

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 301

[Docket No. APHIS–2007–0104]

#### Asian Longhorned Beetle; Additions to Quarantined Areas in New York

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule and request for comments.

**SUMMARY:** We are amending the Asian longhorned beetle regulations by expanding the boundaries of the quarantined areas in New York and restricting the interstate movement of regulated articles from these areas. This action is necessary to prevent the artificial spread of the Asian longhorned beetle to noninfested areas of the United States.

**DATES:** This interim rule is effective August 20, 2007. We will consider all comments that we receive on or before October 19, 2007.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>, select “Animal and Plant Health Inspection Service” from the agency drop-down menu, then click “Submit.” In the Docket ID column, select APHIS–2007–0104 to submit or view public comments and to view supporting and related materials available electronically. Information on using [Regulations.gov](http://www.regulations.gov), including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site’s “User Tips” link.

- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies)

to Docket No. APHIS–2007–0104, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2007–0104.

**Reading Room:** You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

**Other Information:** Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael B. Stefan, ALB National Coordinator, Emergency and Domestic Programs, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1231; (301) 734–4387.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Asian longhorned beetle (ALB, *Anoplophora glabripennis*), an insect native to China, Japan, Korea, and the Isle of Hainan, is a destructive pest of hardwood trees. It attacks many healthy hardwood trees, including maple, horse chestnut, birch, poplar, willow, and elm. In addition, nursery stock, logs, green lumber, firewood, stumps, roots, branches, and wood debris of half an inch or more in diameter are subject to infestation. The beetle bores into the heartwood of a host tree, eventually killing the tree. Immature beetles bore into tree trunks and branches, causing heavy sap flow from wounds and sawdust accumulation at tree bases. They feed on, and over-winter in, the interiors of trees. Adult beetles emerge in the spring and summer months from round holes approximately three-eighths of an inch in diameter (about the size of a dime) that they bore through branches and trunks of trees. After emerging, adult beetles feed for 2 to 3 days and then mate. Adult females then lay eggs in oviposition sites that they make on the branches of trees. A new generation of ALB is produced each year. If this pest moves into the

hardwood forests of the United States, the nursery, maple syrup, and forest product industries could experience severe economic losses. In addition, urban and forest ALB infestations will result in environmental damage, aesthetic deterioration, and a reduction in public enjoyment of recreational spaces.

The regulations in 7 CFR 301.51–1 through 301.51–9 restrict the interstate movement of regulated articles from quarantined areas to prevent the artificial spread of ALB to noninfested areas of the United States. Recent surveys conducted in New York by inspectors of the Animal and Plant Health Inspection Service (APHIS) have revealed that infestations of ALB have occurred on Prall’s Island and in an area of Staten Island in Richmond County. These areas are outside the existing quarantined areas, and are in close proximity to the Middlesex/Union County quarantined area in New Jersey and could potentially reinfest that area. Officials of the U.S. Department of Agriculture and officials of State, county, and city agencies in New York are conducting intensive survey and eradication programs in the infested area, and the State of New York has quarantined the infested area and is restricting the intrastate movement of regulated articles from the quarantined area to prevent the further spread of ALB within that State. However, Federal regulations are necessary to restrict the interstate movement of regulated articles from the quarantined area to prevent the spread of ALB to other States and other countries.

The regulations in § 301.51–3(a) provide that the Administrator of APHIS will list as a quarantined area each State, or each portion of a State, in which ALB has been found by an inspector, where the Administrator has reason to believe that ALB is present, or where the Administrator considers regulation necessary because of its inseparability for quarantine enforcement purposes from localities where ALB has been found. Less than an entire State will be quarantined only if (1) the Administrator determines that the State has adopted and is enforcing restrictions on the intrastate movement of regulated articles that are equivalent to those imposed by the regulations on the interstate movement of regulated articles and (2) the designation of less

than an entire State as a quarantined area will be adequate to prevent the artificial spread of ALB. In accordance with these criteria and the recent ALB findings described above, we are amending the list of quarantined areas in § 301.51–3(c) to include an additional area in Richmond County, NY. The expanded quarantined area is described in the regulatory text at the end of this document.

