

PART 58—[AMENDED]

■ 1. The authority citation for 7 CFR part 58 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 2. Amend § 58.133 by revising paragraphs (b)(5) introductory text, (b)(5)(ii), and (b)(6) to read as follows:

§ 58.133 Methods for quality and wholesomeness determination.

* * * * *

(b) * * *

(5) Whenever the official test indicates the presence of more than 750,000 somatic cells per ml. (1,500,000 per ml. for goat milk), the following procedures shall be applied:

* * * * *

(ii) Whenever two out of the last four consecutive somatic cell counts exceed 750,000 per ml. (1,500,000 per ml. for goat milk), the appropriate State regulatory authority shall be notified and a written notice given to the producer. This notice shall be in effect as long as two of the last four consecutive samples exceed 750,000 per ml. (1,500,000 per ml. for goat milk).

(6) An additional sample shall be taken after a lapse of 3 days but within 21 days of the notice required in paragraph (b)(5)(ii) of this section. If this sample also exceeds 750,000 per ml. (1,500,000 per ml. for goat milk), subsequent milkings shall not be accepted for market until satisfactory compliance is obtained. Shipment may be resumed and a temporary status assigned to the producer by the appropriate State regulatory agency when an additional sample of herd milk is tested and found satisfactory. The producer may be assigned a full reinstatement status when three out of four consecutive somatic cell count tests do not exceed 750,000 per ml. (1,500,000 per ml. for goat milk). The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

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■ 3. Amend § 58.134 by revising the section heading and paragraphs (b), (c) introductory text, (d), and (e) and removing paragraphs (c)(1) and (2).

The revisions read as follows:

§ 58.134 Sediment content for milk in cans.

(b) *Sediment content classification.* Milk in cans shall be classified for sediment content, regardless of the results of the appearance and odor examination required in § 58.133(a), as follows:

USDA SEDIMENT STANDARD

No. 1 (acceptable)—not to exceed 0.50 mg. or equivalent.

No. 2 (acceptable)—not to exceed 1.50 mg. or equivalent.

No. 3 (probational, not over 10 days)—not to exceed 2.50 mg. or equivalent.

No. 4 (reject)—over 2.50 mg. or equivalent.

(c) *Frequency of tests.* At least once each month, at irregular intervals, one or more cans of milk selected at random from each producer shall be tested.

(d) *Acceptance or rejection of milk.* If the sediment disc is classified as No. 1, No. 2, or No. 3, the producer's milk may be accepted. If the sediment disc is classified No. 4 the milk shall be rejected: *Provided that*, If the shipment of milk is commingled with other milk in a transport tank the next shipment shall not be accepted until its quality has been determined before being picked up; however, if the person making the test is unable to get to the farm before the next shipment it may be accepted but no further shipments shall be accepted unless the milk meets the requirements of No. 3 or better. In the case of milk classified as No. 3 or No. 4, all cans shall be tested. Producers of No. 3 or No. 4 milk shall be notified immediately and shall be furnished applicable sediment discs and the next shipment shall be tested.

(e) *Retests.* On test of the next shipment all cans shall be tested. Milk classified as No. 1, No. 2, or No. 3 may be accepted, but No. 4 milk shall be rejected. The producers of No. 3 or No. 4 milk shall be notified immediately, furnished applicable sediment discs and the next shipment tested. This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for not more than 10 calendar days. If at the end of this time all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2), it shall be rejected.

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Dated: May 22, 2012.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2012–13065 Filed 5–29–12; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2012–0003]

Asian Longhorned Beetle; Quarantined Areas in Massachusetts, Ohio, and 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 to make changes to the list of quarantined areas by adding portions of Worcester County, MA, and Clermont County, OH, to the list of quarantined areas. We are also removing a portion of Suffolk County, NY, from the list of quarantined areas based on our determination that the area meets our criteria for removal. These actions are necessary to prevent the artificial spread of Asian longhorned beetle to noninfested areas of the United States and to relieve restrictions on certain areas that are no longer necessary.

