includes records of individuals who have received and are receiving benefits under the Social Security Act. SSA will extract employer identity information from the Earnings Recording and Self-Employment Income System, SSA/OSR 60–0059, referred to as the Master Earnings File (MEF) published at 71 FR 1819 (January 11, 2006) and maintained at the NCC. This file contains earnings records of individuals including identifying information of their employers.

CMS will utilize a database, Medicare Advantage Prescription Drug System (MARx) CMS System No. 09–70–4001, published at 70 FR 60530 (October 18, 2005), maintained at the CMS Data Center, located in Baltimore, Maryland, of the GHP information received from employers containing verified instances of employment and GHP coverage for Medicare beneficiaries and Medicare-eligible spouses identified from the IMF and MEF extracts.

CMS will match GHP information against the Medicare Multi Carrier Claims System (MCS) (formerly known as Carrier Medicare Claims Records), CMS System No. 09–70–0501, published at 71 FR 64968 (November 6, 2006), maintained at the CMS Data Center, located in Baltimore, Maryland.

These files contain information received from employers containing verified instances of employment and GHP coverage for Medicare beneficiaries and Medicare-eligible spouses identified from the IMF and MEF extracts.

CMS will match GHP information against the Fiscal Intermediary Shared System (FISS) (formerly known as Intermediary Medicare Claims Records, CMS System No. 09–70–0503, published at 71 FR 64961 (November 6, 2006), maintained at the CMS Data Center, located in Baltimore, Maryland. This file contains information or records needed to properly process and pay Medicare benefits to, or on behalf of, eligible individuals. The file is accessed when a claim is submitted for payment.

CMS will match GHP information against the National Claims History (NCH), which is contained in the National Claims History File, CMS System No. 09–70–0558, published at 71 FR 67137 (November 20, 2006), maintained at the CMS Data Center, located in Baltimore, Maryland. NCH contains records needed to facilitate obtaining Medicare utilization review data that can be used to study the operation and effectiveness of the Medicare program.

INCLUSIVE DATES OF THE MATCH:
The Matching Program shall become effective 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the FR, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

FOR FURTHER INFORMATION CONTACT:
Steven M. Gendel, Center for Food Safety and Applied Nutrition (HFS–06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2290.

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 issued an assessment of the relative risk to the public health from foodborne L. 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/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 Public Health Risk Assessment: Listeria monocytogenes in Soft-Ripened Cheese supports the agency’s commitment to fulfilling the Listeria Action Plan.

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 dairy foods, soft unripened cheese was considered to present a high risk, and fresh soft cheese, semi-soft cheese, and soft-ripened cheese was considered to present a moderate risk of listeriosis. This risk assessment estimated that the risk of listeriosis from the consumption of fresh soft cheese made using unpasteurized (raw) milk could be as much as 40-fold higher than the risk from consumption of these cheeses made from pasteurized milk.

The United States (U.S.) and Canada have experienced sporadic illnesses and outbreaks of listeriosis associated with the consumption of cheese. In both countries, there is a strong epidemiological correlation between consumption of soft cheese and listeriosis. For example, a 1985 outbreak of listeriosis associated with the consumption of Mexican-style soft cheese resulted in 142 illnesses in Los Angeles (Ref. 4), a similar outbreak in 2000 in North Carolina resulted in 12 illnesses, and a 2002 soft cheese-
associated outbreak in Quebec resulted in 17 illnesses including 2 premature births (Ref. 5). Both FDA and Health Canada (HC) continue to evaluate the safety of soft cheese, particularly soft cheese made from unpasteurized milk.

As a followup to the Listeria risk assessment, FDA and HC have agreed to collaborate on the development of a model for the production of soft-ripened cheese that will evaluate the public health impact of factors such as the microbiological status of milk used in cheese production, the impact of various cheese manufacturing steps, conditions during distribution and storage, and cross contamination during processing and handling. The risk assessment model also will be used to evaluate the effectiveness of various process changes and intervention strategies in reducing human illness.

Specifically, the objectives of the Listeria in soft-ripened cheese risk assessment model are to quantitatively evaluate the impact on public health of the following: (1) Variations in L. monocytogenes levels in the raw materials used to produce cheese; (2) changes in L. monocytogenes levels as a result of growth, inactivation, or re-contamination at each step of the manufacturing process, between final packaging and sale at retail, and between retail sale and consumption; and (3) the impact of various intervention and control strategies.

II. Request for Comment and for Scientific Data and Information

FDA requests comments on the risk assessment approach outlined previously in this document and the submission of data and information relevant to the risk assessment. The agency specifically requests information for the following:

(1) Characteristics of the manufacturing and marketing processes for soft-ripened cheese including:
- The number of large and small (artisan) facilities producing soft-ripened cheese in the U.S. and Canada, and
- The amount of soft-ripened cheese produced each year in the U.S. and Canada by large and small facilities including information on different sizes of cheese that are produced and the relative production volumes for these sizes.

(2) Factors that influence the levels of L. monocytogenes in milk used for cheese manufacturing including:
- On-farm practices that influence the frequency and level of L. monocytogenes in raw milk used for cheese making,
- L. monocytogenes levels and/or frequencies in raw milk in the U.S. and Canada.
- Bulk tank sizes and mixing practices used by large and small manufacturers,
- Growth of L. monocytogenes in raw milk,
- Conditions of storage (temperatures and times) encountered by milk prior to cheese manufacture, and
- The identity and effectiveness of processes other than pasteurization used to treat raw milk prior to cheese making. (3) Factors that influence the levels of L. monocytogenes in products during cheese manufacturing including:
- Changes in L. monocytogenes levels and frequency (i.e., growth, inactivation, or re-contamination) at each step in cheese manufacturing (i.e., during curd formation, ripening, packaging, aging);
- Conditions of storage (temperatures and times) encountered during post-production holding at the producer; and
- Pathways for transfer of L. monocytogenes to soft-ripened cheese from environmental sources during packaging, cutting, transport, and handling at retail, including data on frequencies or amounts of transfer.

(4) Factors that influence the levels of L. monocytogenes in cheese post-production including:
- Levels and/or frequencies of L. monocytogenes that occur in cheese at retail; and
- The conditions (temperature and time) encountered during transport and storage throughout the distribution process, including at retail, in the U.S. and Canada.

(5) Factors that influence the levels of L. monocytogenes in cheese at consumption including:
- Storage conditions (temperature and times) encountered in consumers’ homes, and
- Consumption patterns for soft cheese (including serving size and frequency) in the U.S. and Canada.

(6) The identity and effectiveness of control measures or interventions to reduce levels and frequency of L. monocytogenes in cheese during processing, manufacturing, packaging, storage, and transportation prior to retail sale.

(7) Any other data related to the occurrence, growth, and control of L. monocytogenes in soft-ripened cheese.

Interested persons should submit comments, scientific data, and information to the Division of Dockets Management (see ADDRESSES). Three copies of all comments, scientific data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered, except by petition under 21 CFR 10.30.

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 we are not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the Federal Register.)


Jeffrey Shuren,
Assistant Commissioner for Policy.