



OCT - 7 1997

Dear Producer or User of Clay Products in Animal Feeds,

For the past several months, the Food and Drug Administration, the Environmental Protection Agency, and the Food Safety Inspection Service of the USDA have been tracing the source of elevated levels of dioxins first found in chickens grown in the southern United States. The source of the dioxin contamination was traced to a mined clay product called "ball clay," which is occasionally used as an anti-caking agent in soybean meal, in other feed components and in complete animal feeds. As a result of this information, FDA is requesting that the use of ball clay in all animal feeds and feed ingredients cease.

The term "ball clay" originated from an early English mining practice of rolling the highly plastic clay into balls weighing 30 to 50 pounds. Ball clay is used primarily in the ceramic industry for making such items as pottery, dinnerware, tile, stoneware and sanitary ware and much less frequently as an anti-caking agent in animal feed products. Ball clay is composed of poorly crystalline kaolinite with small amounts of illite and/or smectite, also known as montmorillonite. The ratio of the kaolinite to the other clay minerals is about 3 to 1. The predominant nonclay mineral in ball clay is quartz.

Ball clay is not specifically listed in Title 21 of the Code of Federal Regulations (CFR) Part 582 as a Generally Recognized As Safe (GRAS) substance or in 21 CFR Part 573 as an approved food additive; however, it has a history of use in animal feeds. It is listed in the Association of American Feed Control Officials, Inc. Official Publication (1997 Edition) as an acceptable anti-caking agent and pelleting aid not to exceed 2.5% in finished feeds.

Although there are a large number of dioxins, those generally referenced are 28 compounds which share similar chemical structures and a common set of toxicological properties. This family includes seven chlorinated dibenzo-p-dioxins (CDDs) and ten chlorinated dibenzo furans (CDFs) and eleven polychlorinated biphenyls (PCBs). The dioxins found in ball clay were almost exclusively CCDs. The most toxic form of dioxin is 2,3,7,8-tetrachlorodibenzo-p-dioxin or TCDD.

Dioxins are found throughout the environment in very low levels, often originating as a waste by-product of chlorinated chemical manufacture, bleaching and combustion. Because of the lipophilic properties and environmental persistence of dioxins, humans and animals accumulate dioxins over time. Continued exposure to elevated dioxin levels in animal feed increases the risk of adverse health effects in animals and to humans consuming animal - derived food products.

In addition to the original samples of ball clay traced back to a mine in Mississippi, samples of ball clay from the other major deposits in Kentucky and Tennessee have revealed elevated dioxin concentrations. Since the dioxin levels in the ball clay were significantly elevated, some samples contained more than 100 times the dioxin levels commonly found in most surface soils, we are recommending that the use of ball clay in animal feeds be discontinued. FDA intends to initiate the process specified in 21 CFR Part 570.38 to determine, based on the elevated levels of dioxin in ball clay, that ball clay for use in animal feeds is not GRAS and that, in the absence of a food additive regulation issued under Section 409 of the Federal Food, Drug and Cosmetic Act, its use in animal feeds is prohibited.

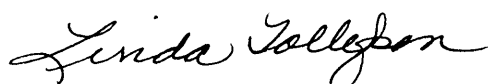
Although the investigating agencies have no data showing that other mined clay products have similarly elevated levels of dioxins, the possibility cannot at this time be dismissed. The FDA and EPA are continuing to investigate the ultimate origin and scope of dioxin presence in clay deposits. Until more is known about the source and pattern of distributions of these dioxins, mined clay products of all types should be used with caution in the production of animal feeds.

We request those companies mining and using ball clay products to cease their use in animal feeds and feed ingredients. Those companies offering other mined clay products for animal feed uses are advised to assure that their products are not similarly contaminated with dioxins.

The federal investigation of this issue has benefited significantly from cooperation by the food, feed and mining industries. Industry assistance moved this investigation forward quickly. We look forward to continued cooperation in this effort.

If you have any additional questions or comments, please do not hesitate to contact us.  
(Call Ms. Judy Gushee (301)827-0150 for general information; Dr. Randall Lovell  
(301)827-0176 for science questions.)

Sincerely yours,

A handwritten signature in cursive script that reads "Linda Tollefson".

Linda Tollefson, D.V.M., M.P.H.  
Director, Office of  
Surveillance and Compliance  
Center for Veterinary Medicine