Information From United States Firms and Processors That Export to the European Community

OMB Control No. 0910-0320

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The European Community (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. The European Commission, the executive branch of the EC, requires countries trading with any of the EC member countries to provide lists of firms and processors approved to export certain animal-derived commodities to the EC. As stated in the notice published in the Federal Register of April 4, 1996 (61 FR 15077), FDA established a list of U.S. firms and processors that intended to export shell eggs, dairy products, and game meat and game meat products to the EC.

Although the 1996 Federal Register notice did not include on the list firms and processors exporting raw, bulk collagen, and gelatin intended for human consumption, EC directives require that shipments of raw, bulk collagen, and gelatin products be accompanied by certification stating that the product, derived from ruminant bones, bovine hides, and pigskins, has been produced in compliance with EC Council Directive 2003/863/EC. The directive contains the requirements for sourcing, manufacture, transport, and storage of raw materials and manufacture of finished products. Chapter III, Article 23, of the directive requires lists identifying non-EC firms and processors that meet EC requirements and have the appropriate animal and public health certificates. Therefore, FDA is revising this information collection in order to facilitate exports of raw, bulk collagen, and gelatin originating from the United States into the EC. The description of the data elements to be collected from firms and processors of raw, bulk collagen, and gelatin products follows. The estimated burden hours associated with this information collection remain 37 total hours.

Through this process, FDA is implementing the general policy-making authority granted the Commissioner under 21 U.S.C. 393(d)(2).

2. Purpose and Use of the Information Collection

FDA requests the following information from each firm or processor seeking to be included on the lists for shell eggs, dairy products, game meat, game meat products, and animal casings:

- 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.

FDA uses the information to maintain lists of firms and 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 firms and processors that meet U.S. regulatory requirements. Products processed by firms and processors not on the lists are subject to detention and possible refusal at the port.

FDA requests the following information from each firm or processor seeking to be included on the lists for raw, bulk collagen, and gelatin:

- Business name and address;
- Name, telephone number, and email address of contact person;
- List of products presently shipped to the EC and those intended to be shipped within the next 2 years;
- Name and address of the manufacturing and processing plant for each product;
- Names and affiliations of any Federal, State, and local governmental agencies that inspect the plant, government assigned plant identifier, such as plant number and last date of inspection; and
- A copy of the most recent (within 1 year of the date of application) inspection report issued by a State, local or Federal public health regulatory agency and a copy of a recent laboratory analysis as required by the EC of the finished product including: Total aerobic bacteria, coliforms (30 ˚C), coliforms (44.5 ˚C), anaerobic sulphite-reducing bacteria (no gas production), Clostridium perfringens, Staphylococcus aureus, Salmonella, Arsenic , Lead, Cadmium, Mercury, Chromium , Copper, Zinc, Moisture (105 ˚C), Ash (550 ˚C), SO_2, and H_2O_2.

FDA will use the information to maintain a list of approved firms and processors that will be posted on FDA's Web site. FDA intends to place on the list only firms and processors that are not the subject of an unresolved regulatory enforcement action. If a listed firm or processor subsequently becomes the subject of a regulatory enforcement action or an unresolved warning letter, FDA will view such a circumstance as evidence that the firm or processor is no longer in compliance with applicable U.S. laws and regulations. Should this occur, FDA will take steps to remove that firm or processor from the list and send a revised list to the EC authorities, usually within 48 to 72 hours after the relevant FDA action. If a firm or processor has been delisted as a result of a regulatory enforcement action or unresolved warning letter, the firm or processor will have to reapply for inclusion on the list once the regulatory action has been resolved.

FDA intends to update the list of firms and processors eligible to export raw, bulk collagen, and gelatin to the EC quarterly. Firms and processors placed on the approved exporters list are subject to audit by FDA and EC officials. Complete requests for inclusion must be submitted to FDA every 12 months to remain on the list. Inclusion on the list is voluntary. However, raw, bulk collagen,

and gelatin products from firms or processors not on the approved exporters list for these products will not receive an export certificate, and these products may be detained at EC ports of entry.

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. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Through the use of improved information technology the agency is always seeking ways to reduce the burden of maintaining such lists. Firms may submit the required information electronically, by e-mail. The agency estimates that about seventy-five percent (75%) of the responses would be collected electronically.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of effort in this area. No other agency collects this information. The Food Safety Inspection Service (FSIS) and the Agricultural Marketing Service (AMS) of the U. S. Department of Agriculture (USDA) perform some voluntary inspection and grading of the commodities but maintains no lists of those companies that export to the EC.

