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[Notices]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 96N-0089]

Establishment of Lists of U.S. Firms/Processors Exporting Shell Eggs, Dairy Products, Game Meat and Game Meat Products to the European Community; Request for Information From Such Firms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to establish lists of U.S. firms/processors exporting shell eggs, dairy products, game meat and game meat products to the European Community (EC) that manufacture products in compliance with U.S. food laws and regulations. FDA is taking this action in response to current changes in the EC legislation that will require countries trading with any of the EC member countries to provide lists of firms exporting certain animal derived commodities to the EC. FDA is requesting that U.S. firms presently exporting, or who anticipate exporting these commodities to the EC, provide the agency with information for inclusion on the appropriate list. This list will be updated on a quarterly basis and will be submitted to the EC. This notice is intended to alert all U.S. exporters to the EC requirement for lists of companies processing animal derived commodities that are exported to the EC member states. The agency is also requesting comments on the best mechanisms to be used in obtaining future changes and additions to the EC lists for these commodities.

DATES: Written comments and information for inclusion on the EC list by April 30, 1996. Written comments on the information collection requirements by May 6, 1996.

ADDRESSES: Submit written information for inclusion on the EC list to Marilyn F. Balmer, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX 202-205-4422 or E-mail MFB@FDACF.SSW.DHHS.GOV.

Submit written comments on the best mechanisms to be used in obtaining future changes and additions to the EC lists for dairy products, shell eggs, game meat and game meat products to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be

identified with the Docket number found in brackets in the heading of this document.

Submit written comments on the information collection requirements to DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0320), Hubert Humphrey Bldg., 200 Independence Ave. SW., rm. 531-H, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Marilyn F. Balmer, Center for Food

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Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4400.

SUPPLEMENTARY INFORMATION:

I. Introduction

The EC is a group of 15 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among the member states. Those countries which are members of the EC are as follows: United Kingdom, France, Italy, Spain, Portugal, Germany, Netherlands, Belgium, Denmark, Luxembourg, Ireland, Greece, Austria, Finland, and Sweden.

Lists of processors (businesses) and the use of public and/or animal health certificates are an integral part of EC legislation 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 that must be followed by the member states for intracommunity trade in commodities. Member states of the EC are required by EC legislation to maintain lists of processing firms which meet these EC directives. The lists of processors approved by member states are published in the Official Journal of the European Community. Public and/or animal health certificates issued by the government of the country of origin are required to accompany every shipment of these products. For animal derived commodities, these directives were developed with regard to animal and public health considerations. Dates are being established at which time importation of commodities from third countries (i.e., the United States and other non-EC countries) will be subject to the minimum requirements of these directives. The Department of Agriculture and FDA are presently negotiating with the EC with a view to establishing agreement on the comparability of U.S. and EC regulatory systems to ensure that commodities trade with the EC is not disrupted. The EC directives on shell eggs, dairy products, game meat and game meat products are as follows:

1. EC Council Directive 92/46/EEC contains the rules for the production and sale of raw milk, heat-treated milk and milk-based products. In chapter III, article 23 of this directive, for importation into the EC from third countries, lists and certificates are required. The list identifies the establishments which meet the EC requirements and the certificates are health certificates (animal and public).

2. EC Council Directive 92/45/EEC contains the rules for slaughter and sale of wild-game meat. In chapter III, articles 16 and 17 of this directive, for importation into the EC from third countries (non-EC) lists and certificates are required. The list identifies establishments which meet EC requirements and the certificates are both public and animal health certificates.

3. EC Council Directive 91/495/EEC contains the rules for the production, slaughter, and sale of rabbit meat and farmed-game meat. EC Council Directive 92/118/EEC, annex 1, chapter 11 requires that for imported rabbit meat and farmed game meat that animal and public health certificates be provided and that chapters II and III from Directive 91/495/EEC be followed. Directive 91/495/EEC requires lists of establishments which meet the requirements.

4. EC Council Directive 92/5/EEC contains the rules for the production and marketing of meat products including those derived from game meats. EC Council Directive 92/118/EEC, annex II, chapter 1 requires that imported meat products have a public health certificate and that rules from Directive 77/99/EEC, which was amended by Directive 92/5/EEC be followed. Within these directives lists of establishments are required. Meat products are those prepared from or with meat which has undergone treatment such that the cut surface no longer has the characteristics of fresh meat.

5. EC Council Directive 94/65/EC contains the rules for production and marketing of meat preparations. Meat preparations include those products derived from game meat. The EC directive further distinguishes these products by specifying that the cut surface of the meat preparations has not lost the characteristics of fresh meat. In chapter V, article 13, certificates and lists are required for importation of these products from third countries (non-EC).

6. EC Council Decision 94/371/EEC, Council Regulation EEC N 1907 and Commission Regulation EEC N 1274/91 contains the rules for the production and marketing of shell eggs. Council Directive 92/118 lays down the animal and public health requirements for trade and imports not subject to specific EC rules. Within these directives lists and certificates are required.

Shell eggs, hard cooked eggs and imitation egg products; dairy products; and game meats and game meat products (i.e., non-FSIS mandatorily inspected meat and poultry) are commodities for which the FDA is the Federal agency responsible for public health protection. Other governmental agencies such as Agriculture Marketing Service and Food Safety Inspection Service offer voluntary inspection of these commodities.

II. Intention to Establish Lists of U.S. Firms/Processors

Initially, FDA intends to establish lists of U.S. firms/processors that meet U.S. regulations and export to the EC the following products: Shell egg, dairy products and game meat commodities. Inclusion of U.S. firms/processors on these lists is voluntary. However, commodities from firms not on these lists could be detained at the EC port of entry. In the past, seafood shipments from firms not on the seafood list were detained and not allowed into the EC. FDA officials accompanied by EC officials may visit any firm placed on these lists for auditing of the U.S. public and animal health systems.

U.S. firms/processors that export the previously mentioned products to the EC and want to be included in the appropriate lists that the agency is developing should submit the following information to FDA to Marilyn F. Balmer (address above):

1. Business name and address;
2. Name and telephone number of contact person;

3. List of products presently shipped to EC and those intended to be shipped in the next 2 years;

4. Name and address of the manufacturing plant 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.

The mechanism for updating and maintaining these lists is being reviewed. Comments on methods for maintenance are welcome.

FDA is presently considering procedures for certificates and will notify exporters in an appropriate manner.

III. Paperwork Reduction Act

OMB has approved this collection of information under the emergency processing provision of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j)) and has assigned OMB control number 0910-0320. Public reporting burden for this voluntary collection of information is estimated to average 0.25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and

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completing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing the burden, to: DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0320), Hubert Humphrey Bldg., 200 Independence Ave. SW., rm 531-H, Washington, DC 20201. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number.

Submit written information for inclusion on the EC list to Marilyn F. Balmer (address above).

Submit written comments on the best mechanisms to be used in obtaining future changes and additions to the EC lists for dairy products, shell eggs, game meat and game meat products to the Dockets Management Branch (address above). All comments should be identified with the docket number found in the brackets in the heading of this document.

Dated: March 29, 1996.
William K. Hubbard,
Associate Commissioner for Policy Coordination.
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