January 6, 1985

R. A. Guyton, M.D.

Subject: Environmental Health/Industrial Hygiene/Toxicology
Activity Report - December, 1985

1. From the NO JOB CODE SURVEY report, it is apparent that we are experiencing difficulties with coordinating job surveys with exposure monitorings being done. We are receiving monitoring records but are not receiving job survey updates to identify the exposures to the jobs. As a result, we do not know if medical exams are required or not, and will not be able to provide accurate employee exposure profiles. At this time, the problem is most evident in the tire plants where there is no industrial hygienist to supervise the correct handling and dissemination of the needed information. We also no longer have a way to keep abreast of new jobs being established at the plants and of various existing jobs being combined to form new ones.

2. We have received the proposed NF Monographs for Carbomers 910, 934, 940 and 941 from the U.S.P. Rather than a family monograph as U.S.P. had proposed, there will be separate monographs for each Carbomer. The monographs are acceptable to us as written and we have so informed U.S.P. They will not address residual acrylic acid or volatile organics at this time.

   Before publication, they must be reviewed by the U.S.P. Revision Committee and be proposed in the Pharmacopeial Forum.

3. At the request of the Tire Group Mr. Katzenmeyer participated in a 2-day workshop with tire safety managers and an outside contractor to assist in designing an employee training program for hazardous materials used in tire plants. This training is required by the OSHA Hazard Communications Standard and must be implemented by May of this year. Each department was reviewed for use of hazardous materials. Materials exhibiting similar hazards were grouped and toxic effects, overexposure symptoms and protective measures were identified.

4. Work was begun by Paul Zakriski at Brecksville in attempting to quantitate the amount of oil that might transfer to the skin during the handling of oil extended rubber materials. Mr. Katzenmeyer handled various rubber stocks and then solvent washed his hands. The solvent washings were analyzed for oil content. The experiment thus far shows that small amounts of oil can be detected. We are evaluating the need to continue any further tests.

5. Assistance was provided to various of the chemical companies in the areas indicated:

   a. The Fabricated Polymers Division in submitting information to EPA on Promac® which is intended for control of mine acid.

   b. The chemical companies in commenting on procedures proposed by the State of Kentucky for setting acceptable levels of air pollutants. A number of issues were identified which must be addressed by the State.

   c. The Geon Group in developing a PMN for Code 10G and in notifying workers of its hazards.

   d. The Specialty Polymers & Chemicals Company by providing assistance in obtaining approval by the State of Florida of a reformulation of one of its Aqua-feed products which are used in reverse-osmosis water treatment.

   e. Mrs. Dillon performed an information search on PVC and Combustion Toxicity for Dan Kent per R. K. Hinderer's request.

   f. Mrs. Dillon entered documents into the EREF file on animal modeling for R. K. Hinderer and forwarded a computer printout of the documents to Lee Fishbein For R. K. Hinderer.

6. Dr. Dietz and Mr. Katzenmeyer met with Mr. Daniel Allebach, outside attorney, and Susan Watters to discuss BFG's defense in a claim that a case of leukemia in a former employee at the Oaks Plant was due to solvent exposure in that plant. Dr. Dietz later travelled to Washington D.C. to assist Mr. Allebach in the cross-examination of Dr. Peter Infante who was being deposed by the plaintiff's attorney.

7. Mr. Bachtel has received the data requested by the FDA for our Goodrite 3125 petition from the Brecksville Environmental Lab. The detection limit for Goodrite 3125 in aqueous extracts now appears to be higher than originally assumed. The net effect is a rise in the estimated daily intake of Goodrite 3125 by about 0.15 mg per day. This slight increase may lead to some further use restrictions by the FDA. The results will be submitted to the FDA with a copy to Ciba-Geigy.

8. The new HYTOX MSDS Report Module was received and implemented. The Report source code needed some refinement once it was installed. This task was done via telecommunication between Sherrill Snedecker and Randy Emmelhaing (programmer for the "MSDS Report"). A trial run of the MSDS Report was run on all the records in the HYTOX file and it appears to be giving us the finished product we desire.

