *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*.
- *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.

- *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.

- *Risk Characterization.* The integration of the exposure and dose-response data to 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](http://www.cfsan.fda.gov).

Dated: July 11, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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