

Dated: April 8, 2010.

Yvette Roubideaux,

Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0195]

Risk Profile: Pathogens and Filth in Spices: Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and scientific data and information that would assist the agency in its plans to conduct a risk profile for pathogens and filth in spices. The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and potential new interventions to reduce or prevent illnesses from contaminated spices.

DATES: Submit electronic or written comments and scientific data and information by June 21, 2010.

ADDRESSES: Submit electronic comments and scientific data and information to <http://www.regulations.gov>. Submit written comments and scientific data and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1914.

SUPPLEMENTARY INFORMATION:

I. Background

A risk profile is a science-based document that describes the current state of knowledge about a specific food safety problem or issue and provides an evaluation of the data and information to support current interventions or new approaches to reduce or prevent illnesses (Ref. 1). FDA has adapted this tool as a new approach to assist the agency in its regulatory decisionmaking. Unlike a quantitative risk assessment,

which provides information about the number of people affected by a hazard in food and how this number might be changed if various control options were implemented, a risk profile provides qualitative answers to questions about the hazard and options for controlling it, based on available data. The information in a risk profile may affect a range of decisions, such as whether or not to commission a quantitative risk assessment or a request for research, or whether or not to implement an immediate and/or provisional regulatory decision. In some cases, it may reveal that no further action is needed.

The risk profile for pathogens and filth in spices will provide information for FDA to use in the development of plans to reduce or prevent illness from spices contaminated by microbial pathogens and/or filth. Concerns regarding the effectiveness of current control measures to reduce or prevent illness from spices have been renewed by recent outbreaks of *Salmonella* associated with spices, including the imported ground white and black pepper products linked to an April 2009 outbreak of *Salmonella* Rissen illness, and the black and red pepper products recalled in March 2010 in response to an outbreak of *Salmonella* Montevideo illness (Refs. 2 and 3).

For the purpose of this risk profile, the term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, whose significant function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed. The specific hazards in spices to be considered in this risk profile include those microbiological pathogens and filth in spices that are identified in the published literature, outbreaks, recalls, and submissions to the Reportable Food Registry (RFR).¹ For purposes of this risk profile, FDA considers "filth" to mean "extraneous materials" as defined in FDA's Defect Levels Handbook (Ref. 4). The Defect Levels Handbook defines "extraneous materials" as "any foreign matter in a product associated with objectionable conditions or practices in production, storage, or distribution * * * [including] objectionable matter contributed by insects, rodents, and birds; decomposed material; and

miscellaneous matter such as sand, soil, glass, rust, or other foreign substances."

The overall objectives of the risk profile are to:

- Describe the nature and extent of the public health risk, by identifying the most commonly occurring microbial and filth hazards in spices;
- Describe and evaluate current mitigation and control options;
- Identify potential additional mitigation or control options;
- Identify research needs and data gaps.

The specific questions to be addressed by the risk profile include:

- What is known about the frequency and levels of pathogen and/or filth contamination of spices throughout the food supply chain (e.g., on the farm, at primary processing/manufacturing, intermediary processing (where spices are used as ingredients in multi-component products), distribution (including importation), retail sale/use, and the consumer's home)?
- What is known about differences in production and contamination of imported and domestic spices?
- What is known about the effectiveness, cost, and practicality of currently available and potential future interventions to prevent human illnesses associated with pathogen and/or filth contamination of spices (e.g., practices and/or technologies to reduce or prevent contamination, surveillance, inspection, import strategies, or guidance)?
- What are the highest priority research needs related to prevention or reduction of pathogens and/or filth in spices?

II. Request for Comments and for Scientific Data and Information

FDA is requesting comments on the risk profile approach outlined previously in this document and the submission of scientific data and information relevant to the risk profile. The agency is particularly interested in the following types of information:

1. Data, including unpublished data, on the incidence of contamination in spices according to:
 - a. Date tested,
 - b. Country exporting the spice and/or country of origin if different,
 - c. Type of spice,
 - d. Pathogen(s) and/or filth type (e.g., insect, rodent, extraneous),
 - e. Quantitative (enumeration) or qualitative (presence/absence) results, and
 - f. Other product sample information (e.g., pre- or post-treatment, treatment type, stage of production/processing).

¹ The RFR is an electronic portal where responsible parties are required to file a report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals (Ref. 5).

