

listed in MSB 00-5C, dated October 10, 2000, unless core samples have been taken and TCM has approved it for return to service.

(c) Crankshaft material inspections (crankshaft propeller flange core samples) that were done using TCM MSB 00-5, dated April 14, 2000; MSB 00-5A, dated April 28, 2000; or MSB 00-5B, dated May 25, 2000, comply with this AD and must not be repeated.

#### Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

**Note 5:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Atlanta ACO.

#### Incorporation by Reference Material

(e) The actions required by this AD shall be performed in accordance with Teledyne Continental Motors MSB 00-5C, dated October 10, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Teledyne Continental Motors, PO Box 90, Mobile, AL 36601; telephone toll free 1-888-200-7565, or on the TCM internet site "www.tcmlink.com". Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

#### Effective Date of This AD

(f) This amendment becomes effective on December 12, 2000.

Issued in Burlington, Massachusetts, on November 13, 2000.

**David A. Downey,**

*Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 00-29496 Filed 11-24-00; 8:45 am]

**BILLING CODE 4910-13-U**

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1211

#### Safety Standard for Automatic Residential Garage Door Operators

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Consumer Product Safety Commission is amending regulations on the Safety Standard for Automatic Residential Garage Door Operators, to

reflect changes made by Underwriters Laboratories, Inc. in its standard UL 325.

**DATES:** The rule will become effective on December 27, 2000. The incorporation by reference of certain publications in this rule is approved by the Director of the Federal Register as of December 27, 2000.

**FOR FURTHER INFORMATION CONTACT:** Renae Rauchschalbe, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207, telephone 301-504-0608, ext. 1362.

**SUPPLEMENTARY INFORMATION:** The Commission issued part 1211 on December 21, 1992 to minimize the risk of entrapment by residential garage door openers. As mandated by section 203 of Public Law 101-608, subpart A of part 1211 codifies garage door operator entrapment provisions of Underwriter Laboratories, Inc. ("UL") standard UL 325, third edition, "Door, Drapery, Louver and Window Operators and Systems." Subparagraph (c) of section 203 of Pub. L. 101-608 also required the Commission to incorporate into part 1211 any revisions that UL proposed to the entrapment protection requirements of UL 325, unless the Commission notified UL that the revision does not carry out the purposes of Pub. L. 101-608.

UL proposed revisions to UL 325 on June 30, 1998, and made them final on September 18, 1998. The Commission determined that the entrapment related revisions do carry out the purposes of Public Law 101-608. On June 14, 2000, the Commission proposed a rule incorporating into subpart A of part 1211 those revisions that relate to entrapment by residential automatic garage door operators and also correcting a few typographical errors in part 1211. 65 FR 37318. The Commission received one comment on the proposed rule from six students at Florida International University. Their comment discussed generally the entrapment hazard posed by garage doors and precautions that garage door owners should take. They suggested a mandatory standard requiring both an external entrapment-sensing safety device and a constant contact control button. However, this would mean that the consumer would have to stand in the garage at the button until the door is completely closed. Aside from the inconvenience of such a requirement, it is beyond the scope of this rulemaking, the narrow purpose of which is to revise the existing Commission standard to reflect recent changes to UL 325.

The changes to the UL standard allow for advances in the state of the art in

garage door safety. Some new garage door operators have an inherent entrapment protection system that can continuously monitor the position of the door. The UL revisions add requirements for this type of system. Some new garage door operators have an inherent secondary door sensor that is independent of the primary entrapment protection system. The UL revisions add requirements for this type of new system. Finally, the UL standard adds some new and revised provisions concerning instructions and field installed labels. The final rule incorporates these changes into the CPSC mandatory standard.

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant impact on a substantial number of small entities. Most of the changes are editorial and minor. The substantive changes only affect the few companies that are developing the new type of garage door operators discussed above. Moreover, UL has already made these changes to its UL 325 standard which is widely followed by the industry. The Commission also certifies that this rule will have no environmental impact. The Commission's regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

Public Law 101-608 contains a preemption provision. It states: "those provisions of laws of States or political subdivisions which relate to the labeling of automatic residential garage door openers and those provisions which do not provide at least the equivalent degree of protection from the risk of injury associated with automatic residential garage door openers as the consumer product safety rule" are subject to preemption under 15 U.S.C. 2075. Pub. L. 101-608, section 203(f).

