

February 2, 1988

H. W. Dietz

ACTIVITIES REPORT FOR JANUARY, 1988

1. National Sanitation Foundation (NSF)

I attended the Drinking Water Additives Health Effects Task Group meeting at NSF on January 13-14.

A report on evaluating the proposed toxicity testing requirements based on data available for an assortment of substances currently approved as drinking water and food additives was presented. The report was prepared by V. J. Ciccone and Associates, currently an EPA subcontractor for water additives. The report was prepared to determine if the testing requirements associated with each exposure level will serve the desired purpose and to validate the selected exposure thresholds. It was concluded that the proposed NSF scheme for integrating exposure with toxicity testing requirements is a reasonable and workable method for evaluating drinking water additives for potential health hazards.

Further refinements were made to the overall health effects evaluation scheme, particularly in the teratology, developmental effects and short term exposures. The document will be rewritten for submission to the task group and peer review group as the final draft. The final document is very similar to the testing scheme I had originally proposed.

This was the last officially scheduled meeting for the Health Effects Task Group. A tentative meeting to address any Peer Review Group concerns may be necessary in late March.

Standard 60 - Drinking Water Chemicals - (i.e. direct additives) was adopted 12-7-87. NSF will begin product listing in early summer 1988 for Std. 60. Standard 61, Drinking Water System Components, is scheduled for adoption in June with listings programs starting in June.

The listing of FPD and Geon Vinyl's products under NSF Std. 51, Food Service Equipment, remains confused. While at NSF for the Health Effects Task Group, I met, again, with the NSF listing representatives to try to resolve this situation. Hopefully, the confusion can be resolved in short order.

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2. No Foul

We received the annual Pesticides Report for Pesticide Producers from EPA for Plant 6. I discussed the current No Foul production application situation with the EPA, Region V office. As a result we have inactivated the Establishment Number for Akron and have begun the necessary paper work to have the Jacksonville, Florida plant registered.

3. Hydrophilics

There has been considerable interest in the use of calcium polycarbophil and polycarbophil in a variety of applications. I met with the Polycarbophil group to determine what need to be done to reestablish the USP Polycarbophil monograph and to upgrade the monograph testing procedures.

From all indications the USP monograph test procedures were established on a noncommercial product. The test methods cannot be used with ground commercial product. We are working with a Professor Robinson who holds use patents for various polycarbophil applications. Prof. Robinson is vitally interested in reestablishing the USP Polycarbophil monograph and resolving the test methods. He has close ties with USP and FDA.

4. Vinyl Institute

The "Packaging Forum" column in the January, 1988 issue of the Medical Device and Diagnostic Industry journal cautioned interested parties about the use of PVC packaging because of toxic combustion products PCDD and PCDF and nonrecycling characteristics. I sent Roy Gottesman a copy of the article. Dr. Gottesman responded to the magazine about the misinformation.

5. Geons

There is interest in the use of six Geon compounds for medical applications in Venezuela. The Venezuelan authorities have asked for documentation of the suitability of these compounds for such application. Tom Bialke asked me to review the formulation and data on these six compounds and provide a statement about their acceptability for such use.

The information I could obtain is confusing. One compounds, Geon 86155, is said to be obsolete, yet it appears that a recipe date 1-88 was issued. Four of the

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compounds were subjected to USP toxicity tests but not all under the same conditions. Cytotoxicity tests were performed on three. The results of the above tests indicate some effects from the plasticizer. In addition, I am told the compounds are being reformulated and will be sent out for toxicity testing.

Consequently, it is difficult at best to provide a statement as to the suitability of these compounds for medical applications.

We have run into our first requests for certification that some flexible PVC cap liner compounds will comply with California Proposition 65. The compounds involved are made for Alcoa for beverage bottles. The certifications were returned stating only that the compounds complied with the Federal Food, Drug and Cosmetic law and improvising regulations.

6. USDA

Hobart wants to use Fiberloc 803GR10 Cream 020 in a scale housing for use in food processing plants including meat and poultry plants. I advised R&D that USDA would most likely not approve the compound because of the heavy metal colorant used. Because R&D felt the compound color was crucial to this application, I submitted the formulation to USDA. As expected, USDA would not give acceptance to the Fiberloc compound due to the colorant. A reformulation of the above Fiberloc compound with an acceptable colorant system has been resubmitted to USDA. Unfortunately this will cause a two to three month delay for Hobart.

7. Cure-rite 18

The need for eye and skin irritation statements on the MSDS and labeling (U.S. and Europe) for Cure-rite 18 were discussed with Jim Tanzilli. Bob Hinderer and I reviewed the eye and dermal irritation data available on Cure-rite 18. Based on a review of the available data, particularly the latest samples tested, we believe there is no convincing evidence that Cure-rite 18 is an eye and skin irritant as defined by EEC or U.S. regulations. We have informed J. Tanzilli of our conclusions that Cure-rite 18 need not be labeled as a skin and eye irritant.

8. North American Science Associates (NAMSA)

On January 15th I made a laboratory site visit to the NAMSA laboratory in Northwood. NAMSA specializes in medical device and cosmetic toxicological evaluations. The laboratory is clean, well equipped and efficient for their specialty.

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While there, I took the opportunity to discuss some reporting/invoicing problems. Due to our decentralization and persons from various divisions sending test samples without any coordination, test results and invoices have been sent to the wrong people. One division has received invoices for tests done for another division. Recently an invoice was sent to me after it had gone to four different people in two different divisions. I then sent it for payment to the correct requestor from the third division.

To avoid delay and confusion in test results and invoices, I have requested NAMSA to sent this department a copy, or as a minimum, the summary of any toxicity studies performed for BFGoodrich.

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cc: R. K. Hinderer

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