SUPPORTING STATEMENT

Request for Information from U.S. Processors That Export
to the European Community

A. JUSTIFICATION

1. Circumstances that make the information collection necessary.

The European Community (EC) is the group of fifteen European countries that have agreed to harmonize their commodity requirements to facilitate commerce among the member states. Ten additional countries will join the EC in May 2004. The U. S. Department of Agriculture and the Food and Drug Administration (FDA) have negotiated a trade agreement with the EC on sanitary measures to protect public and animal health in the trade of live animals and animal products. The Council of the EC has issued Directives which contain the rules and procedures which must be followed by the member countries for intra community trade as well as intercommunity trade. Within these directives are requirements for certificates to accompany each shipment of animal derived products imported into the EC and for the producers/ processors to be on a list which is established by the member country or non-EC country. The following directives are applicable for those commodities for which the FDA is the responsible federal agency:

EC Council Directive 92/46/EEC - milk and milk based products

EC Council Directive 92/45/EEC - wild game meat

EC Council Directive 91/495/EEC with 92/118/EEC - farmed game meat

EC Council Directive 92/5/EEC with 92/118/EEC and 77/99/EEC - meat products including those derived from game meat

EC Council Directive 94/65/EC - meat products derived from game meat

EC Council Directive 91/371/EEC, Council Regulation EEC N 1907 and Commission Regulation 1274/91 with Council Directive 92/118- shell eggs

EC Council Directive 92/118/EEC - animal casings

EC Commission Decision 99/724/EC - amends 92/118/EEC – gelatin

EC Commission Decision 2003/42/EC – Collagen

Dates have been established at which time importation of commodities from the United States and other non-EC countries will be subject to the minimum requirements of these directives.

Therefore, the FDA has established lists of processing firms for the commodity areas of dairy products, shell eggs, game meat and game meat products, animal casings, gelatin and collagen. These lists are not a requirement of any US regulation but are of the EC directives. U.S. companies are exporting these commodities to EC member countries. These lists must be maintained as processors and products of trade will change.

The establishment of the processor lists for the EC involves answering the following questions:

1) business name and address,

2) name and telephone number of person designated as business contact,

3) list of products presently being shipped to the EC and those intended to be shipped in the next two years,

4) name and address of manufacturing plant 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.

6)assurances 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 Title 18, Chapter 47 Section 1001, United States Code (U.S.C.). This statue states that it is a criminal offense to knowingly and willfully make a false and fraudulent statement or to make or use a false document in any manner within the jurisdiction of a department or agency to a department or agency of the United States or to knowingly and willfully falsify, conceal, or cover up any trick, scheme or device a material fact in any matter within the jurisdiction of a department or agency of the United States.

7) assurances that the firm or individual is familiar with the EC directives and is in compliance with their requirements.

FDA inspects firms in the affected product categories periodically, and as such its information on the full scope of firms exporting these products and which products they are exporting to the EC is not current. The Department of Agriculture or state agencies perform voluntary inspection and grading of some of these products. Thus FDA needs to periodically update the processor list required by the EC to facilitate trade with the EC.

Inclusion on a list is voluntary. However, commodities from firms not on these lists have been detained at the EC port of entry.

2. Indicate how, by whom, and for what purpose the information is to be used.

The information obtained would be used by the FDA to update and maintain the lists presently required by the EC directives for trade with the U.S. The updated lists of US firms would be given to the EC periodically to facilitate trade. Under present EC policy the lists would be published in the Official Journal of the European Community. Without the list, trade of the US animal derived commodities under FDA's jurisdiction could be detained at the EC port of entry. In the past, seafood shipments and dairy shipments from firms not on the seafood or dairy list were detained and not allowed into the EC.

3. Indicate the extent to which information technology is applicable.

Companies or individuals will be free to use whatever form of information technology is available and convenient for them to use. This will include mail, facsimile and e-mail. This should reduce the burden of the firms to report the information by allowing them to use the easiest method for the firm.

4. Describe efforts to identify duplication.

Lists of processors that export their commodities to the EC were established but processors and commodities change. These changes in exporters and commodities are not regularly maintained within the FDA. 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. If the records of certificates were reviewed at the circuit or branch level of FSIS and AMS a partial updating list might be obtained. This would not be easily obtained nor would it include those firms that do not use these services. Animal and Plant Health Inspection Service of the USDA has signed some certificates in the past and maintains no records of these certificates. Some states have signed certificates for game meat but it is not completely known which states have been involved. Additionally prior to the EC completion of the harmonization and implementation of the regulation for trade with non-EC countries, some US firms were able to export to specific countries without certificates.

5. Impact on small business

The impact on any business large or small would be the small amount of time required to answer the seven questions asked of them.

6. Describe the consequences to Federal programs or policy activities if the collection is not conducted

The collection is strictly voluntary. It is not required by any current U. S. regulation. The lists are required by the EC for specific commodities of animal origin to enter into any of the EC

member states. The impact is on the US exporters of dairy, shell eggs, animal casings, gelatin, collagen and game meat and game meat products with the detaining of commodities at the EC port of entry.