The rule will become effective 30 days from publication in the **Federal Register** and will apply to garage door operators entering the chain of distribution on or after that date. The 30-day effective date is appropriate because the substantive changes affect only a few companies and they are identical to changes already made to UL 325, which is widely followed by the industry.

#### List of Subjects in 16 CFR Part 1211

Consumer protection, Incorporation by reference, Imports, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 1211 is amended as follows:

**PART 1211—SAFETY STANDARDS FOR AUTOMATIC RESIDENTIAL GARAGE DOOR OPENERS**

1. The authority citation for part 1211 is revised to read as follows:

**Authority:** Sec. 203 of Pub. L. 101-608, 104 Stat. 3110; 15 U.S.C. 2063 and 2065.

**§ 1211.2 [Amended]**

2. Section 1211.2 is amended as follows:

(a) In the first sentence of § 1211.2(c) remove the word "1993" and add, in its place "1999".

(b) In the second sentence of § 1211.2(c) add "5" before "U.S.C.".

**§ 1211.3 [Amended]**

3. In the first sentence of § 1211.3 remove the words "as given in these requirements" and "an equivalent" and add the word "a" between the words "by" and "value".

**§ 1211.4 [Amended]**

4. Section 1211.4 is amended as follows:

a. In the first sentence of § 1211.4(c) before the word "Tests" add the words "Safety for".

b. In the first sentence of § 1211.4(c) remove the words "1st ed., dated July 19, 1991" and add, in their place "second edition, dated June 23, 1995".

c. In the second sentence of § 1211.4(c) add "5" before "U.S.C.".

d. In the third sentence of § 1211.4(c) remove the words "Underwriters Laboratories, Inc. 333 Pflugsten Road, Northbrook, Ill. 60062-2096" and add, in their place "Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, Telephone (800) 854-7179 or Global Engineering Documents, 7730 Carondelet Ave., Suite 470, Clayton, MO 63105, Telephone (800) 854-7179."

**§ 1211.5 [Amended]**

5. Section 1211.5 is amended as follows:

a. In the first sentence of § 1211.5(a) and § 1211.5(b)(3) before the word "Tests" add the words "Safety for".

b. In § 1211.5(a) and (b)(3) remove the words "1st ed., dated July 19, 1991" and add, in their place "second edition, dated June 23, 1995".

c. In the second sentence of § 1211.5(b)(3) add "5" before "U.S.C.".

d. In the third sentence of § 1211.5(b)(3) remove the words "Underwriters Laboratories, Inc. 333 Pflugsten Road, Northbrook, Ill. 60062-2096" and add, in their place "Global

Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, Telephone (800) 854-7179 or Global Engineering Documents, 7730 Carondelet Ave., Suite 470, Clayton, MO 63105, Telephone (800) 854-7179."

e. Revise paragraphs (a)(1), (a)(6), and (a)(7); and add a new paragraph (a)(9) to read as follows:

**§ 1211.5 General testing parameters.**

(a) \* \* \*

(1) With regard to electrical supervision of critical components, an operator being inoperative with respect to downward movement of the door meets the criteria for trouble indication.

\* \* \* \* \*

(6) When a Computational Investigation is conducted,  $\lambda_p$  shall not be greater than 6 failures/10<sup>6</sup> hours for the entire system. For external secondary entrapment protection devices that are sold separately,  $\lambda_p$  shall not be greater than 0 failures/10<sup>6</sup> hours. For internal secondary entrapment protection devices whether or not they are sold separately,  $\lambda_p$  shall not be greater than 0 failures/10<sup>6</sup> hours. The operational test is conducted for 14 days. An external secondary entrapment protection device that is sold separately, and that has a  $\lambda_p$  greater than 0 failures/10<sup>6</sup> hours meets the intent of the requirement when for the combination of the operator and the specified external secondary entrapment protection device  $\lambda_p$  does not exceed 6 failures/10<sup>6</sup> hours. See § 1211.15(i) and (k).

