

Ms. Marsha Clark
President
Anitox Corporation
1825 Anitox Drive
Buford, Georgia 30519

Dear Ms. Clark:

We are responding to your letter of March 4, 1999, in which you requested our opinion on the labeling of a complete feed containing ingredients treated with formaldehyde.

As a general statement, a complete feed must list all ingredients comprising the feed in the ingredient statement. Title 21, Code of Federal Regulations, §501.100 (Animal food; exemptions from labeling) does permit exemptions from the labeling requirements under certain circumstances.

Section (a) of § 501.100 states “The following foods are exempt from compliance with requirements of section 403(i)(2) of the act [Federal Food Drug, and Cosmetic Act] (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).” Part (a)(3) of § 501.100 discusses incidental additives and (a)(3)(i) further defines incidental as:

“Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.”

The data submitted in support of 21 CFR § 573.460 (b) demonstrated that 5.4 pounds of a 37% aqueous solution of formaldehyde per ton of ingredient or complete feed are required for the technical effect of maintaining feed salmonella negative. Based on this information, amounts below 5.4 pounds that become incorporated into a complete feed through the inclusion of ingredients would be considered an incidental additive. Thus, a feed containing ingredients that were treated with formaldehyde would not need to be labeled with the caution statement nor would formaldehyde need to be listed separately in the ingredient statement.

When treating a feed, the contribution of formaldehyde from individual components of the feed is not to be used in determining the amount of formaldehyde to add.

I trust this answers your inquiry. Please contact Dr. Dan McChesney at 301-827-6653 should you have any further questions.

Sincerely,

George Graber, Ph.D.
Director
Division of Animal Feeds
Center for Veterinary Medicine