

electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: P. Michael Bolger, Chief, Risk Assessment Staff, Center for Food Safety and Applied Nutrition (HFS-308), 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1941, FAX 301-436-2632, or e-mail: Mike.Bolger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The interim safety/risk assessment was prepared by FDA in collaboration with FSIS and in consultation with the Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Department of Homeland Security. The purpose of the safety/risk assessment is to assist FDA and FSIS in the ongoing investigation of contaminated vegetable protein products imported from China that were mislabeled as "wheat gluten" and "rice protein concentrate," and ensuring the safety of the U.S. food supply. The interim safety/risk assessment concludes that, based on currently available data and information, the consumption of even large amounts of pork, chicken, fish, and/or eggs from animals that had been inadvertently fed animal feed contaminated with melamine and its analogues is very unlikely to pose a human health risk. This safety/risk assessment was developed rapidly due to the extremely time-sensitive need to understand the nature of the potential risk. However, we are seeking public comment on this interim safety/risk assessment, and in addition it will undergo expert peer review.

II. Safety/Risk Assessment

A human health safety/risk assessment is a scientifically-based methodology used to estimate risk to human health from exposure to specific compounds such as contaminant(s) in food. The interim melamine and its analogues safety/risk assessment addresses:

- (1) The chemical characteristics of melamine and its analogues;
- (2) The toxicological profile of melamine and its analogues, including the observed results from controlled animal studies conducted with melamine; and
- (3) The likelihood that consumption of pork, chicken, fish and eggs from animals fed feed contaminated with melamine and its analogues poses a health risk to humans.

FDA used the following methodology to develop the safety/risk assessment.

The safety/risk assessment was based on the currently available scientific data and information. FDA estimated human exposure to melamine and its analogues based on the estimated levels in specific foods and the estimated consumption of those foods. The agency compared the exposure estimate to a "Tolerable Daily Intake" level, which was derived using available toxicity data on the level of melamine that did not cause adverse renal effects in a laboratory-animal (13-week rat) bioassay study. FDA adjusted this level, "the No Observed Adverse Effect Level" for uncertainty in the data by dividing by a safety/uncertainty factor of 100 to account for differences in sensitivity within and across species.

Recognizing the time-sensitive need for the safety/risk assessment, FDA invites comments concerning:

- (1) The assessment approach used;
- (2) The assumptions made;
- (3) The data used; and
- (4) The transparency and clarity of the report.

III. 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.

IV. Electronic Access

The interim safety/risk assessment is available electronically at <http://www.cfsan.fda.gov/~dms/melamra.html>.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

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

that the following committee will convene its fifty-sixth meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: June 10, 2007, 1 p.m.–5:45 p.m., June 11, 2007, 8:45 a.m.–5 p.m., June 12, 2007, 8:50 a.m.–10:45 a.m.

Place: Fort Collins Hilton, 425 Prospect Road, Fort Collins, CO 80526, *Phone:* 970-482-2626.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Sunday afternoon, June 10, at 1 p.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable David Beasley. Jim Wescott, Senior Demographer with Colorado State will be give an overview of Rural Colorado. Following this presentation will be two panels on health and human services issues. The first will be a health panel. The speakers will be Mark Wallace, President of Northern Colorado Health Alliance, and Dr. Jack Westfall, Associate Dean for Rural Health at the Colorado University School of Medicine. The second will be a human services panel. The speakers will be Patricia Brewster-Willeke, a Public Health Nurse, and Kindra Mulch, Administrator of Kit Carson County Health and Human Services. Following the panel discussions will be an overview of Monday's site visits by Lou Ann Wilroy with the Colorado State Office of Rural Health. The Sunday meeting will close at 5:45 p.m.

Monday morning, June 11, at 8:30 a.m., the Committee will break into Subcommittee format for the site visits. At 8:45 a.m., both Subcommittees will depart for site visits. The Health Subcommittee will depart to East Morgan County Hospital in Brush, Colorado. The Human Services Subcommittee will depart to the Area Agency on Aging in Fort Morgan, Colorado. Transportation to these sites will not be provided. Both Subcommittees will return to Fort Collins Hilton and resume meeting in Subcommittee format at 4 p.m. The Monday meeting will close at 5 p.m.