(7) When the Demonstrated Method Test is conducted, the multiplier is to be based on the continuous usage level, and a minimum of 24 units for a minimum of 24 hours per unit are to be tested.

(8) \* \* \*

(9) For the Electrical Fast Transient Burst Test, test level 3 is to be used for residential garage door operators.

\* \* \* \* \*

**§ 1211.6 [Amended]**

6. Section 1211.6 is amended by revising paragraphs (a), (b) introductory text, (b)(1)(ii), (b)(1)(iii), (b)(2), adding a new paragraph (b)(3), revising paragraphs (c) and (d), and removing paragraph (e) to read as follows:

**§ 1211.6 General entrapment protection requirements.**

(a) A residential garage door operator system shall be provided with primary inherent entrapment protection that complies with the requirements as specified in § 1211.7.

(b) In addition to the primary inherent entrapment protection as required by

paragraph (a) of this section, a residential garage door operator shall comply with one of the following:

(1) \* \* \*

(i) \* \* \*

(ii) Reverse direction and open the door to the upmost position when constant pressure on a control is removed prior to operator reaching its lower limit, and

(iii) Limit a portable transmitter, when supplied, to function only to cause the operator to open the door;

(2) Shall be provided with a means for connection of an external secondary entrapment protection device as described in §§ 1211.8, 1211.10, and 1211.11; or

(3) Shall be provided with an inherent secondary entrapment protection device as described in §§ 1211.8, 1211.10, and 1211.12.

(c) A mechanical switch or a relay used in an entrapment protection circuit of an operator shall withstand 100,000 cycles of operation controlling a load no less severe (voltage, current, power factor, inrush and similar ratings) than it controls in the operator, and shall function normally upon completion of the test.

(d) In the event malfunction of a switch or relay (open or short) described in paragraph (c) of this section results in loss of any entrapment protection required by §§ 1211.7(a), 1211.7(f), or 1211.8(a), the door operator shall become inoperative at the end of the opening or closing operation, the door operator shall move the door to, and stay within, 1 foot (305 mm) of the uppermost position.

7. Revise Section § 1211.7 to read as follows:

**§ 1211.7 Inherent entrapment protection requirements.**

(a) Other than the first 1 foot (305mm) of travel as measured over the path of the moving door, both with and without any external entrapment protection device functional, the operator of a downward moving residential garage door shall initiate reversal of the door within 2 seconds of contact with the obstruction as specified in paragraph (b) of this section. After reversing the door, the operator shall return the door to, and stop at, the full upmost position, unless an inherent entrapment circuit senses a second obstruction or a control is actuated to stop the door during the upward travel. Compliance shall be determined in accordance with paragraphs (b) through (i) of this section.

(b) A solid object is to be placed on the floor of the test installation and at various heights under the edge of the

door and located in line with the driving point of the operator. When tested on the floor, the object shall be 1 inch (25.4 mm) high. In the test installation, the bottom edge of the door under the driving force of the operator is to be against the floor when the door is fully closed. For operators other than those attached to the door, the solid object is to be located at points at the center, and within 1 foot of each end of the door.

(c) An operator is to be tested for compliance with paragraph (a) of this section for 50 open-and-close cycles of operation while the operator is connected to the type of residential garage door with which it is intended to be used or with the doors specified in paragraph (e) of this section. For an operator having a force adjustment on the operator, the force is to be adjusted to the maximum setting or at the setting that represents the most severe operating condition. Any accessories having an effect on the intended operation of entrapment protection functions that are intended for use with the operator, are to be attached and the test is to be repeated for one additional cycle.

(d) For an operator that is to be adjusted (limit and force) according to instructions supplied with the operator, the operator is to be tested for 10 additional obstruction cycles using the solid object described in paragraph (b) of this section at the maximum setting or at the setting that represents the most severe operating condition.

(e) For an operator that is intended to be used with more than one type of door, one sample of the operator is to be tested on a sectional door with a curved track and one sample is to be tested on a one-piece door with jamb hardware and no track. For an operator that is not intended for use on either or both types of doors, a one-piece door with track hardware or a one-piece door with pivot hardware shall be used for the tests. For an operator that is intended for use with a specifically dedicated door or doors, a representative door or doors shall be used for the tests. See the marking requirements at § 1211.16.

