

modeled in our risk and benefit analysis was modest. When we modeled actual baseline consumption for the range of methylmercury concentrations (low to high) the assessment indicated a significant probability of a net adverse effect for 1/10 of 1 percent of children for the central estimate. The highest estimated net adverse effect was also quite modest. For fatal coronary heart disease and stroke, commercial fish baseline consumption is averting a central estimate of over 30,000 deaths per year from coronary heart disease and over 20,000 deaths per year from stroke. The results of our quantitative risk and benefit assessment are generally consistent with research reported in recent years in the scientific literature.

The draft summary of published research identifies primarily secondary analyses of the large body of scientific research on the impact of fish and omega-3 fatty acids on cardiovascular and neurologic endpoints, including research on both prenatal and post-natal exposures. In addition to the IOM report, these secondary analyses include reports by the American Heart Association, the European Food Safety Authority, the International Society for the Study of Fatty Acids and Lipids, the World Health Organization and a previous investigation by FDA. This compendium of research was developed by FDA for use in developing its quantitative risk benefit assessment and provides background for that document. The draft summary of published research identifies and delineates the lines of scientific evidence that indicate the association of fish and omega-3 fatty acid consumption with cardiovascular and neurodevelopmental health outcomes. When available, the compendium of research also identifies reports of quantitative dose-response relationships which may be relevant for risk and benefit assessment modeling. The draft summary of published research describes the context of the overall body of scientific evidence currently available for potential application to the risk and benefit assessment modeling and the draft risk and benefit assessment report.

The agency designated the draft risk and benefit assessment report and the draft summary of published research as a "highly influential scientific assessment" under the Office of Management and Budget's (OMB) Final Information Quality Bulletin for Peer Review (the Bulletin) (70 FR 2664, January 14, 2005). In August 2008, FDA submitted a draft of the risk and benefit assessment report (which at the time also incorporated the draft summary of

published research) to seven scientific experts outside the Federal Government, from a range of scientific disciplines, for purposes of obtaining each expert's independent, written peer review. The draft risk and benefit assessment report and the draft summary of published research that are being made available for public comment reflect revisions made to date in response to the peer reviewers' comments and suggestions. The Information Quality Act Bulletin for Peer Review requires FDA to post at its Web site a report of the peer review that: (1) Contains the names and credentials of the peer reviewers; (2) sets forth the "charge," i.e., the scientific questions asked of the reviewers; (3) provides the verbatim comments submitted by each reviewer (without attribution); and (4) discusses what FDA has done to the documents in response to the peer reviewers' comments. We have posted at our Web site an interim draft of this report that provides this information at <http://www.cfsan.fda.gov/~dms/mehg109.html>, although we expect and plan to finalize this report after revising our draft risk and benefit assessment report and the draft summary of published research, in response to further expert and peer review comments.

Separately, FDA solicited and received comments from scientists at other Federal agencies, including EPA, the National Institutes of Health, the Centers for Disease Control and Prevention, and the National Oceanic and Atmospheric Administration during a review coordinated by OMB. The draft risk and benefit assessment report and the draft summary of published research being made available for comment have been revised to reflect revisions made in response to the inter-agency reviewers' comments.

At the same time we are making these draft documents available for public comment, we plan to provide a revised draft to the original peer reviewers to enable them to submit any further comments. We will revise the draft risk and benefit assessment report and the draft summary of published research as necessary after considering the public comments and any additional comments from the independent peer reviewers. We also plan to provide the revised version of the documents, a summary of the public comments that address significant scientific issues, and the external peer review report to an FDA scientific advisory committee.

After public and advisory committee review of these documents are complete, appropriate risk management actions will then be considered on the basis of currently available scientific

information. The release of these documents for public comment and peer review do not in any way modify the recommendations set forth in the 2004 advisory on fish consumption.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

The draft documents described in this notice are available electronically at <http://cfsan.fda.gov/~dms/mehg109.html>.

## IV. Access to Related Documents

All references listed in the reports are available in FDA's Division of Dockets Management (see **ADDRESSES**). Computer programs used in the risk and benefit assessment modeling are available from Clark Carrington, Center for Food Safety and Applied Nutrition (HFS-301), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1947, e-mail: [Clark.Carrington@fda.hhs.gov](mailto:Clark.Carrington@fda.hhs.gov).