The final session will be convened Tuesday morning, June 12, at 8:50 a.m. A Committee member, Mayor Larry Otis, will present a case study titled Employee Health Care in Rural Mississippi. Following this presentation will be a review of the site visits, discussion on the letter to the Secretary, and discussion of the upcoming September meeting. The meeting will be adjourned at 10:45 a.m.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), Telephone (301) 443-0835. The Committee meeting agenda will be posted on ORHP's Web site <http://www.ruralhealth.hrsa.gov>.

Due to scheduling difficulties, this notice will publish in the **Federal Register** less than 15 days before the date of the meeting.

Dated: May 24, 2007.

Caroline Lewis,

Associate Administrator for Management.

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BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Proposed Collection; Comment Requested; Study to Improve Thyroid Doses from Fallout Exposure in Kazakhstan

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 18, 2007, pages 2286-2287 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Study to improve thyroid doses from fallout exposure in Kazakhstan, Radiation Epidemiology Branch,

Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI). This is a dose reconstruction effort. Additional data will be acquired to improve on published estimates of individual internal and external radiation dose and better characterize the underlying dose uncertainties for individuals exposed as children to radioactive fallout from nuclear tests conducted at the Semipalatinsk Nuclear Test Site (SNTS) in Kazakhstan during the 1950s. Village residents near the test site received high doses of internal and external radiation to the thyroid gland (up to 10 Gy for internal and 0.6 Gy for external radiation) as a result of multiple nuclear tests. Internal radiation exposure occurred primarily through consumption of milk and other dairy products from animals grazing on pastures contaminated with radioactive iodine. The external dose received by individuals was a function of the exposure rate when the fallout was deposited, shielding provided by buildings and the number of hours spent outdoors on a daily basis. Collection from small focus groups of persons who were young adults at the time of the nuclear tests of specific information about children's milk consumption and time spent indoors and outdoors, shielding, and pasturing and feeding of dairy animals for the months following the nuclear tests will allow dosimetrists to evaluate and change, as appropriate, the current assumptions and input values for the parameters of the dose estimation model. The new data will allow more objective model assumptions and result in a more informed characterization of uncertainty.

Type of information collection request: NEW. The Kazakhstan population was exposed to high levels of radiation from external as well as internal sources, unlike the vast majority of persons living downwind from the Chernobyl accident who were exposed only to radioactive isotopes of ingested and inhaled iodine. Availability of accurate dose estimates will allow evaluation of the relative biological effectiveness (RBE) of internal vs. external radiation exposures in terms of thyroid disease risk within a single

population. The conditions of fallout exposure in Kazakhstan are directly relevant to conditions following a hypothetical nuclear accident or a terrorist attack involving high levels of local fallout.

Need and Use of Information Collection: NCI proposes a small-scale field study to acquire new data to improve published estimates of internal and external radiation doses to individuals exposed to fallout from nuclear tests conducted at the SNTS during 1949-1962. Retrospective information about factors influencing radiation dose to the thyroid gland in children of two distinct ethnic groups (Kazakh and Russian) will be collected using focus group interviews. New data to be collected on milk and milk product consumption, time typically spent outdoors, radiation shielding provided by dwellings and other buildings, and seasonal practices of pasturing and supplemental feeding of dairy animals at the time of the nuclear tests will enable dosimetrists to address key weaknesses in the current dosimetry models. Since the objective is to estimate group-specific mean values (and ranges) and not to collect individual data, focus groups are better suited than conventional in-depth individual interviews. Focus group members will be recruited from among women and men who speak Russian or Kazakh and have a verified history of residence in the village at the time of the nuclear tests. In each village, three groups of 8 women, age 70 or older, who had children or provided care to other children (e.g., younger siblings, nieces and nephews) who were under age 21 at the time of the nuclear tests will be enrolled. In each village, 8 men, age 70 or older, who were engaged in farming and the care of dairy animals at the time of the nuclear tests will be enrolled.

Frequency of Response: Once. *Affected Public:* Individual and household. *Type of Respondent:* Women and men, age 70 or older. *Estimated Number of Respondents:* 128. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 2.0. *Annual Burden Hours Requested:* 85.3.

TABLE 1.—ESTIMATES OF ANNUALIZED HOUR BURDEN TO RESPONDENTS

Type of respondent	Number of respondents	Frequency of response	Average hours per response	Total hours (3 yr)	Annual hour burden
Focus group					
Kazakhstan villagers (adults) ≥70 yrs old	128	1	1.9	243	81.1