#### Emergency Action

This rulemaking is necessary on an emergency basis to prevent the artificial spread of ALB to noninfested areas of the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

#### Executive Order 12866 and Regulatory Flexibility Act

This interim rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This interim rule amends the ALB regulations by expanding the boundaries of the quarantined areas in New York and restricting the interstate movement of regulated articles from these areas. This action is necessary to prevent the artificial spread of the ALB to noninfested areas of the United States.

The Regulatory Flexibility Act (RFA) requires that agencies consider the economic impact of their rules on small entities, such as small businesses, organizations, and governmental jurisdictions. The businesses potentially affected by this rule are nurseries, tree care services, firewood retailers, lawn maintenance and landscaping companies, general contractors, garden centers, recyclers of waste material, and lumber and building material outlets. These businesses could be affected by the regulations in two ways. First, if a business wishes to move regulated articles interstate from a quarantined area, that business must either: (1) Enter into a compliance agreement with

APHIS for the inspection and certification of regulated articles to be moved interstate from the quarantined area; or (2) present its regulated articles for inspection by an inspector and obtain a certificate or a limited permit, issued by the inspector, for the interstate movement of regulated articles. The inspections may be inconvenient, but not costly; businesses operating under a compliance agreement would perform the inspections themselves and for those businesses that elect not to enter into a compliance agreement, APHIS would provide the services of an inspector without cost. There is also no cost for the compliance agreement, certificate, or limited permit for the interstate movement of regulated articles.

Second, there is a possibility that, upon inspection, a regulated article could be determined by the inspector to be potentially infested with the ALB and, as a result, the inspector would not issue a certificate. In this case, the entity's ability to move regulated articles interstate would be restricted. However, the affected entity could conceivably obtain a limited permit under the conditions of § 301.51–5(b).

Additionally, entities may incur additional costs in disposing of regulated articles such as wood debris from tree pruning and removal.

Within the quarantined area added by this interim rule, there are approximately 15 entities potentially affected, including 2 nursery dealers, 1 nursery grower, 6 landscaping companies, 3 general contractors, 2 transfer stations, and a compost facility. While the size of these entities is unknown, it is reasonable to assume that most would be classified as small entities, based on the U.S. Small Business Administration's size standards.

Because the newly regulated area is primarily urban, the entities located in that area are more likely to be receiving regulated articles from outside the quarantined area than they are to be shipping regulated articles interstate to nonquarantined areas. It is unlikely, therefore, that most entities located in the newly regulated area would be moving regulated articles that would require inspection in the first place.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance

under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we are amending 7 CFR part 301 as follows:

#### PART 301—DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

**Authority:** 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.51–3, paragraph (c), under the entry for New York, the entry for New York City is amended by designating the text as paragraph (1) and adding a new paragraph (2) to read as follows:

#### § 301.51–3 Quarantined areas.

\* \* \* \* \*

(c) \* \* \*

New York

*New York City.* \* \* \*

(2) That area in the Borough of Richmond in the City of New York bounded by a line drawn as follows: Beginning at a point on the New York/New Jersey State line due north of the intersection of Richmond Terrace and South Avenue; then south from that point to the intersection of South Avenue and Richmond Terrace; then south on South Avenue to Fahy Avenue; then east on Fahy Avenue to Arlene Street; then south on Arlene Street until

it becomes Park Drive North; then south on Park Drive North to Rivington Avenue; then east on Rivington Avenue to Mulberry Avenue; then south on Mulberry Avenue to Travis Avenue; then northwest on Travis Avenue to the point where it crosses Main Creek; then south along the west shoreline of Main Creek to Fresh Kills Creek; then west along the north shoreline of Fresh Kills Creek to Little Fresh Kills Creek; then west along the north shoreline of Little Fresh Kills Creek to the Arthur Kill; then west to the New York/New Jersey State line in the Arthur Kill; then north along the New York/New Jersey State line to the point of beginning.

\* \* \* \* \*

Done in Washington, DC, this 14th day of August 2007.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E7-16297 Filed 8-17-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 101

[Docket No. 2004N-0382]

RIN 0910-ZA23

#### Food Labeling: Safe Handling Statements: Labeling of Shell Eggs

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its food labeling regulations to permit the egg industry to place the safe handling statement for shell eggs on the inside lid of egg cartons if the statement "Keep Refrigerated" appears on the principal display panel (PDP) or information panel. This final rule will provide the industry greater flexibility in the placement of safe handling instructions on egg cartons, while continuing to provide consumers with this important information. This action is in response to numerous requests from the egg industry.

