

Guidance for Industry

DIOXIN IN ANTI-CAKING AGENTS USED IN ANIMAL FEED AND FEED INGREDIENTS

This guidance is intended to notify members of the feed industry of recent finding regarding the presence of dioxin congeners that may be present in clay-based anti-caking agents and to offer general advice regarding the monitoring of these clays.

This guidance represents the agency's current thinking on the presence of dioxin congeners in clay-based anti-caking agents. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

Comments and suggestions regarding this guidance document should be submitted to the Dockets Management Branch (HFV-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the Docket Number found in the heading of the Federal Register notice that announces the availability of this document. Comments may be submitted at any time.

If you have questions, please do not hesitate to contact us. For general questions regarding this document, contact Judy Gushee, Center for Veterinary Medicine (HFV- 230), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-0150 (e-mail: jgushee@cvm.fda.gov). For scientific questions regarding this document, contact Randall Lovell, Center for Veterinary Medicine (HFV- 222), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-0176 (e-mail: rlovell@cvm.fda.gov).

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Nearly two years ago, a multi-agency investigation tracked a previously unknown source of dioxins in our food supply back to a mined clay anti-caking agent, called ball clay, used in animal feeds and feed ingredients. Together, industry and government moved to swiftly eliminate the use of ball clay in the animal feeds and thereby, remove a source of dioxins in the human food chain.

In our October 7, 1997, letter to members of the feed industry, we stated that the ultimate origin and the scope of dioxin presence in clay deposits were unknown and, for this reason, mined clay products of all types should be used with caution in the production of animal feeds. We advised companies offering mined clay products for animal feed uses to assure that their products were not contaminated with dioxins.

Many industry participants tested clay products used in animal feeds in 1998. In particular, the American Feed Industry Association (AFIA) led a "Dioxin Task Force" that assembled dioxin data from a variety of sources and products. Based on our experiences with ball clay, only one dioxin congener, 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD), was thought to be predominant. Consequently, TCDD was all that was reported by the Dioxin Task Force to the CVM in September 1998. Fifty-nine, non-ball clay, mined product samples were reported to all be below the limit of detection for TCDD, with the detection limit in general being below 0.75 ppt TCDD.

Also, in late 1998, FDA collected samples of mined clay products from feed and oilseed sites where they were being used. The Environmental Protection Agency (EPA) subjected the samples to the complete analysis for all dioxin congeners of toxicological importance. The results of this sampling have now been received. These results prompted this guidance in order to share our findings, their implications for industry monitoring of mined clay products, and our further plans.

In brief, nine of fifteen samples of anti-caking, flow, and pelleting aids were found to contain detectable dioxins varying from less than 1 part per trillion toxicity equivalents (ppt TEQ) to over 20 ppt TEQ. Unexpectedly, the primary dioxin congener contributing to the TEQ was 1,2,3,7,8-pentachlorodibenzodioxin (1,2,3,7,8 - PeCDD). Very little 2,3,7,8-TCDD was found in the samples. None of the samples appeared to be ball clay, but were labeled "montmorillonite," "bentonite," "ground clay," and even "silicate" and "lime."

FDA and EPA are continuing to investigate the sources of the more elevated samples; however, the information thus far indicates the need for increased caution in industry surveillance for dioxins in feed ingredients.

First, there is now evidence that dioxins can be present in mined clay products other than ball clay. The current findings do not discount a natural origin for these residues. Second, dioxin congeners other than TCDD, particularly 1,2,3,7,8-PeCDD, may be present in important amounts. Therefore, analyses for dioxins should be for the entire congener group that contributes to the TEQ measurement, rather than just TCDD. Persons retaining samples of clay

extracts that were evaluated only for TCDD, for example, samples reported by the Dioxin Task Force, may wish to consider re-submitting the samples for a more thorough analysis.

Third, the significance to public health of the relatively low concentrations of dioxins found in the latest samples is presently unclear. On the one hand, these would seem to be small contributions of dioxin to the human food chain. The concentrations found are on the order of one-one thousandth of the highest concentrations found in ball clay. On the other hand, the limited samples may not be representative of the full range of concentrations of dioxins that may be found in these products.

Because dioxins were not detected in six of fifteen samples, it appears that dioxins can be minimized or avoided altogether in anti-caking agents. All mined clay products for use in feeds or feed ingredients should be carefully monitored for dioxins, without regard to how remote or pristine the source. We recommend that companies not use any mined clay products contaminated with dioxin in animal feed and feed ingredients.

CVM plans to continue to sample regulated mined clay products for dioxins, in conjunction with EPA and other government agencies. We will report back to you, as new information becomes available.