

Dated: February 3, 2011.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2011-2760 Filed 2-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2009-F-0525]

Food Additives Permitted in Feed and Drinking Water of Animals; Formic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of formic acid as an acidifying agent in swine feed. This action is in response to a food additive petition filed by Kemira Oyj of Finland.

DATES: This rule is effective February 9, 2011. Submit either electronic or written objections and requests for a hearing by March 11, 2011. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and a request for a hearing, identified by Docket No. FDA-2009-F-0525, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

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

Written Submissions

Submit written objections in the following ways:

Fax: 301-827-6870.

Mail/Hand delivery/Courier (For paper, disk, or CD-ROM 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 Agency name and Docket No. FDA-2009-F-0525 for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any

personal information provided. For additional information on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, 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:

Isabel W. Pocurull, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853, e-mail: isabel.pocurull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of December 7, 2009 (74 FR 64091), FDA announced that a food additive petition (animal use) (FAP 2262) had been filed by Kemira Oyj, Porkkalantatu 3, P.O. Box 330, 001000 Helsinki, Finland. The petition proposed to amend the food additive regulations to provide for the safe use of formic acid as an acidifying agent at levels not to exceed 1.2 percent in swine feed. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment. One comment was received that was not substantive.

II. Conclusion

FDA concludes that the data establish the safety and utility of formic acid for use as proposed with modification and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(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 Veterinary Medicine by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), the Agency will delete from the documents materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or

cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision 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. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for 21 CFR part 573 continues to read as follows:

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

■ 2. Revise § 573.480 to read as follows:

§ 573.480 Formic acid.

The food additive, formic acid, may be safely used in accordance with the following conditions:

(a) The additive is used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of

the silage on a dry weight basis or 0.45 percent when direct cut, as follows:

- (1) The top foot of silage stored should not contain formic acid and
- (2) Silage should not be fed to livestock within 4 weeks of treatment.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.

(1) The additive consists of not less than 85 percent formic acid (CAS 64–18–6).

(2) The additive meets the following specifications:

- (i) Free methyl alcohol not to exceed 1,000 parts per million (ppm);
- (ii) Methyl formate not to exceed 1,000 ppm; and
- (iii) Moisture not to exceed 15 percent.

(3) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug and Cosmetic Act, the label and labeling shall contain:

- (i) The name of the additive.
- (ii) Adequate directions for use including a statement that formic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing formic acid.

(4) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b)(3) of this section, the label and labeling shall contain:

- (i) Appropriate warnings and safety precautions concerning formic acid (85 percent formic acid).
- (ii) Statements identifying formic acid (85 percent formic acid) as a corrosive and possible severe irritant.
- (iii) Information about emergency aid in case of accidental exposure.

(A) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(B) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

Dated: February 3, 2011.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

[FR Doc. 2011–2789 Filed 2–8–11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100, 117, 147, and 165

[USCG–2011–0399]

Quarterly Listings; Safety Zones, Security Zones, Special Local Regulations, Drawbridge Operation Regulations and Regulated Navigation Areas

AGENCY: Coast Guard, DHS.

ACTION: Notice of expired temporary rules issued.

SUMMARY: This document provides required notice of substantive rules issued by the Coast Guard and temporarily effective between February 2008 and October 2010, that expired before they could be published in the **Federal Register**. This document lists temporary safety zones, security zones, special local regulations, drawbridge operation regulations and regulated navigation areas, all of limited duration and for which timely publication in the **Federal Register** was not possible.

DATES: This document lists temporary Coast Guard rules between February 15, 2008 and October 10, 2010 that became effective and were terminated before they could be published in the **Federal Register**.

ADDRESSES: The Docket Management Facility maintains the public docket for this notice. Documents indicated in this notice will be available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building ground floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. **FOR FURTHER INFORMATION CONTACT:** For questions on this notice contact Yeoman First Class Denise Johnson, Office of Regulations and Administrative Law, telephone (202) 372–3862. For questions on viewing, or on submitting material to the docket, contact Ms. Angie Ames, Docket Operations, telephone 202–366–5115.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. *Safety zones* may be established for safety or environmental purposes. A safety zone may be

stationary and described by fixed limits or it may be described as a zone around a vessel in motion. *Security zones* limit access to prevent injury or damage to vessels, ports, or waterfront facilities and may also describe a zone around a vessel in motion. *Special local regulations* are issued to enhance the safety of participants and spectators at regattas and other marine events. *Drawbridge operation regulations* authorize changes to drawbridge schedules to accommodate bridge repairs, seasonal vessel traffic, and local public events.

Regulated Navigation Areas are water areas within a defined boundary for which regulations for vessels navigating within the area have been established by the regional Coast Guard District Commander. Timely publication of these rules in the **Federal Register** is often precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels enforcing the restrictions imposed by the rule. Because **Federal Register** publication was not possible before the beginning of the effective period, mariners were personally notified of the contents of these safety zones, security zones, special local regulations, regulated navigation areas or drawbridge operation regulations by Coast Guard officials' on-scene prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary safety zones, security zones, special local regulations, regulated navigation areas and drawbridge operation regulations. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if sufficient time is available to do so before they are placed in effect or terminated. The temporary rules listed in this notice have been exempted from review under Executive Order 12666, Regulatory Planning and Review, because of their emergency nature, or limited scope and temporary effectiveness.

The following unpublished rules were placed in effect temporarily during the period between February 2008 and October 2010 unless otherwise indicated.