(f) An operator, using an inherent entrapment protection system that monitors the actual position of the door, shall initiate reversal of the door and shall return the door to, and stop the door at, the full upmost position in the event the inherent door operating "profile" of the door differs from the originally set parameters. The entrapment protection system shall monitor the position of the door at increments not greater than 1 inch (25.4 mm). The door operator is not required

to return the door to, and stop the door at, the full upmost position when an inherent entrapment circuit senses an obstruction or a control is actuated to stop the door during the upward travel.

(g) An operator, using an inherent entrapment protection system that does not monitor the actual position of the door, shall initiate reversal of the door and shall return the door to and stop the door at the full upmost position, when the lower limiting device is not actuated in 30 seconds or less following the initiation of the close cycle. The door operator is not required to return the door to and stop at the full upmost position when an inherent entrapment circuit senses an obstruction or a control is actuated to stop the door during the upward travel. When the door is stopped manually during its descent, the 30 seconds shall be measured from the resumption of the close cycle.

(h) To determine compliance with paragraph (f) or (g) of this section, an operator is to be subjected to 10 open-and-close cycles of operation while connected to the door or doors specified in paragraphs (c) and (e) of this section. The cycles are not required to be consecutive. Motor cooling-off periods during the test meet the intent of the requirement. The means supplied to comply with the requirement in paragraph (a) of this section and § 1211.8(a) are to be defeated during the test. An obstructing object is to be used so that the door is not capable of activating a lower limiting device.

(i) During the closing cycle, the system providing compliance with §§ 1211.7(a) and 1211.7(f) or 1211.7(a) and 1211.7(g) shall function regardless of a short- or open-circuit anywhere in any low-voltage external wiring, any external entrapment devices, or any other external component.

8. Section 1211.8 is revised to read as follows:

**§ 1211.8 Secondary entrapment protection requirements.**

(a) A secondary entrapment protection device supplied with, or as an accessory to, an operator shall consist of:

(1) An external photoelectric sensor that when activated results in an operator that is closing a door to reverse direction of the door and the sensor prevents an operator from closing an open door,

(2) An external edge sensor installed on the edge of the door that, when activated results in an operator that is closing a door to reverse direction of the door and the sensor prevents an operator from closing an open door,

(3) An inherent door sensor independent of the system used to comply with § 1211.7 that, when activated, results in an operator that is closing a door to reverse direction of the door and the sensor prevents an operator from closing an open door, or

(4) Any other external or internal device that provides entrapment protection equivalent to paragraphs (a)(1), (a)(2), or (a)(3) of this section.

(b) With respect to paragraph (a) of this section, the operator shall monitor for the presence and correct operation of the device, including the wiring to it, at least once during each close cycle. In the event the device is not present or a fault condition occurs which precludes the sensing of an obstruction, including an open or short circuit in the wiring that connects an external entrapment protection device to the operator and device's supply source, the operator shall be constructed such that:

(1) A closing door shall open and an open door shall not close more than 1 foot (305 mm) below the upmost position, or

(2) The operator shall function as required by § 1211.6(b)(1).

(c) An external entrapment protection device shall comply with the applicable requirements in §§ 1211.10, 1211.11 and 1211.12.

(d) An inherent secondary entrapment protection device shall comply with the applicable requirements in § 1211.13. Software used in an inherent entrapment protection device shall comply with the Standard for Safety for Software in Programmable Components, UL 1998, Second Edition, May 29, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, Telephone (800) 854-7179 or Global Engineering Documents, 7730 Carondelet Ave., Suite 470, Clayton, MO 63105, Telephone (800) 854-7179. Copies may be inspected at the Consumer Product Safety Commission, Office of the Secretary, 4330 East West Highway, Bethesda, Maryland or at the Office of the Federal Register, 800 North Capitol Street, N.W. suite 700, Washington, D.C.

