

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 1998F-0522]

**Food Additives Permitted in Feed and Drinking Water of Animals;  
Formaldehyde**

**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 to provide for the safe use of formaldehyde to improve the handling characteristics of canola and soybean oilseeds and/or meals in feed for beef and dairy cattle, and to provide a description of the food additive. This action is in response to a food additive petition filed by Rumentek Industries Pty Ltd.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and request for hearing by [*insert date 60 days after date of publication in the Federal Register*]. 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 51 of certain publications in 21 CFR 573.460 as of [*insert date of publication in the Federal Register*].

**ADDRESSES:** Submit written objections and request for hearing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit objections electronically to <http://www.fda.gov/dockets/ecomments>.

DMB

Display Date 11-20-03

Publication Date 11-21-03

Certifier A. Corbin

**FOR FURTHER INFORMATION CONTACT:** Karen Ekelman, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6653, e-mail: *kekelman@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In a notice published in the **Federal Register** of August 11, 1998 (63 FR 42856), FDA announced that a food additive petition (animal use) (FAP 2241) had been filed by Rumentek Industries Pty Ltd., 63-69 Market St., South Melbourne, Vic 3205 Australia. The petition proposed to amend the food additive regulations in part 573 (21 CFR part 573) to provide for the safe use of formaldehyde to improve the handling characteristics of soybean and canola oilseeds and/or meals in feeds for beef and dairy cattle. The notice of filing provided for a 60-day comment period on the petitioner's environmental assessment. No substantive comments have been received.

In the regulation in § 571.1(c) (21 CFR 571.1(c)), paragraph E of the form for petitions requires full reports of investigations of the safety of a food additive. The Center for Veterinary Medicine (CVM) evaluated information in the petition and in the scientific literature and has determined that the use of formaldehyde to improve the handling characteristics of soybean and canola oilseeds and/or meals in feeds for beef and dairy cattle is safe under the conditions of use prescribed in the amended regulation (§ 573.460).

**II. Conclusion**

FDA concludes that the data establish the safety and utility of formaldehyde for use as proposed 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 CVM by appointment with the information contact person listed previously. As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

### **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 objections (see **DATES**). Each objection must be separately numbered, and each numbered objection must 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 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, 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 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. Section 573.460 is amended by revising paragraph (a) to read as follows:

#### **§ 573.460 Formaldehyde.**

\* \* \* \* \*

(a) The additive is used, or intended for use, to improve the handling characteristics of fat by producing a dry, free-flowing product, as follows:

(1) For animal fat in combination with certain oilseed meals, as a component of dry, nonpelletted feeds for beef and nonlactating dairy cattle.

(i) An aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 303, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference

in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 4 percent of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) Adequate directions for use providing that the feed as consumed does not contain more than 25 percent of the mixture.

(2) For soybean and canola seeds and/or meals to which there may be added vegetable oil as a component of dry, nonpelleted feeds for beef and dairy cattle, including lactating dairy cattle.

(i) An aqueous blend of oilseed and/or meals, with or without added vegetable oil, in a ratio such that, on a dry matter basis, the final protein level will be 25 to 35 percent and the fat content will be 20 to 45 percent. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 301, 307, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance

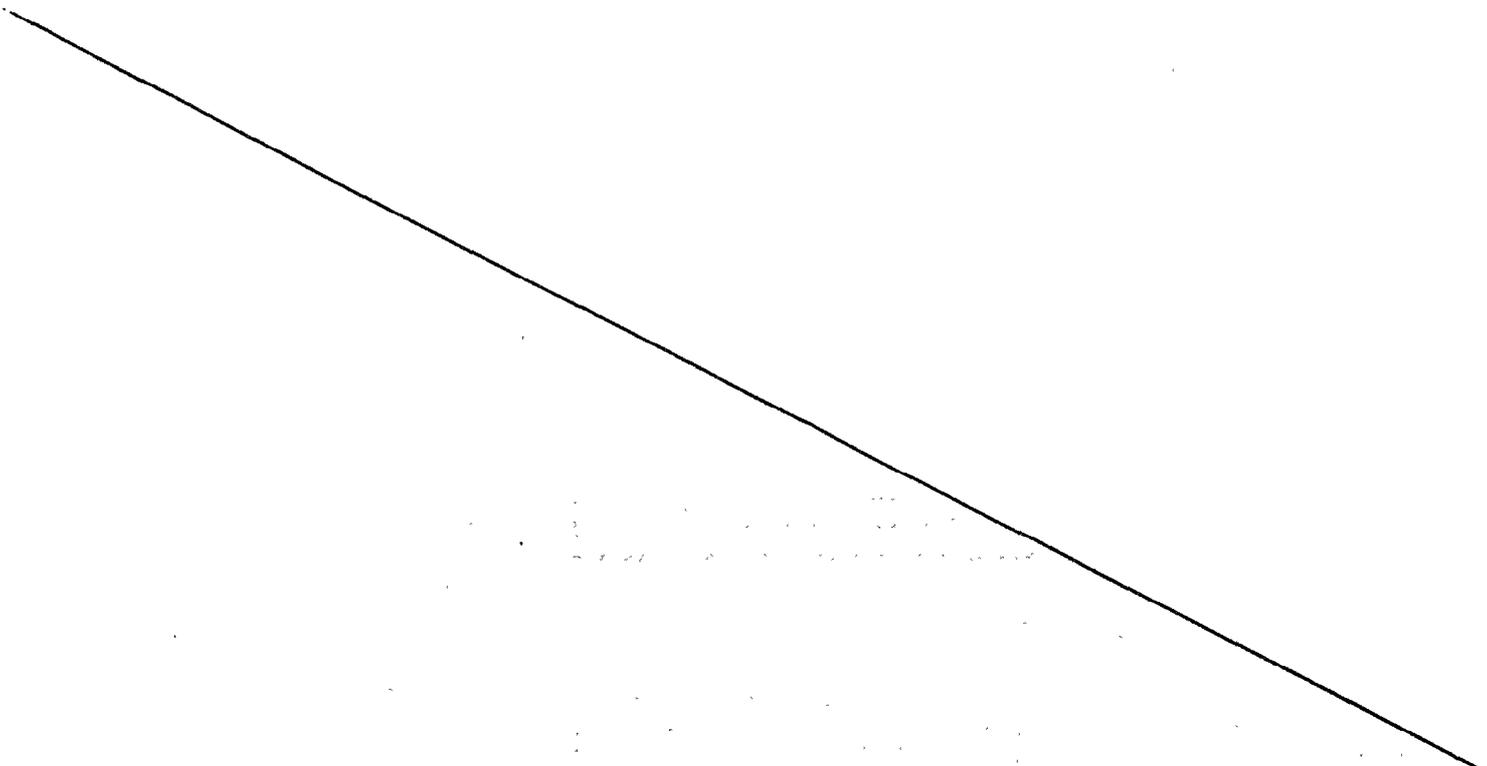
with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers lane, rm. 1061, Rockville, MD 20852, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 2.7 percent of the dry matter weight basis of the oilseeds and/or meals and the vegetable oil. This mixture, upon drying, contains not more than 0.5 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the act, the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) The statement, "This supplement is not to exceed 12.5% of the total ration. Dietary calcium and magnesium levels should be considered when supplementing the diet with fat."



(C) The minimum and maximum levels of crude fat must be guaranteed and must be between -5 percent and +5 percent of the analyzed fat content for each batch.

\* \* \* \* \*

Dated: 11/7/03

November 7, 2003.

Linda Tollefson

Linda Tollefson,  
Acting Director,  
Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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COPY OF THE ORIGINAL

[Signature]