Dated: January 14, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-1081 Filed 1-15-09; 11:15 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0658]

#### **Risk Assessment of the Public Health Impact From Foodborne *Listeria monocytogenes* in Some Ready-to-Eat Foods Sliced, Prepared, and/or Packaged in Retail Facilities; 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 assessment of the public health impact of foodborne *Listeria monocytogenes* in some ready-to-eat foods sliced, prepared, and/or packaged in retail facilities. The purpose of the risk assessment is to ascertain the impact on public health of current practices and potential interventions that reduce or prevent *L. monocytogenes* contamination in ready-to-eat food.

**DATES:** Submit comments and scientific data and information by April 21, 2009.

**ADDRESSES:** 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. Submit electronic comments, scientific data, and information to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 301-436-2355, e-mail: [sherri.dennis@fda.hhs.gov](mailto:sherri.dennis@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Department of Health and Human Services' *Healthy People 2010* is a comprehensive set of disease prevention and health promotion objectives for the Nation to achieve over the first decade of the new century. Created by scientists both inside and outside of government, it identifies a wide range of public health priorities and specific, measurable objectives. One of these objectives calls on Federal food safety agencies to reduce foodborne listeriosis (Ref. 1). In support of this goal, in 2003, FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) issued an assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat (RTE) foods (*Listeria* risk assessment, Ref. 2). The *Listeria* risk assessment formed the basis of the 2003 FDA and Centers for Disease Control and Prevention (CDC) *Listeria* Action Plan (Ref. 3), which identifies prevention and control activities that FDA and CDC will take to reduce the incidence of foodborne listeriosis in the United States.

The 2003 *Listeria* risk assessment provided the first quantitative estimate of the relative risk of listeriosis from consumption of a variety of RTE foods. Among the RTE foods evaluated in the

2003 risk assessment, deli meats (e.g., luncheon meats) were considered to present the highest risk per serving and the highest risk per annum. This rank was the result of a moderate contamination frequency, a high number of servings consumed and high growth rates of *L. monocytogenes*. Additional data obtained in California and Maryland showed that *L. monocytogenes* prevalence and levels in luncheon meats, deli-style salads, and seafood salads were higher for in-store-packaged than for manufacturer-packaged foods (Ref. 4). This observation was confirmed for meat and poultry products in a study by the National Alliance for Food Safety and Security performed in northern California, Georgia, Minnesota, and Tennessee in 2008 (Ref. 5). Using these latter results, it was estimated that most of the listeriosis cases attributed to ready-to-eat meat and poultry deli meats are from products sliced and packaged at retail (FSIS/USDA, unpublished results).

Little is known about how *Listeria* contamination occurs in retail facilities. Retail practices may result in either cross-contamination from one product to another or through contamination from the retail environment. There is thus a need to identify potential sources and practices that may increase *L. monocytogenes* contamination in retail settings and practices or interventions that could reduce or eliminate *L. monocytogenes* contamination of food products (sold to consumers at the retail level) and resulting human illness.

FDA is engaged in a risk assessment that will evaluate the dynamics of *L. monocytogenes* contamination in retail facilities contributing to listeriosis. It will evaluate how specific practices could affect the overall level and frequency of contamination, and the relative effectiveness of various process changes and intervention strategies intended to reduce human illness. The project will address FDA and USDA regulated RTE foods. It will focus on RTE foods that are sliced, prepared, and/or packaged for the consumer in the retail environment and consumed in the home. Cheeses, deli meats, and deli-type salads (as defined in Ref. 2) will be studied as representative examples.

This risk assessment of the public health impact of *L. monocytogenes* in RTE foods sliced, prepared, and/or packaged in retail facilities supports the agency's commitment to fulfilling the *Listeria* Action Plan (Ref. 3).

**II. Request for Comments and for Scientific Data and Information**

FDA requests comments on the risk assessment goals outlined in this document and the submission of scientific data and information relevant to the risk assessment. Specifically, we request data and information about the following:

