

Guidance for Industry and FDA

Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile

GUIDANCE

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For questions regarding this document contact Ms. Esther Lazar at the Center for Food Safety and Applied Nutrition (CFSAN) at (Tel) 301-436-1485, (Fax) 301-436-2632, or e-mail elazar@cfsan.fda.gov.

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance document is being published to notify the public of FDA's efforts to assist U.S. firms that wish to export dairy products to Chile. FDA took this action in response to discussions with Chile that were adjunct to the negotiations of the United States-Chile Free Trade Agreement. As a result of those discussions, Chile recognized FDA as the competent food safety authority in the United States to identify U.S. dairy product manufacturers and processors eligible to export to Chile and concluded that it will not conduct individual inspections of U.S. firms identified on a list established by the FDA as eligible to export to Chile. The list identifies U.S. firms that have expressed interest to FDA in exporting dairy products to Chile, that are subject to FDA jurisdiction, and that are not the subject of a pending judicial enforcement action (e.g., an injunction or seizure) or a pending warning letter. The List of U.S. Dairy Product

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Manufacturers/Processors with Interest in Exporting to Chile established by FDA is posted on FDA's Internet site and shared with Chile. Every two years, Chile passes an authorizing resolution accepting this list and provides the list to their ports of entry to facilitate the importation of U.S. dairy products. Chile has requested that this list be updated every two years at the expiration of the current authorizing resolution. Therefore, FDA intends to contact the U.S. firms that are on the list every two years to verify that the information they have provided to FDA is still valid. FDA intends to report this updated list to Chile so that Chile can reauthorize its resolution for another two-year period.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

This is a revision of the first edition of this guidance, which FDA issued in May 2003.

II. DISCUSSION

A. Establishment of a List of U.S. Dairy Product Manufacturers/Processors

FDA has established and is maintaining a list identifying U.S. firms that have expressed to FDA their interest in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (e.g., an injunction or seizure) or a pending warning letter. The list is sent to responsible authorities in Chile, and is posted on FDA's Internet site at: <http://www.cfsan.fda.gov/~comm/expcllst.html>. Subsequent to the publication of the draft guidance, Chile informed FDA that Chile needed more than just the names and addresses of the U.S. dairy firms eligible to export to Chile. Consequently, FDA is revising the list so that it will now include the plant numbers; names, telephone numbers, and e-mail addresses of the contact persons; and lists of products being exported to Chile, in addition to the names and addresses of the firms' manufacturing and processing plants. Application for inclusion on this list is voluntary. However, Chile has advised that dairy products from firms not on this list could be prevented by Chilean authorities from entering commerce in Chile. The term "dairy products" for purposes of this list is not intended to cover the raw agricultural commodity raw milk.

FDA has requested that U.S. dairy product manufacturers and processors provide certain information, as discussed below, if they currently export, or intend in the future to export, their dairy products to Chile and wish to be included on the list. At Chile's request, FDA is now asking that this information be updated every two years in order to maintain the accuracy of the list. In order to either update the information included on the list or to be initially included on the list, the following information should be submitted to Ms. Esther Lazar, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, (Fax) 301-436-2632, or e-mail elazar@cfsan.fda.gov:

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1. Business name and address;
2. Name, telephone number, and e-mail (if available) of contact person;
3. List of products presently shipped to Chile and those intended to be shipped in the next 3 years;
4. Name and address of the manufacturing plant for each product;
5. Name of any Federal, State, or local governmental agencies that inspect the plant, along with the government assigned plant identifier (e.g., plant number) and date of last inspection; and
6. Copy of last inspection notice and, if other than an FDA inspection, copy of last inspection report.

The list on FDA's Internet site and the information shared with Chile, some or all of which may be posted on Chile's website, includes the plant numbers; names, telephone numbers, and e-mail addresses of the contact persons; and lists of products being exported to Chile, in addition to the names and addresses of the firms' manufacturing and processing plants. The other information identified above for submission to FDA is intended to assist FDA in establishing and maintaining the list. FDA considers the information on this list, which is provided voluntarily with the understanding that it will be communicated to Chile and posted on the Internet, to be information that is not protected from disclosure under 5 U.S.C. § 552(b)(4).

B. Inclusion on the List

For each manufacturer or processor that submits an application, FDA intends to review the applicant's recent inspection history, including FDA or other Federal or State agency inspections. FDA intends to place the names and addresses of firms that are not the subject of a pending judicial enforcement action (e.g., injunction or seizure) or a pending warning letter on the list. FDA intends to deny listing a firm if the firm is the subject of a pending judicial enforcement action or a pending warning letter.

FDA intends to send a confirmation e-mail or letter to the applicants to notify them of FDA's decision with respect to their eligibility or ineligibility for inclusion on the list. Every two years, FDA also intends to send a letter to manufacturers that are currently listed, requesting that they update the information they initially provided and indicate whether they wish to continue being listed.

C. Updating the List

FDA intends to provide Chilean authorities with an updated list of firms on a quarter annual basis. The quarterly update will list any additional firms that have applied to FDA within the previous three-month period and have been determined by FDA to meet the criteria for inclusion on the list. FDA also intends to delete from the list on a quarter annual basis those firms that FDA has determined (either by notice from the firm or by FDA inspection) have gone out of business or have indicated to FDA in writing that they no longer intend to export dairy products to Chile. FDA also intends to remove from the list any firms that do not respond to FDA's request every two years for updated information. The quarter annual update schedule along with

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the two-year request for updated information is intended to provide FDA and dairy manufacturers/processors with a structured and predictable schedule for updating the list and to provide the agency with sufficient time to determine the eligibility or ineligibility of firms applying for placement on the list.

If a listed firm subsequently becomes the subject of a pending judicial enforcement action or a pending warning letter, FDA intends to remove that firm from the list posted on the Internet and to send a revised list to Chilean authorities as soon as possible after the firm becomes the subject of the pending judicial enforcement action or pending warning letter, usually within 48-72 hours after the relevant FDA action. Since a pending judicial enforcement action or a pending warning letter, if associated with a food safety concern, necessitates a more expedient process to protect public health, FDA intends to remove such a firm from the list as soon as possible, rather than to wait for the quarter annual update described above.

FDA intends for each issuance of the list, whether issued as a result of a scheduled quarter annual update or as a result of removal of a firm due to a pending judicial enforcement action or a pending warning letter, to be numbered sequentially and dated to indicate the date of the most recent update.