5. Impact on Small Businesses or Other Small Entities

FDA recognizes that some of the affected firms, approximately twenty-five percent (25%), are small businesses, and has kept their particular needs in mind throughout the development of this list process. There is no known way to reduce the burden on a small business wishing to participate in the list process. FDA aids small businesses in complying with the agency's requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

The lists are required by the EC for specific commodities of animal origin to enter into any of the EC member states. Less frequent collection would not impact any federal program. The impact would be on U.S. producers of shell eggs, dairy products, game meat, game meat products, animal casings, gelatin, and collagen; their commodities would be detained at the EC port of entry. Requests for inclusion on the lists of firms and processors eligible to the EC must be submitted to FDA every 12 months to remain on the list. Thus, data collection occurs yearly.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of August 18, 2010 (75 FR 51077). FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information collected is used in lists transmitted to the EC and published on the Internet in order to facilitate trade. Thus, FDA makes no assurance of confidentiality of the information provided by respondents.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden[1]

Products	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	10	1	10	0.25	3
Dairy	120	1	120	0.25	30
Game Meat and Game Meat Products	5	1	5	0.25	1
Animal Casings	5	1	5	0.25	1
Gelatin	3	1	3	0.25	1
Collagen	3	1	3	0.25	1
Total					37

[1] There 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 the 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. 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 one submission from five game meat and game meat product producers annually, for a total of five 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 one submission from five animal casings producers annually, for a total of five 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 one submission from three gelatin producers

annually, for a total of three 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 one submission from three collagen producers annually, for a total of three 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.

12 b. Annualized Cost Burden Estimate

FDA estimates that there are 146 respondent firms. We estimate the average hourly wage of an employee responding to the information collection to be equivalent to that of a base GS-12, step 5 hourly wage ($32.73/hour per the 2010 GS Salary Table). Doubling this wage to account for overhead costs, FDA estimates the hourly cost to respondents to be $65.46. Thus, the estimated cost incurred by the respondents is $2,422 (37 burden hours x $65.46/hr = $2,422.02).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA employees review the information collected and maintain the list process. The 146 respondent firms submit one response each. We estimate that each response will take two hours of time, or 292 hours annually for all responses (146 x 2 = 292). We estimate the average hourly wage of this Federal employee to be that of a base GS-13, step 5 ($38.92/hour per the 2010 GS Salary Table). Doubling this wage to account for overhead costs, FDA estimates the hourly cost to the Federal government to be $77.84. Thus, the annual cost to the Federal government is estimated to be $22,729 (292 hours x $77.84/hr = $22,729.28).

15. Explanation for Program Changes or Adjustments

As required by the a change in EC directives, the data elements collected from firms and processors exporting raw, bulk collagen, and gelatin have changed from those data elements previously approved. The estimated total burden hours have not changed from the burden hours shown in the current inventory. This revision is being characterized as a program change due to agency discretion.

EC Council Directive 2003/863/EC requires specified information from a firm or processor seeking to be included on the lists for raw, bulk collagen, and gelatin. This is a change from the previous data elements of this collection; the change in data elements does not apply to a firm or processor seeking to be included on the lists for shell eggs, dairy products, game meat, game meat products, and animal casings. Compare the two bulleted lists in Section 2 above. The bulleted data elements for collagen, and gelatin (copied and pasted below) are *substantially* the same as those required for the other firms *with the addition of the last bullet*, which requires copies of two documents. These two documents are available in the firm's files, so we have not increased the burden estimate to cover the task of providing the two copies. We believe that a 15 minute burden estimate remains an appropriate estimate for the tasks required for inclusion on the list.

The change in EC directives requires the following information from each firm or processor seeking to be included on the lists for raw, bulk collagen, and gelatin:

- Business name and address;
- Name, telephone number, and email address of contact person;
- List of products presently shipped to the EC and those intended to be shipped within the next 2 years;
- Name and address of the manufacturing and processing plant for each product;
- Names and affiliations of any Federal, State, and local governmental agencies that inspect the plant, government assigned plant identifier, such as plant number and last date of inspection; and
- A copy of the most recent (within 1 year of the date of application) inspection report issued by a State, local or Federal public health regulatory agency and a copy of a recent laboratory analysis as required by the EC of the finished product including: Total aerobic bacteria, coliforms (30 °C), coliforms (44.5 °C), anaerobic sulphite-reducing bacteria (no gas production), Clostridium perfringens, Staphylococcus aureus, Salmonella, Arsenic , Lead, Cadmium, Mercury, Chromium, Copper, Zinc, Moisture (105 °C), Ash (550 °C), SO_2, and H_2O_2.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA publishes the lists on the Internet.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.