1. Characteristics of ready-to-eat food markets in the United States, including:
  - a. Volumes of cheeses and deli meats sliced by manufacturers and the volumes sliced in retail facilities,
  - b. Volumes of deli-type salads prepared by manufacturers and the volumes prepared in retail facilities, and
  - c. Volumes of ready-to-eat food sold in delicatessen departments of major grocery chains (i.e., large supermarket facilities) and the volumes sold in other groceries (i.e., multipurpose independent small or local facilities).
2. Characteristics of deli departments in groceries, including the proportion of separated seafood/meat/dairy deli departments in groceries.
3. Product contamination data, including:
  - a. *L. monocytogenes* levels and/or frequencies in wholesale products (deli meats (chubs), cheeses, fresh produce, seafood) arriving at retail facilities; and
  - b. *L. monocytogenes* levels and/or frequencies in cheeses, deli meats, and deli-type salads sold by retail facilities.
4. Factors that influence the growth of *L. monocytogenes* in cheeses, deli meats, and deli-type salads, including:
  - a. Growth rates of *L. monocytogenes* in cheeses, deli meats, and deli-type salads and the effects of different ingredients in and compositions of those products;
  - b. Chemical characteristics of cheeses, deli meats, and deli-type salads that could influence *L. monocytogenes*, including pH and water activity;
  - c. Proportions of deli meats treated with growth inhibitors, the inhibitors used, the level of growth inhibitors, and their efficiency;
  - d. Data on the temperatures to which cheeses, deli meats, and deli-type salads are exposed at retail, including time and temperature for walk-in coolers or refrigerators, display cabinets, and ambient displays; and
  - e. Data on the use of advisory "use-by" or "best by" labels for ready-to-eat food sold by retail facilities.
5. Environmental contamination data, including:
  - a. Data and information on the prevalence and levels of *L. monocytogenes* in the retail environment including, e.g., drains, countertops, walls, and equipment; and

b. Data on the growth of *L. monocytogenes* on non-food surfaces including environmental biofilm growth.

6. Factors that influence the environmental contamination and the cross-contamination of food by *L. monocytogenes* in retail facilities, including:

a. Data and information on the potential transfer of *L. monocytogenes* to food from the retail environment, e.g., experimental studies on the transfer to food from drains, slicers, food contact surfaces, and non-food contact surfaces; and

b. Data and information on food handlers' activities, e.g., observations of food handlers' practices and monitoring of specific food safety actions in retail facilities (e.g., glove usage, hand hygiene practices, and cleaning practices).

7. Identity and effectiveness of control measures or interventions intended to reduce levels and frequency of *L. monocytogenes* in the retail environment, including:

a. Environmental sanitation procedures including the sanitizers and protocols used, frequency of application, and efficiency; and

b. Worker sanitation procedures including frequencies, protocols, and efficiency.

8. Any other data related to the occurrence, growth, and control of *L. monocytogenes* in retail facilities.

As the project progresses, additional data needs may be identified.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

### III. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may

be seen by interested persons 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. U.S. Department of Health and Human Services, *Healthy People 2010*, v. 1. Washington, DC, 2000, <http://healthypeople.gov>.

2. U.S. Department of Health and Human Services and U.S. Department of Agriculture/Food Safety and Inspection Service, "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods," September 2003, <http://www.foodsafety.gov/~dms/lmr2-toc.html>.

3. U.S. Department of Health and Human Services, Food and Drug Administration/Centers for Disease Control and Prevention, "Reducing the Risk of *Listeria monocytogenes* FDA/CDC 2003 Update of the Listeria Action Plan," November 2003, <http://www.cfsan.fda.gov/~dms/lmr2plan.html>.

4. Gombas, D.E., Chen, Y., Clavero, R.S., and Scott, V.N. (2003). Survey of *Listeria monocytogenes* in ready-to-eat foods. *Journal of Food Protection*, 66(4), 559-569.

5. Draughon, A.F. (2006). A collaborative analysis/risk assessment of *Listeria monocytogenes* in ready-to-eat processed meat and poultry collected in four FoodNet states. Symposium S-16: Contamination of ready-to-eat foods: transfer and risk: *Listeria monocytogenes* and other microorganisms. International Association for Food Protection 93rd Annual Meeting, Calgary, Alberta. August 13-16.

Dated: January 12, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-938 Filed 1-16-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* National Advisory Council on Migrant Health.

*Dates and Times:* February 9, 2009, 8:30 a.m. to 5 p.m.; February 10, 2009, 8:30 a.m. to 5 p.m.

*Place:* The Parklawn Building, Twinbrook Room, 3rd Floor, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 594-4303, Fax: (301) 443-0248.

*Status:* The meeting will be open to the public.

*Purpose:* The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

*Agenda:* The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels.

Agenda items are subject to change as priorities indicate.

*For Further Information Contact:* Gladys Cate, Office of Minority and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Maryland 20857; telephone (301) 594-0367.

**Wendy Ponton,**

*Director, Office of Management.*

[FR Doc. E9-1067 Filed 1-16-09; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Mice With a Conditional LoxP-Flanked Glucosylceramide Synthase Allele Controlling Glycosphingolipid Synthesis

*Description of Technology:* Glycosphingolipids are organizational building blocks of plasma membranes that participate in key cellular