**§ 1211.9 [Amended]**

9. Section 1211.9 is amended by revising paragraph (a), redesignating paragraphs (b) and (c) as paragraphs (c) and (d) respectively, and adding a new paragraph (b) to read as follows:

**§ 1211.9 Additional entrapment protection.**

(a) A means to manually detach the door operator from the door shall be supplied. The gripping surface (handle) shall be colored red and shall be easily distinguishable from the rest of the operator. It shall be capable of being adjusted to a height of 6 feet (1.8 m) above the garage floor when the operator is installed according to the instructions specified in § 1211.14(a)(2). The means shall be constructed so that a hand firmly gripping it and applying a maximum of 50 pounds (223 N) of force shall detach the operator with the door obstructed in the down position. The obstructing object, as described in § 1211.7(b), is to be located in several different positions. A marking with instructions for detaching the operator shall be provided as required by § 1211.15(i).

(b) A means to manually detach the door operator from the door is not required for a door operator that is not directly attached to the door and that controls movement of the door so that:

(1) The door is capable of being moved open from any position other than the last (closing) 2 inches (50.8 mm) of travel, and

(2) The door is capable of being moved to the 2-inch point from any position between closed and the 2-inch point.

\* \* \* \* \*

**§ 1211.10 [Amended]**

10. Section 1211.10 is amended as follows:

a. In the first sentence of paragraph (a)(3), after the word "minimum" add the words "and maximum"; at the beginning of the second sentence add the words "For doors," and revise the word "If" to "if".

b. In the first sentence of paragraph (c)(2) revise the phrase "An external entrapment protection device is" to read "External entrapment protection devices are".

c. In paragraph (d), first sentence, before the word "Polymeric" add the words "Safety for".

d. In paragraphs (d) and (e)(2), remove the words "3rd ed., dated July 1, 1991" and add, in their place "4th ed., dated December 27, 1995".

e. In paragraph (f), second sentence, insert "5" before "U.S.C."

f. In paragraph (d), third sentence, remove the words "Underwriters Laboratories, Inc. 333 Pflingsten Road, Northbrook, Ill. 60062-2096" and add, in their place "Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, Telephone (800) 854-7179 or Global Engineering

Documents, 7730 Carondelet Ave., Suite 470, Clayton, MO 63105, Telephone (800) 854-7179."

g. In paragraph (e)(1), second sentence, remove the words "After being subjected to this" and add, in their place the words "As a result of the".

h. In paragraph (e)(1)(ii), add at the end thereof and before the period the words "or, if dislodged after the test, is capable of being restored to its original condition".

**§ 1211.12 [Amended]**

11. Section 1211.12 is amended as follows:

a. In paragraph (c)(2), first sentence, before the word "Polymeric" add the words "Safety for".

b. In paragraph (c)(2), first sentence, remove the words "3rd ed., dated July 1, 1991" and add in their place "4th ed., dated December 27, 1995".

c. In paragraph (c)(2), second sentence, insert "5" before "U.S.C."

d. In paragraph (c)(2), third sentence, remove the words "Underwriters Laboratories, Inc. 333 Pflingsten Road, Northbrook, Ill. 60062-2096" and add, in their place "Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, Telephone (800) 854-7179 or Global Engineering Documents, 7730 Carondelet Ave., Suite 470, Clayton, MO 63105, Telephone (800) 854-7179."

**§§ 1211.13-1211.16 [Redesignated as §§ 1211.14-1211.17]**

12. Redesignate §§ 1211.13 through 1211.16 as §§ 1211.14 through 1211.17, respectively, and add a new § 1211.13 to read as follows:

**§ 1211.13 Inherent force activated secondary door sensors.**

(a) *Normal operation test.* (1) A force activated door sensor of a door system installed according to the installation instructions shall actuate when the door applies a 15 pound (66.7 N) or less force in the down or closing direction and when the door applies a 25 pound (111.2 N) or less force in the up or opening direction. For a force activated door sensor intended to be used in an operator intended for use only on a sectional door, the force is to be applied by the door against the longitudinal edge of a 1 $\frac{7}{8}$  (47.6 mm) diameter cylinder placed across the door so that the axis is perpendicular to the plane of the door. See Figure 6 of this part. The weight of the door is to be equal to the maximum weight rating of the operator.