DATES: This interim rule is effective May 30, 2012. We will consider all comments that we receive on or before July 30, 2012.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0003-0001>.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2012–0003, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0003> or in our reading room, which 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Claudia Ferguson, Regulatory Policy Specialist, Regulations, Permits and Manuals, PPQ, APHIS, 4700 River Road, Unit 26, Riverdale, MD 20737–1236; (301) 851–2352.

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. The ALB regulations in 7 CFR 301.51–1 through 301.51–9 (referred to below as the regulations) restrict the interstate movement of regulated articles from quarantined areas to prevent the artificial spread of ALB to noninfested areas of the United States.

On October 25, 2011, an ALB infestation was discovered in the central portion of Shrewsbury in Worcester County, MA. On June 17, 2011, an ALB infestation was discovered in the townships of Monroe and Tate, and in the East Fork State Park in Clermont County, OH. These States have quarantined the infested areas and are restricting the intrastate movement of regulated articles from the quarantined areas to prevent the further spread of ALB within each State. Federal regulations are necessary to restrict the interstate movement of regulated articles from the quarantined areas to prevent the interstate spread of ALB.

The regulations in § 301.51–3(a) provide that APHIS will list as a quarantined area each State, or each portion of a State, where 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 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 adding the Town of Shrewsbury in Worcester County, MA, and a portion of the Township of Monroe, the entire Township of Tate, and the entire acreage of East Fork State Park in Clermont County, OH, to the list of quarantined areas in § 301.51–3(c). The quarantined areas are described in detail in the regulatory text of this document.

In 2000, APHIS established a quarantined area in Islip, Suffolk

County, NY, after ALB was first detected in the area in order to prevent the artificial spread of ALB. After the completion of control and regulatory activities, and based on the results of at least 3 years of negative surveys of all regulated host plants within the quarantined area, APHIS determined that the villages of Bayshore, East Islip, and Islip Terrace in the Town of Islip, Suffolk County, NY, have met the criteria for removal of the Federal quarantine for ALB.

Therefore, in this interim rule, we are amending the list of quarantined areas in § 301.51–3(c) by removing the villages of Bayshore, East Islip, and Islip Terrace in the Town of Islip, Suffolk County, NY. This action relieves restrictions on the movement of regulated articles from those areas that are no longer warranted.

Immediate Action

Immediate action is necessary to help prevent ALB from spreading to noninfested areas of the United States. In addition, this rule also relieves restrictions on certain areas that are no longer warranted. 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 action 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 is subject to under Executive Order 12866. However, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

In accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. The full analysis may be viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov) or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

This rule amends the ALB regulations by adding certain areas in Massachusetts and Ohio to the list of

quarantined areas. This rule also removes certain areas in New York from quarantine based on surveys that indicate these areas have met the criteria for release from regulation. Potentially, about 30 entities may be affected in the expanded quarantine area in Massachusetts, and about 80 entities may be affected in Ohio. These businesses include landscape companies, tree service companies, firewood dealers, construction companies, waste haulers, and other operations that move regulated articles from the quarantined areas. Additional costs of operating such businesses under ALB quarantine are small, and principally derive from self-inspection and certification of regulated material under compliance agreements. In Islip, New York, the approximately 90 entities that have been affected by the quarantine will benefit from its removal by no longer having to satisfy movement restrictions. Most if not all of the businesses that will be affected by this rule in the three States are 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 in conflict 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, Pub. L. 106–113, 113 Stat. 1501 A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.51–3, paragraph (c) is amended as follows:

■ a. Under the heading

“Massachusetts,” by revising the entry for Worcester County;

■ b. Under the entry for “New York,” by removing the second paragraph under the entry for Nassau and Suffolk Counties.

■ c. By adding, in alphabetical order, an entry for “Ohio.”

The revision and addition read as follows:

§ 301.51–3 Quarantined areas.

