

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0467]

Risk Assessment for Food Terrorism and Other Food Safety Concerns; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a risk assessment for food terrorism and other food safety concerns. FDA is making this document available to promote transparency by communicating publicly the risk to public health of acts of food terrorism, as well as incidents of unintentional contamination of food that result in significant foodborne illness. The development of this risk assessment is one of a number of steps the agency is taking to improve its ability to prevent, prepare for, and respond to an incident of food sabotage.

ADDRESSES: Submit written requests for single copies of the risk assessment to the Office of Regulations and Policy (HFS-24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the document may be sent. Alternatively, you may request a copy of the document by calling 301-436-1589, or you may fax your request to 301-436-2637. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the risk assessment.

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Certifier R. LEDESMA

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FOR FURTHER INFORMATION CONTACT: Leslye Fraser, Associate Director for Regulations, Center for Food Safety and Applied Nutrition (HFS-4), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2378.

SUPPLEMENTARY INFORMATION:

I. Background

The events of September 11, 2001, and the subsequent anthrax incidents gave rise to concerns about unconventional terrorist attacks, including the threat of attacks on the U.S. food supply. In the aftermath of those incidents, FDA took steps to improve its ability to prevent, prepare for, and respond to incidents of food sabotage.

As part of this effort, the agency prepared various assessments of the risk of food terrorism. Most of these risk assessments were deemed to be classified. The goal of this document is to communicate publicly the risk to public health of acts of food terrorism, as well as incidents of unintentional contamination of food that result in significant foodborne illness.

II. Risk Assessment for Food Terrorism and Other Food Safety Concerns

The risk assessment presents scientific evidence and various risk scenarios, to the extent that such information is unclassified, on both deliberate and accidental contamination of that portion of the food supply regulated by FDA. Unlike traditional risk assessments, which focus on one hazard, this assessment addresses the broad range of hazards that may be introduced into food intentionally or unintentionally. In addition, the very nature of "bioterrorism" and the fact that it is a relatively new and evolving

threat present challenges in quantitatively evaluating the associated risks. Thus, FDA has prepared a qualitative assessment that follows the generally accepted framework for risk assessments endorsed by the Codex Alimentarius Commission. This framework involves the following steps:

(1) *Hazard identification.* A review of available information on the range of possible biological and chemical agents that might be used by terrorists to deliberately contaminate food or that might be introduced inadvertently into food.

(2) *Hazard characterization.* The assessment of the potential for an act of food terrorism or other food safety emergency to cause illnesses and deaths, economic effects, and social and political implications.

(3) *Exposure assessment.* An evaluation of the likelihood that an act of food terrorism or inadvertent food contamination that results in significant foodborne illness will occur.

(4) *Risk characterization.* The integration of information on potential hazards with the exposure assessment.

The risk assessment also discusses the quality of information available for, and the uncertainties associated with, the assessment.

FDA has determined that this risk assessment, which discusses prior incidents of food contamination and available unclassified information on prior acts of food sabotage, is appropriate to the circumstances.

III. Electronic Access

The risk assessment is available electronically at <http://www.cfsan.fda.gov>.

Dated: October 7, 2003

Signature: Jeffrey Shuren

Jeffrey Shuren
Assistant Commissioner for Policy.

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Reggie DeLeon