

would include all relevant information necessary to demonstrate satisfaction of the minimum conditions for listing of a firm, including a copy of the most current inspection report, whether that inspection was conducted by FDA or by another regulatory entity, i.e., the U.S. Department of Agriculture (USDA) or a State regulatory agency. FDA believes that a copy of the inspection report, appended to the request for placement on the list, is necessary to meet minimum documentation requirements. A firm's presence on any other list would not be sufficient to document satisfaction of the listing criteria. FDA's request to receive information on the Federal or State agency that conducted the most current inspection and, if other than FDA, a copy of the most current inspection report, will facilitate the completion of the documentation file and the review process and will expedite the overall listing procedure.

One comment encouraged FDA to establish a system for adding plants to the list that is simple and rapid, with clear administrative rules and to consider allowing application to the list through the Internet. FDA will be using the Internet to post and maintain the list. FDA is not prepared to allow application to the list through the Internet at this time. Once the list is established and in use, FDA will consider whether it is feasible to use the Internet to receive applications.

One comment expressed concern that FDA, by establishing a list of U.S. dairy product manufacturers/processors that wish to export dairy products to Chile, would do the following actions: (1)

Duplicate existing procedures already in place at USDA and State Departments of Agriculture for obtaining export "documents" necessary for market access of U.S. dairy products into Chile; (2) cause manufacturers to have to obtain such documents from more than one Federal or State agency; and (3) otherwise complicate the procedures whereby U.S. dairy manufacturers could export their products to Chile. These comments also suggested that, in the future, FDA should defer to the USDA on "negotiations" pertaining to export of U.S. dairy products to other countries.

The comments indicate that some clarification of the roles and responsibilities of U.S. Government agencies is necessary. While FDA participates in many cooperative activities with U.S. States and with USDA in the area of food safety, FDA is the principal Federal agency within the U.S. Government responsible for the human health aspects of dairy product safety. As such, FDA is the appropriate U.S. agency to participate in discussions with foreign governments on matters relevant to the public (human) health aspects of U.S. dairy products. As stated in the April 10, 2003, **Federal Register** document, Chilean authorities have recognized FDA as the competent food safety (public health) authority in the United States to identify U.S. dairy product manufacturers eligible to export to Chile. In this context, Chilean authorities will rely on FDA to list these firms and to notify Chile regularly of all U.S. dairy firms that have met the criteria to be listed. On the basis of a

regularly updated list identifying firms that have applied to FDA to be listed, that are under FDA jurisdiction, and that are not the subject of a pending judicial FDA enforcement action or unresolved FDA warning letter, Chilean authorities will consider U.S. dairy products entering Chile to have satisfied public (human) health requirements. Contrary to the suggestion in the comment, no consignment-specific "document" issued by FDA must accompany any individual consignment of these dairy products.

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for dairy product safety with respect to animal health. Many countries, including Chile, mandate that each exported consignment of U.S. dairy products be accompanied by a certificate issued by APHIS attesting to satisfaction of certain animal health requirements. With regard to the present situation, Chilean authorities will still require the consignment-specific certificate demonstrating satisfaction of certain animal health provisions. The establishment of the proposed list of U.S. dairy product manufacturers and processors by FDA will not affect the requirement for the consignment-specific APHIS certificate.

Negotiations with Chile which led to the proposal for, and decision to move forward with, the list were conducted by a U.S. Government team comprised of, among others, both FDA and several USDA agencies, including APHIS and Agricultural Marketing Service.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
75 ²	1	75	1.5	112.5
8 ³	1	8	1.5	12
8 ⁴	1	8	0.5	4
Total				129

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² First year burden.

³ Recurring burden.

⁴ Recurring burden in reporting changes, including time reviewing collection of information and corresponding to FDA.

The estimate of the number of firms is based on the actual number of U.S. firms that applied to be placed on the list as a result of the **Federal Register** of May 23, 2003 (68 FR 28237), publication of the availability of a guidance entitled "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to

Chile." The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms. We estimate that for the first year a firm will require 1.5 hours to read

the **Federal Register**, gather the information needed, and to prepare a communication to FDA that contains the information and

requests that the firm be placed on the list. We estimate the recurring burden in subsequent years to be 1.5 hours for a new firm to be placed on the list and 0.5