2. Factors that influence the survival, growth, and levels of pathogens in spices including:
 - a. On-farm practices,
 - b. Manufacturing, processing, or marketing practices,
 - c. Shipping, storage, and distribution practices,
 - d. Storage conditions encountered throughout the farm-to-table continuum, and
 - e. Pathways for transfer of pathogens to spices, including data on frequencies or amounts of transfer (e.g., cross-contamination potential).
3. Consumption patterns (including serving size and frequency) in the United States.
4. Intended use (e.g., ready-to-eat, ingredient in a prepared food).
5. Manufacturing practices, including the use of spices as ingredients in prepared foods.
6. Data, including unpublished data, on the identity and effectiveness of control measures or interventions to reduce levels and frequency of pathogens and/or filth in spices during growing, harvesting, processing, manufacturing, packaging, storage, and transportation prior to retail sale including:
 - a. Description of treatment or other control measure,
 - b. Country exporting spice using this treatment/control measure,
 - c. Name of the specific spice and its form (e.g., whole, cracked, ground),
 - d. Effect of the treatment/control measure on pathogen and/or filth levels, and
 - e. Types of validation protocols used to verify the effectiveness of treatment/control measures.
7. Data relating to supplier specifications including required treatments, performance standards, microbial testing, and audit programs.
8. Any other data related to the occurrence and control of pathogens and/or filth in spices that are applicable to the risk profile.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and scientific data and information regarding this document. Submit a single copy of electronic comments and scientific data and information to <http://www.regulations.gov> or two copies of any mailed comments and scientific data and information, except that individuals may submit one paper copy. Submissions are to be identified with the docket number found in brackets in

the heading of this document. Received comments and scientific data and information may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

We have placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). You may see them between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Codex Alimentarius Commission, 19th Procedural Manual, http://www.codexalimentarius.net/web/procedural_manual.jsp, accessed April 13, 2010.

2. Food and Drug Administration, "FDA Alerts the Public to Uncle Chen and Lian How Brand Dry Spice Product Recall," April 2, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149555.htm>, accessed April 13, 2010.

3. Food and Drug Administration, "FDA Update on the Investigation into the Salmonella Montevideo Outbreak," March 17, 2010, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm204917.htm>, accessed April 13, 2010.

4. Food and Drug Administration, Defect Levels Handbook, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/ucm056174.htm>, accessed April 13, 2010.

5. Food and Drug Administration, "Reportable Food Registry for Industry," <http://www.fda.gov/food/foodsafety/FoodSafetyPrograms/RFR/default.htm>, accessed April 13, 2010.

Dated: April 14, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2010-0266]

Information Collection Request to Office of Management and Budget; OMB Control Numbers: 1625-0007, 1625-0074, 1625-0084, 1625-0093, and 1625-0102

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit Information Collection Requests (ICRs)

and Analyses to the Office of Management and Budget (OMB) requesting an extension of its approval for the following collections of information: (1) 1625-0007, Characteristics of Liquid Chemicals Proposed for Bulk Water Movement; (2) 1625-0074, Direct User Fees for Inspection or Examination of U.S. and Foreign Commercial Vessels; (3) 1625-0084, Audit Reports under the International Safety Management Code; (4) 1625-0093, Facilities Transferring Oil or Hazardous Materials in Bulk—Letter of Intent and Operations Manual; and (5) 1625-0102, National Response Resource Inventory. Before submitting these ICRs to OMB, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before June 21, 2010.

ADDRESSES: To avoid duplicate submissions to the docket [USCG-2010-0266], please use only one of the following means:

(1) **Online:** <http://www.regulations.gov>.

(2) **Mail:** Docket Management Facility (DMF) (M-30), U.S. Department of Transportation (DOT), West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(3) **Hand deliver:** Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) **Fax:** 202-493-2251.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at <http://www.regulations.gov>.

Copies of the ICRs are available through the docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-611), Attn. Paperwork Reduction Act Manager, U.S. Coast Guard, 2100 2nd St., SW., Stop 7101, Washington, DC 20593-7101.

FOR FURTHER INFORMATION CONTACT:

Contact Mr. Arthur Requina, Office of Information Management, telephone 202-475-3523, or fax 202-475-3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager,