

January 5, 1988

H. W. Dietz

ACTIVITIES REPORT FOR DECEMBER, 1987

1. SPI - Food, Drug and Cosmetic Packaging Materials Committee (FDCPMC)

I attended the FDCPMC semiannual meeting December 3 and 4. The committee was brought up to date on a number of issues relevant to FDA, California Proposition 65 and related items as they apply to plastics.

The technical subcommittee presented plans to develop realistic extraction guidelines for food contact articles particularly for high temperature heat sterilizable conditions (retort pouches). A motion was approved to appropriate \$33,000 to have such studies performed by Dow under an approved protocol.

The Study of Acceptable Risk Task Force (formally Threshold of Regulation) has been set back by the unexpected death of one of the key reviewers. Meetings have been held with Ian Munro (formerly with Health & Welfare Canada) to undertake the study. Plans are to have a draft paper by the end of April with a paper for publication by the end of June. Successful completion of this project and acceptance of a Threshold of Regulation by FDA could save considerable time and expense by avoiding the filing of unnecessary FDA petitions for packaging materials.

The Chemical Abstract Services' decision to assign numbers to polymers based on the monomer content and structure (i.e. random, block, etc.) rather than monomer content only may potentially cause serious problems with FDA clearance and EPA-PMN filings. A task force has been established to address this issue.

The recent Court of Appeals color additives-Delaney Clause decision striking down FDA's clearance of D&C Orange 17 and D&C Red 19 does not have an effect on colorants for plastics. Such colorants are considered food additives. The decision actually strengthened FDA's de minimis and constituents policies as they apply to packaging materials.

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The FDA Cancer Assessment Group has completed their assessment of DEHP and feel it is not a major concern. If necessary, it may be possible to determine DEHP is a secondary carcinogen and not a carcinogen for Delaney consideration since a no effect level could be set.

Dr. Bruce Ames, Steven Brook, M.D. (SAP Prop. 65), Carl Pope (co-author of Prop.65) and George Burditt (Council of Labeling Uniformity) spoke on the effect of Proposition 65 as it applies to FD&C contact articles.

I was volunteered to serve on the nominating committee to nominate officers for election in June, 1988.

2. Geon 460X46

Scott Paper wants to use Geon 460X46 in a consumer product where skin contact could be a problem. A copy of the repeated patch tests were sent; however, Scott required a cytotoxicity study be performed. A cytotoxicity study was completed with favorable results. Geon 460X46 was found to be nontoxic. These results were submitted to Scott Paper which is not evaluating the product.

3. Carbopol 1342

Go-Jo Industries wants to use Carbopol 1342 in a hand rinse product in food processing plants. Carbopol 1342 is not listed as an FDA acceptable sanitizing solution ingredient. Consequently, the USDA insists on an advisory opinion from the FDA on such use of Carbopol 1342 before it will permit its use in meat and poultry processing plants. I have sent the information used to obtain the CTFA Carbomer 1342 monograph to Go-Jo for use in their FDA advisory opinion request.

4. Geon 103F76

A shipment of Geon 103F76 from the Waterloo plant to Ciba-Geigy Canada Ltd. was being held up for a statement certifying the resin was on the TSCA Inventory. I wrote and had FAXed a certifying statement to Ciba-Geigy, Canada so that the shipment could be released.

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cc: R. K. Hinderer

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