Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 57

[Doc. No. AMS–LPS–14–0055]

Revisions to the Electronic Submission of the Import Request of Shell Eggs

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule with request for comments.

SUMMARY: This proposed rule invites comments on revising the regulations (7 CFR part 57) governing the inspection of eggs. This rule would streamline the importation process for table eggs, hatching eggs and inedible liquid egg by requiring that applications for inspection be submitted electronically.

DATES: Comments on this proposed rule must be received by August 10, 2015 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit comments concerning this proposed rule by using the electronic process available at *http://www.regulations.gov.* Written comments may also be sent to Michelle Degenhart, Assistant to the Director, Quality Assessment Division (QAD), Livestock, Poultry, and Seed Program, Agricultural Marketing Service, U.S. Department of Agriculture, Stop 0258, Room 3932S, 1400 Independence Avenue SW., Washington, DC 20250 or by facsimile to (202) 690–2746. All comments should reference the docket number (AMS–LPS–14–0055), the date and page number of this issue of the **Federal Register**. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Michelle Degenhart, Assistant to the Director, QAD, Livestock, Poultry, and Seed Program, Agricultural Marketing Service, U.S. Department of Agriculture, Stop 0258, Room 3932S, 1400 Independence Avenue SW., Washington, DC 20250 or by facsimile to (202) 690–2746 or via email *Michelle.Degenhart@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Agricultural Marketing Service (AMS) administers the Shell Egg Surveillance Program, a mandatory inspection program for shell eggs under the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). This inspection program ensures that shell eggs sold to consumers contain no more restricted eggs than are permitted in the standards for consumer grades. Restricted eggs may contain dirty or cracked shells, eggs leaking internal contents, and eggs with meat or blood spots in the interior. Regulations governing the EPIA are contained in 7 CFR part 57.

On February 19, 2014, the President signed Executive Order 13659 (EO), streamlining the export/import process for America's businesses. EO 13659 outlines the use of the International Trade Data System (ITDS) to modernize and simplify the import and export of cargo. ITDS will allow traders to make a single electronic report and the relevant data will be distributed to the appropriate agencies. Costs will be reduced for business and government. An agency will obtain data more quickly through electronic filings. Automated processing will enhance an agency's ability to process cargo more expeditiously and to identify unsafe, dangerous, or prohibited shipments. This information will be assessed electronically by the relevant government agency resulting in border related decisions which will be electronically sent back to the trade. AMS will incorporate electronic filing of import requests for shell eggs to comply with EO 13659.

Automated Commercial Environment (ACE) Interface

AMS has participated in the development of the ITDS, a government-wide project to build an electronic ''single-window'' for collecting and sharing trade data for reporting imports and exports among Federal agencies. The goal of the ITDS is to eliminate the redundant reporting of data, replacing multiple filings, many of which are on paper, with a single electronic filing. The U.S. Customs and Border Protection (CBP) has developed the Automated Commercial Environment (ACE), a U.S. commercial trade processing system that automates border processing of products. The ACE system connects the trade community and participating government agencies by providing a single, centralized, online access point. When applicants file entries with the CBP through ACE, relevant data is electronically distributed to appropriate government agencies. AMS considers any electronic data entered in ACE as certified by the applicant. In addition, AMS considers any electronic records, digital images, data, or information from a foreign government for foreign inspection and foreign establishment certification to be equivalent to paper records and certified by the foreign government. When developing, procuring, maintaining, or using electronic information technology (EIT), Federal agencies are required by Section 508(a) (1) (a) of the Rehabilitation Act of 1973 (29 U.S.C. 794d) to ensure that EIT is accessible to people with disabilities, including employees and members of the public. The ACE interface meets these requirements.

Therefore, for the reasons specified above, we are proposing to amend the shell egg import regulations to include that applicants may submit LPS Form 222-Import Request electronically.

Executive Order 12866, 13563 and the Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 603 we have performed an initial regulatory flexibility analysis regarding economic effects of this proposed rule on small entities. Copies of the analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

Based on the information we have, the AMS Administrator has made a preliminary determination that, this proposed rule would not have a significant impact on a substantial number of small entities.

Executive Order 12988

This proposal has been reviewed under executive order 12988, Civil

Justice Reform. If adopted, this rule: would have no retroactive effects: and would not require administrative proceedings before parties may file suit in court challenging this rule. Pursuant to section 23 of the EPIA (21 U.S.C. 1052), states or local jurisdictions are preempted from requiring the use of standards of quality, condition, weight, quantity, or grade which are in addition to or different from Federal standards for any eggs which have moved or are moving in interstate or foreign commerce.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175. Consultation and coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35.) the Office of Management and Budget (OMB) has approved the information collection and recordkeeping requirements included in this proposed rule, and there are no new requirements. Should any changes become necessary they would be submitted to OMB for approval. The assigned OMB control number is 0581–0113.

AMS is committed to compliance with the Government Paperwork Elimination Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

E-Government Act

AMS is committed to complying with the E-Government Act to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 7 CFR Part 57

Eggs and egg products, Exports, Food grades and standards, Imports, Reporting and recordkeeping requirements.

For the reasons set forth in this Proposed Rule, it is proposed that 7 CFR part 57 be amended as follows:

PART 57—INSPECTION OF EGGS (EGG PRODUCTS INSPECTION ACT)

■ 1. The authority citation for part 57 continues to read as follows:

Authority: 21 U.S.C. 1031–1056.

■ 2. Revise § 57.920 to read as follows:

§ 57.920 Importer to make application for inspection of imported eggs.

Each person importing any eggs as defined in these regulations, unless exempted by § 57.960 shall make application for inspection upon LPS Form 222—Import Request, to the Chief, Grading Branch, Poultry Programs, AMS, U.S. Department of Agriculture, Washington, DC 20250, or to the Poultry Programs, Grading Branch office nearest the port where the product is to be offered for importation. The application may be filed through electronic submission via *QAD.importrequesteggs@ams.usda.gov,* or by accessing the U.S. Customs and Border Protection's International Trade Data System. Application shall be made as far in advance as possible prior to the arrival of the product. Each application shall state the approximate date of product arrival in the United States, the name of the ship or other carrier, the country from which the product was shipped, the destination, the quantity and class of product, and the point of first arrival in the United States.

Dated: June 5, 2015.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015–14180 Filed 6–9–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2015–N–0540]

Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of public hearing that appeared in the **Federal Register** of March 27, 2015. In the notice of public hearing, FDA requested comments on a number of specific questions identified in the document. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of public hearing published March 27, 2015 (80 FR 16327). Submit either electronic or written comments by August 21, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA–2015–N–0540) for this notice of public hearing. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lesley DeRenzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5161, Silver Spring, MD 20993–0002, 240–402–4612.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 27, 2015, FDA published a notice of public hearing with a 60-day comment period following the public hearing and requested comments on a number of specific questions identified throughout the document. Comments on the notice