RECEIVED U.S. E.P.A.

2005 APR 11 PH 1: 49

October 18, 2004

CHVIR, APPEALS BOARD

The Honorable William B. Moran Administrative Law Judge U.S. Environmental Protection Agency Mail Code 1900L 401 M. Street S.W. Washington, D.C. 20460

Summary and Response to EPA Trial Brief and Proposed Finding of Fact

- 1. Time between inspections and enforcement actions: The initial inspection by Mr. Uthlaut on May 11, 1999 was followed by a second inspection on September 12, & 13, 2002. Followed by notification by certified mail on December 11, 2003. If the product was such an acute hazard both to humans and the environment why the 3 years 4 months time between inspections? And why an additional 15 months from the last inspection until initiating enforcement action?
- 2. Mr. Uthlaut made his initial inspection of May 11, 1999. During this inspection he obtained label copies and sales invoices for the product Root Eater. Mr. Uthlaut performed a second inspection on September 12, & 13, 2002. Again he obtained label copies and sales invoices for the product Root Eater. If EPA is so certain that the product is so acutely hazardous as alleged why was enforcement action not begun after the first inspection on May 11, 1999?
- 3. Lack of written notification: During both inspections (May 11, 1999 and September 12, & 13, 2002), Mr. Uthlaut stated that in his opinion the Root Eater label made pesticidal claims. No written follow up on this point was ever received from Mr. Uthlaut or from EPA. FRM Chem Inc. a.k.a. Industrial Specialties experience dealing with other Federal regulatory agencies such as Department of Transportation and Food & Drug Administration has been that every Notice, Warning, Statement, Opinion, e.t.c. is in writing.

- 4. Copper Sulfate as GRAS: Per 21 CFR 184.1261 Copper Sulfate is affirmed Generally Recognized as Safe (GRAS). As a long time FDA regulated veterinary preparation producing establishment we were aware that Copper Sulfate was approved by FDA to be " used in food with no limitation other than current Good Manufacturing Practices" and as such did not believe it would be a problem using Copper Sulfate in a cleaning product.
- 5. Removes as a cleaning term: Virtually every cleaning product on the market today uses the word remove(s) on their labels. Phrases such as "removes dirt and odors" on a laundry detergent or removes spots and stains on a carpet cleaner label. It is our contention that the use of the word "removes" is strictly in the context of cleaning.
- 6. Penalty calculation: In Appendix B Gravity Adjustments, line 7b Human Harm was assessed a rating of 3, "Potential serious or widespread harm to human health". Line 7c Environmental harm was assessed a rating of 3, "Potential serious or widespread harm to the environment". According to testimony by Mr. Leifer of EPA this type of formulation is recognized by EPA as appropriate for it's intended use, the only problem being a lack of EPA registration and labeling changes. If Mr. Liefers testimony is correct how can "Potential serious or widespread harm to human health" and "Potential serious or widespread harm to human health" and "Potential serious or widespread harm to the environment" occur?

Conclusion

It is our contention that such a long time elapsed between initial inspection and enforcement action because of EPA uncertainty as to whether this rose to the level of a violation of FiFRA.

No written notification, opinion, warning or cease and desist order were ever received by FRM Chem Inc. a.k.a. Industrial Specialties prior to receipt of the Notice of Enforcement.

Because of the small amount of product distributed, and the fact that this type of formulation is recognized by EPA as appropriate for it's intended use, is not a banned substance and if registration and labeling concerns were met this product would meet EPA criteria, we believe that the \$5,500 proposed penalty per each of the 3 counts is excessive.

Sincerely;

Raymond E. Kastendieck

President

FRM Chem Inc.