

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0069]

DMB

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Agency Information Collection Activities; Submission for OMB Review; Comment Request; Information From U.S. Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Request for Information From U.S. Processors That Export to the European Community
(OMB Control Number 0910-0320)—Extension**

The European Community (EC) is a group of 15 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed below in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations and State authorities, FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the list are subject to detention and possible refusal at the port. FDA requests the following information from each processor:

1. Business name and address;
 2. Name and telephone number of person designated as business contact;
 3. Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;
 4. Name and address of manufacturing plants for each product;
 5. Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier, such as plant number, and last date of inspection;
- and

6. Assurance that the firm or individual representing the firm and submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of section 1001 of Title 18, United States Code. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

In the **Federal Register** of February 28, 2001 (66 FR 12802), the agency requested comments on the proposed collection of information. One comment was received. In this comment there were two concerns regarding burden. The first was that States may incur more than “information” burden. The impact on a few States has been to retrieve inspection reports from FDA contracted inspections or from a State inspection. The second concern was that FDA “assumed no operating or maintenance costs”. The burden on a company for placement on an EC required list is only the initial information asked for in the **Federal Register** notice. A company may inquire about the status during the review process for placement on the list but this is of their choosing.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Products	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Shell eggs	10	1	10	0.25	2.5
Dairy	100	1	100	0.25	25
Game meat and meat products	10	1	10	0.25	2.5
Animal casings	15	1	15	0.25	3.75
Gelatin	6	1	6	0.25	1.5
Total					35.25

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

The estimated number of respondents is based on the volume of exports and responses received to date. The estimated number of yearly responses has decreased from the estimate in FDA’s previous notice seeking comment for this collection of information (63 FR 29738, June 1, 1998) because the actual number of responses has been decreasing. Companies do not need to reapply unless they have a compliance problem. An estimate for processors that export gelatin also has been added because these processors are now being included in the listing process.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Respondents	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Trade association	15	1	15	8	120
State	50	1	50	8	400
Total					520

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

The burden estimated for the trade associations assumes the trade associations will disseminate FDA's information request through mass mailings to their membership or publish it in their trade magazine or newsletter. The burden estimated for State authorities assumes dissemination of information to the processors or dissemination of information about processors to FDA.

Dated: 5/29/01
May 29, 2001.

Margaret M. Dozel

Margaret M. Dozel,
Associate Commissioner for Policy.

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Suzette N. Reese