7. Explain any special circumstances to the information collection

Not applicable

8. Describe the efforts to obtain comments on the information collection before submission to OMB

In the Federal Register of April 16, 2004 (69 FR 20630), the FDA solicited comments from the public on the collection of information. No comments were received.

9. Explain any decision to provide payment or gift to respondents.

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

10. Describe any assurance of confidentiality

This information collected is to be used in the formation of lists to be transmitted to the EC in order to facilitate trade. This lists are published in the Official Journal of the European Community and therefore are not confidential.

11. Provide additional justification for any questions of a sensitive nature

The information to be collected is not of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information

FDA estimates the burden for this collection as follows:

Table 1 Estimated Annual Reporting Burden

Products	No. of Respondents	No. Of Responses per Respondent	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	5				

Table 1 Estimated Annual Reporting Burden					
Meat Products		1	5	0.25	1.25
Animal Casings	5	1	5	0.25	1.25
Gelatin	3	1	3	0.25	0.75
Collagen	3	1	3	0.25	0.75
TOTAL					31.5

Table 2 Estimated Annual Reporting Burden (Disclosure)					
Respondent	No. of Respondents	No. of Responses per Respondent	Total annual Responses	Hours per Response	Total Hours
Trade Association	15	1	15	8	120
State	50	1	50	8	400
TOTAL					520

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

It is estimated that the annual burden would be no more than 31.5 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. The number of respondents is a rough estimate based on volume of exports and responses received to date. For shell egg respondents, it is approximated at 10 each. For game meat and game meat.

Full equivalency with EU directives has not been established to date, therefore the additional assurance of compliance with the EU directives is necessary to be able to continue trade with the EU countries. This will necessitate additional hours for the producer to review the directive this time is estimated at 20 minutes. Therefore the additional time for compliance information is 42 hours (126 responses x 0.33 hours). This is included in the total burden hours.

The annual cost for firms to supply the information necessary to maintain EC processor lists for shell eggs, dairy products, animal casings, gelatin, collagen and game meat and game meat products is estimated as follows:

Estimated total number of hours for response = 31.5
126 responses x 0.25 hours

Estimated cost of response time = $895
hourly cost for response is estimated
as being equivalent to that of a base
GS-12 salary ($28.41/hour)

If the trade associations desire to send out notification to their members or publish in their trade magazine (third party disclosure), this would potentially require an hour to add an article to a trade magazine to approximately a day to print and send a notification to their members for each trade association. The estimate of burden would be approximately 120 hours. The number of associates would be 15 and the total hours per association would be as high as 8 hours.

If state governments notify local processors, this would potentially require an hour to add to a state bulletin or approximately a day to notify processors by other means of communication. The maximum number of states would be fifty and the total hours per state would be as high as 8 hours.

The annual third party disclosure costs for establishment of EC list is estimated as follows:

Estimated total number of hours for disclosure = 520
15 trade associations and 50 states x 8 hours

Estimated cost of disclosure = $14773
Hourly rate equivalent to the base GS-12 salary

13. Provide an estimate of the total annual cost burden, other than hour burden, to respondents.

There are no additional costs.

14. Provide estimates of annualized cost to the Federal government.

The cost to the Federal government would be that of reviewing the information supplied by the firms/processors. This review would include verification of inspection dates for each new firm, obtaining and reviewing inspection reports. The five commodities area lists would be modified and then transmitted to the EC. The lists would be reviewed for any known additions or corrections on a quarterly basis. The annual cost to the Federal government for maintenance is estimated as follows:

Estimated total hours per year = (126 x 2) = 252

estimated number of responses = 126
estimated number of hours for review = 2

Estimated total cost for establishment and review of lists

252 hours x $34/ hour = $8568
hourly costs is estimated as being equivalent to that of a base GS-13 salary

15. Explain the reasons for any program changes or adjustments.

Since the renewal approval to obtain information for the maintenance and updating of these lists an additional trade association has been identified, the response from the shell egg and game meat products areas were slightly less than anticipated and an additional commodity, gelatin and collagen is being listed. In addition, since the list has been established and companies do not need to reapply unless they have a compliance problem, the only additions are those companies that are just beginning trade with the EU. EU implementation dates for directives governing trade with non EU countries are occurring with a trade agreement in which full equivalency has not been determined, therefore the products must be in compliance with the applicable requirements which requires the processor to be aware of the EU requirements and to acknowledge equivalent compliance.

16. Outline plans for tabulation and publication for collections of information whose results will be published.

The lists will contain those firms/processors exporting to the EC which comply with FDA regulations and which comply with EU directives. Publication is handled by the EC according to their procedures.

17. Explain the reason that display of the expiration date for OMB approval of the information would be inappropriate.

Not applicable

18. Explain each exception to the certification statement identified in item 19.

Not applicable

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable