SUPPORTING STATEMENT

REQUEST FOR INFORMATION FROM U.S. PROCESSORS THAT EXPORT TO THE EUROPEAN COMMUNITY

OMB No. 0910-0320

A. Justification

1. Need and Legal Basis

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 (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin), 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 uses a list process to meet this requirement. 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. Through this process, FDA is implementing the general policy-making authority granted the Commissioner under 21 U.S.C. 393(d)(2).

2. Information Users

FDA requests the following information from each processor seeking to be included on the lists:

1. Business name and address;
2. Name and telephone number of person designated as business contact;
3. Lists of products presently being shipped to the EC and those intended to be shipped in the next 6 months;
4. Name and address of manufacturing plants for each product; and,
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.

As noted above, FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements. FDA provides the lists to the EC quarterly and publishes the lists on the Internet at http://www.ams.usda.gov/dairy/eu_prgm.htm.

3. Improved Information Technology

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 in electronic format.

4. Duplication 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. Small Businesses

FDA recognizes that some of the affected firms 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 through the Division of Education and Communication in the Center for Food Safety and Applied Nutrition (CFSAN) and through the scientific and administrative staffs of the agency.

6. Less Frequent Collection

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 the U.S. exporters of dairy, shell eggs, animal casings, gelatin, collagen and game meat and game meat products; their commodities would be detained at the EC port of entry.

7. Special Circumstances

The list process does not involve submission of information to the agency more than quarterly, written responses to the agency in less than 30 days, submission of more than two copies, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA, or require the disclosure of trade secrets or other confidential information.

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), on June 21, 2007 (72 FR 34256), a 60-day notice for public comment was published in the *Federal Register*. No comments were received from the public.

9. Payment/Gift to Respondent

The information collection does not provide for any gift or payment to respondents.

10. Confidentiality

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

11. Sensitive Questions

The information to be collected does not involve questions of a sensitive nature.

12. Burden Estimate (Total Hours and Wages)

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

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

Products	No. of Respondents	No. Of Responses per Respondent	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 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 estimate on the responses received over the past three years. We estimate that the annual reporting burden would be approximately 37 hours. The time to respond to the questions should take approximately 15 minutes using any of the technologies available to transmit the information. All of the information asked for should be readily available. No record retention is required. In previous years, FDA estimated that the agency's communication with trade associations and states resulted in a reporting burden of 520 hours. FDA no longer receives information from trade associations and states pursuant to this program. Accordingly, the proposed annual burden for this information collection has been reduced by 520 hours. Therefore, the proposed annual burden for this information collection is 37 hours.

Cost to the Respondent

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 ($30.57/hour per the 2007 GS Salary Table). Doubling this wage to account for overhead costs, FDA estimates the hourly cost to respondents to be $61.14. Thus, the estimated cost incurred by the respondents is $2,262 (37 burden hours x $61.14/hr = $2,262.18).

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to 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 ($36.36/hour per the 2007 GS Salary Table). Doubling this wage to account for overhead costs, FDA estimates the hourly cost to the Federal government to be $72.72. Thus, the estimated annual cost to the Federal government is estimated to be $21,234 (292 hours x $72.72/hr = $21,234.24).

15. Program or Burden Changes

In previous years, FDA estimated that the agency's communication with trade associations and states resulted in a reporting burden of 520 hours. FDA no longer receives information from trade associations and states pursuant to this program. Accordingly, the proposed annual burden for this information collection has been reduced by 520 hours. In addition, FDA has increased the number of dairy producers it estimates will seek to be on the list, from 100 to 120. Taking into account both the reduction in hours and the increase, the collection has experienced an overall decrease in burden.

16. Publication and Tabulation Dates

FDA publishes a copy of the list on the Internet.

17. Display of OMB Approval Date

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"

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.