

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2010N0422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information From United States Processors That Export to the European Community

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements in implementing the lists of U.S. firms/processors exporting shell eggs, dairy products, game meat, game meat products, animal casings, gelatin, and collagen to the European Community (the EC).

DATES:

Submit either electronic or written comments on the collection of information by [insert date 60 days after date of publication in the Federal Register].

ADDRESSES:

Submit electronic comments on the collection of information to <http://www.fda.gov/regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50400B, Rockville, MD 20850, 3017963793.

SUPPLEMENTARY INFORMATION:

Under the PRA (44 U.S.C. 35013520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. Collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information From U.S. Processors That Export to the European Community (OMB Control Number 09100320) Extension

The EC is a group of 27 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 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.

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 the EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the 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 the EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the lists are subject to detention and possible refusal at the port. FDA requests the following information from each processor seeking to be included on the lists:

- Business name and address;

- Name and telephone number of person designated as business contact;

- Lists of products presently being shipped to the EC and those intended to be shipped in the next 6 months;

- Name and address of manufacturing plants for each product; and

- 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.

Description of Respondents: The respondents to this collection of information include U.S. producers of shell eggs, dairy products, game meat, game meat products, animal casings, gelatin, and collagen.

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

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Table 1. Estimated Annual Reporting Burden1

Products

No. of
Respondents

Annual Frequency per Response

Total Annual
Responses

Hours per
Response

Total Hours

<ROW RUL="s,&qdrt;">Shell Eggs
10
1
10
0.25
3

<ROW RUL="s,&qdrt;">Dairy
120
1
120
0.25
30

<ROW RUL="s,&qdrt;">Game Meat and Game Meat Products
5
1
5
0.25
1

<ROW RUL="s, &qdrt;">Animal Casings

5
1
5
0.25
1

<ROW RUL="s, &qdrt;">Gelatin

3
1
3
0.25
1

<ROW RUL="s, &qdrt;">Collagen

3
1
3
0.25
1

Total
 
 
 
 
37

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

FDA bases its estimates of the number of respondents and total annual responses on the submissions that the agency has received in the past 3 years for each product type. To calculate the estimate for the hours per response values, we assumed that the information requested is readily available to the submitter. We expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission. We believe that this effort should take no longer than 15 minutes (0.25 hour) per response. FDA estimates that it will receive 1 submission from 10 shell egg producers annually, for a total of 10 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 2.5 hours, rounded to 3 hours. FDA estimates that it will receive 1 submission from 120 dairy product producers annually, for a total of 120 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 30 hours. FDA estimates that it will receive 1 submission from 5 game meat and game meat product producers annually, for a total of 5 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive 1 submission from 5 animal casings producers annually, for a total of 5 annual responses. Each submission is

estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive 1 submission from 3 gelatin producers annually, for a total of 3 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. FDA estimates that it will receive 1 submission from 3 collagen producers annually, for a total of 3 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour.

Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: August 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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