

ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS, INC.

INVESTIGATOR REPORT

AND RECOMMENDATION FOR: _____ Special Purpose Products _____

Submitted by: _____ Shannon Jordre _____ Date: _____ 5-28-2010 _____

ACTION: _____ New Tentative Definition _____ Tentative Definition to be made Official
____XX____ Editorial Change _____ Delete Official Definition _____ Other _____

Definition No. _____ 87.15 _____ Name: _____ Formaldehyde Solution _____

87.15 Formaldehyde -- the food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(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, nonpelleted 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 National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(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 National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(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.

(b)(1) The food additive is formaldehyde (CAS No. 50-00-0; 37 percent aqueous solution). It is used at a rate of 5.4 pounds (2.5 kilograms) per ton of animal feed or feed ingredient. It is an antimicrobial agent used to maintain complete animal feeds or feed ingredients *Salmonella* negative for up to 21 days.

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

(i) The name of the additive.

(ii) A statement that formaldehyde solution which has been stored below 40 deg. F or allowed to freeze should not be applied to complete animal feeds or feed ingredients.

(iii) Adequate directions for use including a statement that formaldehyde should be uniformly sprayed on and thoroughly mixed into the complete animal feeds or feed ingredients and that the complete animal feeds or feed ingredients so treated shall be labeled as containing formaldehyde. The label must prominently display the statement: "Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days."

(iv) The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of paragraph (b)(1) of this section is required to carry the following statement: "Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days."

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

(i) Appropriate warnings and safety precautions concerning formaldehyde.

(ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.

(iii) Information about emergency aid in case of accidental inhalation.

(iv) 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.

(v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).

[68 FR 65633, Nov. 21, 2003]

Remarks: The federal regulation, 21 CFR 573.460, was amended significantly in 2003. The AAFCO definition was last updated in 2008, but contains errors when compared with the actual regulation. So, I'm resubmitting it. The definition above is verbatim from the Code of Federal Regulations. I thought it would be easier to copy the current regulation out of the CFR, and simply replace what is currently found in the AAFCO Official Publication, than it would be to try to accurately edit the existing definition.
Shannon

Deadline date: June ____15, 2010____
Submit report and recommendations to:

Richard Ten Eyck, Chair
AAFCO INGREDIENTS DEFINITION COMMITTEE
Oregon Department of Agriculture, Animal Health & Identification Division
635 Capitol St. NE
Salem, Oregon 97301-2532

Recommendation of Ingredients Definition Committee:

Remarks:

Accept as Requested Accept as Amended Do not accept Table until _____