**DATES:** This final rule is effective August 20, 2007.

**FOR FURTHER INFORMATION CONTACT:** Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch

Pkwy., College Park, MD 20740, 301-436-2371.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 5, 2000 (65 FR 76092), FDA (we) published a final rule (hereinafter referred to as the shell egg refrigeration and labeling final rule) to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms (§ 101.17(h) (21 CFR 101.17(h))). The regulation also requires retail establishments to store and display shell eggs under refrigeration (21 CFR 115.50). FDA issued the shell egg refrigeration and labeling final rule because of the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella* Enteritidis that are associated with the consumption of shell eggs. After the publication of the shell egg refrigeration and labeling final rule, the egg industry asked FDA to allow safe handling statements to be placed on the inside lid of egg cartons because of: (1) The lack of equipment to print on the side panels of egg cartons (i.e., the information panel), (2) the high cost to purchase equipment to print on the sides of egg cartons, and (3) the high cost to change the graphic design of the PDP for each brand that manufacturers produce for each customer.

In the **Federal Register** of May 5, 2005 (70 FR 23813), FDA published a proposed rule (the 2005 proposed rule) to allow the egg industry to place the required safe handling statement on the inside lid of egg cartons, if the statement "Keep Refrigerated" appears on the PDP or information panel. We tentatively concluded in the proposed rule that the inside lid would serve as an acceptable panel for the safe handling instructions without diminishing the effectiveness of the message. We further tentatively concluded that providing flexibility to allow the placement of the safe handling statement for shell eggs on the inside lid of egg cartons if the statement "Keep Refrigerated" appears on the PDP or information panel may result in cost savings for the egg industry, and, thus, for consumers.

##### II. Comments and Agency's Responses

FDA received a total of eight responses, each containing one or more comments, to the proposal. The comments were from consumer groups, a State government agency, a consumer, a consulting firm, and a trade association. Some of these comments were about issues that are outside the scope of this rulemaking and will not be addressed in this document. The majority of the remaining comments

supported the proposal. One comment directly opposed the proposal, whereas two comments supported the proposal based on suggested modifications to the proposal.

(Comment 1) The comment that opposed the proposal asserted that there is no "lack of equipment" for printing the safe handling statement on the side panel of egg cartons. The comment contended that all the egg industry has to do is order new packages.

(Response) As we stated in the 2005 proposed rule, the egg industry sent letters to FDA stating that placing the statement on the top or sides of the carton would result in a financial hardship for their companies because of, among other things, the lack of equipment to print on the side panels of egg cartons (i.e., the information panel) and the high cost to purchase equipment to print on the sides of egg cartons. One of these letters provided specific information on the high costs to purchase new equipment required for printing on the information panel and on the high costs to redesign the egg carton. The comment that opposed the proposal did not provide data or other information that shows that the industry has the necessary equipment.

Consequently, we are not persuaded by this comment, and we maintain our view that allowing the safe handling instructions on the inside of the lid could result in cost savings for the industry and ultimately the consumer, while continuing to provide mandatory safe handling instructions to consumers.

(Comment 2) Several comments requested that FDA make format changes for the safe handling statement. Two comments stated that FDA should replace the current standard of "conspicuous" with specific formatting requirements for the safe handling statement, e.g., use of dark color, such as black, blue, dark blue, or brown on a light background. In addition, several comments stated that the type size of the safe handling statement should be increased and two of these comments suggested specific sizes, e.g., 12-point or larger and "10-inch type"<sup>1</sup> or larger. In addition, one of these comments stated that a survey of egg cartons found that the safe handling statement is printed in type as small as 7-point and, sometimes, the statement is printed directly on a gray cardboard carton, which makes the statement difficult to read. Therefore, according to this comment, a significant number of consumers may not notice or

<sup>1</sup> We believe that the comment did not actually mean "10-inch" type but meant another type size, such as a 10-point font.