* * * * *

(c) * * *

Massachusetts

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Worcester County. The portion of Worcester County, including portions or all of the municipalities of Worcester, Holden, West Boylston, Boylston, Auburn, and Shrewsbury that is bounded by a line starting at the intersection of Route 9 (Belmont Street) and the eastern boundary of the town of Shrewsbury; then follow the Shrewsbury town boundary northerly until the Boylston town boundary; then follow the entirety of the Boylston town boundary until it comes to the West Boylston town boundary on the Massachusetts Department of Conservation and Recreation Watershed property; then along the West Boylston town boundary until it intersects Manning Street; then southwest on Manning Street in Holden to Wachusett Street (Route 31); then south on Wachusett Street to Highland Street (still Route 31); then southwest on Highland Street to Main Street; then southeast on Main Street to Bailey Road; then south on Bailey Road to Chapin Road; then south on Chapin Road to its end; then continuing in a southeasterly direction to Fisher Road; then southwest on Fisher Road to Stonehouse Hill Road; then south on Stonehouse Hill Road to Reservoir Street; then southeast on Reservoir Street until it intersects the Worcester city boundary; turn south on Oxford Street to Auburn Street; then southeast on Auburn Street crossing

under the Massachusetts Turnpike (I–90) and continuing southeast on Millbury Street; at the intersection of Washington Street, turn northeast and continue along Washington Street to the northern boundary of the Massachusetts Turnpike (I–90); then east along the northern boundary of the Massachusetts Turnpike (I–90) to the Auburn town boundary; then follow the Auburn town boundary northerly to the Worcester city boundary; continue along the Worcester city boundary until the Shrewsbury town boundary; then follow the entirety of the Shrewsbury town boundary until the point of beginning.

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Ohio

Clermont County. The portion of Clermont County, including all of the municipalities of Tate and East Fork State Park, and the portions of the Township of Monroe that include the following land parcels: 232609C094, 232609C113, 232609C215, 232609C085, 232609C128, 232609B224, 232609B188, 232609E223, 232609B215, 32609B193, 232609E075, 232609B161, 232609E156, 232609E245, 232609E037, 232609E074, 232609E230, 232609E031, 232609E220, 232609E232, 232609E240, 232609E239, 232609E241, 232609E175, 232609E228, 232609E250, 232609E235, 232609E238, 232609E227, 232609E242, 32609E226, 232609E249, 232609E236, 232609E234, 232609C217, 232609C040, 234715.008, 232609C227, 232609C222, 232609C092, 232609C093, 232609C129, 232609C098, 232609C195, 232609C100, 232609C169, 232609C136, 232609C097, 232609C139, 232609C148, 232609C042, 232609C150, 232609C182, 234715.009, 234715.005, 234715.006, 234715.001, 232609E246, 232609E247, 234715.004, 234715.003, 232609E222, 232609C228, 234425.001, 232609E233, 232609C170, 232609C216, 232609C196, 232609C105, 232609E237, 232609C225, 232609C091, 232609C197, 232609C218, 232609C198, 232609C041, 232609C212, 232609C194, 232609C214, 232609E224, 232609E231, 232609E248, 234715.007, 234715.002, 232609C120, 232609C226, 232609C229, and 232609C043.

Done in Washington, DC, this 23rd day of May 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012–13111 Filed 5–29–12; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 558

[Docket No. FDA–2012–N–0002]

New Animal Drugs; Change of Sponsor; Estradiol; Estradiol Benzoate and Testosterone Propionate; Progesterone and Estradiol Benzoate; Trenbolone Acetate; Trenbolone Acetate and Estradiol; Melengestrol; Ractopamine; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 17 new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) for various steroid ear implants for cattle and for melengestrol acetate liquid Type A medicated article and use in combination medicated feeds for heifers fed in confinement for slaughter from Ivy Laboratories, Division of Ivy Animal Health, Inc., to Elanco Animal Health, Division of Eli Lilly & Co.

DATES: This rule is effective May 30, 2012.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300, email: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, has informed FDA that it has transferred ownership of, and all rights and interest in, the NADAs and ANADAs in this table to Elanco Animal Health, Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.