

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 573

[Docket No. FDA–2003–F–0398] (formerly Docket No. 2003F–0048)

## Food Additives Permitted in Feed and Drinking Water of Animals; Methyl Esters of Conjugated Linoleic Acid (Cis-9, Trans-11 and Trans-10, Cis-12-Octadecadienoic Acids)

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

**ACTION:** Final rule.

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**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 methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) as a source of fatty acids in swine diets. This action is in response to a food additive petition filed by BASF Corp. (BASF), 100 Campus Dr., Florham Park, NJ.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*]. Submit written or electronic objections and requests for a hearing by [*insert date 60 days after the date of publication in the Federal Register*]. See section V of this document for information on the filing of objections.

**ADDRESSES:** You may submit objections and a request for a hearing, identified by Docket No. FDA–2003–F–0398, by any of the following methods:

#### *Electronic Submissions*

Submit electronic objections in the following way:

- 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.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal, as described previously in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All objections received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting objections, see the “Objections and Hearing Requests” 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(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:** Michaela G. Alewynse, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6866, e-mail: *mika.alewynse@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In a notice published in the **Federal Register** of March 11, 2003 (68 FR 11567), FDA announced that a food additive petition (animal use) (FAP 2250) had been filed by BASF, 100 Campus Dr., Florham Park, NJ 07932. The petition proposed to amend the food additive regulations to provide for the safe use of methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) as a source of fatty acids in swine diets. The notice of filing provided for a 60-day comment period on the petitioner's environmental information. No comments have been received.

**II. Conclusion**

FDA concludes that the data establish the safety and utility of methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) 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), 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. 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**) written or electronic objections by (see **DATES**). Each objection must be separately numbered, and each numbered objection must 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 must state that a hearing is requested. Failure to request a hearing for any particular objection will constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested must 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 will constitute a waiver of the right to a hearing on the objection. Three copies of all documents must be submitted and must 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 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. Add § 573.637 to read as follows:

**§ 573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).**

The food additive, methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids), may be safely used in swine feed in accordance with the prescribed conditions:

(a) The food additive is manufactured by the reaction of refined sunflower oil with methanol to produce fatty acid methyl esters, which then undergo conjugation to yield methyl esters of octadecadienoic acid. The additive consists of not less than 28 percent methyl ester of cis-9, trans-11-octadecadienoic acid, and not less than 28 percent methyl ester of trans-10, cis-12-octadecadienoic acid with the sum of the other methyl esters of octadecadienoic acid not to exceed 4 percent. The additive shall contain not less than 35 percent of other fatty acid esters composed of oleic acid, palmitic acid, stearic acid, linoleic acid, and other associated acid esters.

(b) The additive is used or intended for use in the feed of growing and finishing swine as a source of fatty acids at levels not to exceed 0.6% in the finished feed.

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(c) The additive meets the following specifications:

(1) Free methyl alcohol not to exceed 0.015%.

(2) Insoluble impurities not to exceed 0.1%.

(3) Moisture not to exceed 0.5%.

(4) Unsaponifiable matter not to exceed 1.0%.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive and any feed premix shall bear the following:

(i) The name of the additive.

(ii) A statement to indicate that methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) must not be added to vitamin or mineral premixes.

(2) The label and labeling of the additive, any feed premix, or complete feed prepared therefrom shall bear adequate directions for use.

Dated: October 23, 2008.

**William T. Flynn,**

*Acting Director, Center for Veterinary Medicine.*

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