(2) The test described in paragraph (a)(1) of this section is to be repeated and measurements made at various

representative points across the width and height of the door. For this test, a door sensor system and associated components shall withstand a total of 9 cycles of mechanical operation without failure with the force applied as follows:

(i) At the center at points one, three, and five feet from the floor,

(ii) Within 1 foot of the end of the door, at points one, three, and five feet from the floor,

(iii) Within 1 foot of the other end of the door at points one, three, and five feet from the floor.

(3) The cycles are not required to be consecutive. Continuous operation of the motor without cooling is not required.

(b) *Adjustment of door weight.* (1) With the door at the point and at the weight determined by the tests of paragraphs (a)(2) and (b)(2) of this section to be the most severe, the door sensor and associated components shall withstand 50 cycles of operation without failure.

(2) At the point determined by the test in paragraphs (a)(1) and (a)(2) of this section to be the most severe, weight is to be added to the door in 5.0 pound (2.26 Kg) increments and the test repeated until a total of 15.0 pounds (66.72 N) has been added to the door. Before performing each test cycle, the door is to be cycled 2 times to update the profile. Similarly, starting from normal weight plus 15.0 pounds, the test is to be repeated by subtracting weight in 5.0 pound increments until a total of 15.0 pounds has been subtracted from the door.

**§ 1211.14 [Amended]**

13. Newly designated § 1211.14 is amended as follows:

a. In paragraph (a)(4), third sentence, remove the word "that" and add in its place "than".

b. In paragraph (b)(1) remove the initial word "If" (in paragraph 4 of the installation instructions) and add, in its place "Where"; remove the word "Mount" and add, in its place "For products requiring an emergency release, mount".

c. In paragraph (b)(2), in the second sentence of paragraph 4 of the safety instructions, remove the number "1" and add in its place the number "1 $\frac{1}{2}$ ".

d. In paragraph (b)(2) before the initial word "If" (in paragraph 5 of the safety instructions), add "For products requiring an emergency release," and revise the word "If" to "if".

**§ 1211.15 [Amended]**

14. Newly designated § 1211.15 is amended as follows:

a. In paragraph (g)(1) remove the words "A child may become" and add, in their place "There is a risk of a child becoming".

b. In paragraph (g)(2)(iv) remove the first word "If" and add, in its place "In the event".

c. In paragraph (g)(2)(iv) add a second sentence to read "For products not having an emergency release use instead 'In the event a person is trapped under the door, push the control button'".

d. In paragraph (g)(3)(i) in the second sentence, remove the word "If" and add it its place "In the event".

e. In paragraph (i) remove the initial word "A" and add, in its place "Except for door operators complying with § 1211.9(b), a".

Dated: November 20, 2000.

**Sadye E. Dunn,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 00-30041 Filed 11-24-00; 8:45 am]

BILLING CODE 6335-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 173

[Docket No. 00F-1332]

#### Secondary Direct Food Additives Permitted in Food for Human Consumption

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on red meat carcasses. This action is in response to a petition filed by Ecolab, Inc.

**DATES:** This rule is effective November 27, 2000. Submit written objections and requests for a hearing by December 27, 2000. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 173.370, as of November 27, 2000.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of June 13, 2000 (65 FR 37155), FDA announced that a food additive petition (FAP 0A4720) had been filed by Ecolab Inc., Ecolab Center, 370 Wabasha St., St. Paul, MN 55102. The petition proposed to amend the food additive regulations in part 173 (21 CFR part 173) to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on red meat carcasses.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent on red meat carcasses. The agency also concludes that the regulation approving the additive should be entitled "Peroxyacids." Reaction of hydrogen peroxide with acetic acid and octanoic acid results in partial conversion to peroxyacetic acid and peroxyoctanoic acid, respectively. Therefore, part 173 is amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch

(address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by December 27, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

#### PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348.

2. Section 173.370 is added to subpart D to read as follows:

#### § 173.370 Peroxyacids.

Peroxyacids may be safely used in accordance with the following prescribed conditions:

(a) The additive is a mixture of peroxyacetic acid, octanoic acid, acetic