9. We are working with the CMA/Rubber Additives panel to respond to the proposed EPA rule which will require considerable human and environmental effects testing. We are beginning to assemble our response and hope to gather some additional environmental release data. It is our position that EPA has overestimated levels in the environment in supporting the need for some testing.

10. NIOSH engineers visited the Marietta plant to conduct an experiment designed to evaluate dust exposure during chemical weigh and batching in the Compound Department. An attempt was made to measure the contribution dirty work clothing and/or depth of scooping from containers had in an employee's overall dust exposure during weighing operations. The experiment was successful in terms of the data collected.

11. Mrs. Dillon updated the HYTOX database and it now contains 165 records. The file also had to be reindexed. The Thesaurus file was also updated which included corrections that were indicated by the previous update. The job that kicks off the Thesaurus File Manager for the HYTOX file has some problems which Battelle will have to address.

12. Mr. Bachtel attended a Managing, Conduct and Data Quality of Toxicological Studies Conference sponsored by the Government and industry, Nov. 18-20 in Raleigh, N.C. The conference addressed current concepts and strategies to improve the quality of toxicological studies. A number of quality assurance programs utilized by government and industry were discussed including management, pre-study conduct, pathology, regulatory and international aspects. The conference was very informative and productive. There were over 600 attendees from government, industry and academia.

13. On December 3-4 Mr. Bachtel attended the SPI-FDCPMC meeting in Orlando, Fla. Updates on food safety legislation and regulation, PVC, and other current FDA, EPA and OSHA activities were discussed.

    The "Third Party" task force held its first meeting. The purpose of this task force is to study the perceived need of a third party to review and certify the status of ingredients as to their GRAS, no migration status. This would be an effort to avoid the long delays experienced with the FDA in such situations. A questionnaire was developed and will be sent to various companies and organizations to determine the need for an independent third party review. In light of FDA's recent "Threshold of Regulation" proposals, we decided not to take more substantive action at this time.

14. The first annual meeting of the Institute for Polyacrylate Absorbents was held on December 17 in Crystal City, Virginia. The purpose of this organization is to address the scientific and regulatory issues which may impact upon the health, safety and environmental aspects of fluid absorbing poly-acrylates. BFG proposes to join the Institute as an affiliate

(non-voting) member. In addition to organizational matters, the chemistry and toxicology of polyacrylate absorbents were discussed. John Moore, Assistant EPA Administrator for Pesticides and Toxic Substances, spoke on the EPA concerns relating to acrylates under TSCA.

15. The FDA is reportedly ready to publish the long-awaited PVC regulation. The regulation will limit the RVCM. The proposed RVCM limits are dependent on the application and range from 5 ppb in flexibles, gaskets, coatings, and 10 ppb in rigid sheet to 50 ppb PVC water pipe.

16. Meetings have taken place between the FDA and industry regarding a "threshold of regulation" concept in relation to FDA's 1985 Action Plan. The proposals presented would involve a three-track system for substances used in food packaging materials. The system would apply a threshold of regulation for some substances, a "fast-track" approval for others and normal food additive petitions for others. Toxicology, the intended use, and either the level of migration or level of detection would be considered in setting the threshold value of a substance.

    Such a system could save considerable time and money in the development of food contact materials.

17. For the first time, the FDA has used the "de minimis" concept for a direct food additive. The FDA has taken a major step toward applying the rule of reason to the interpretation of the Delaney Clause. The Agency has advised it will take no action against the continued use of methylene chloride as a solvent to decaffinate coffee, even though there is some residue in the coffee. Relying on the Monsanto Case, the FDA concluded that the level of methylene chloride residue in the coffee poses an upper bound risk of less than 1×10^{-6} and has ruled that a risk of this magnitude will be deemed de minimis so that the Delaney Clause ban concept need not be applied.

    Should this decision stand up in court, it could have a tremendous effect on packaging material migrants, i.e. indirect additives.

18. The Institut de Biopharmacie Rhône-Poulenc (France) is developing a transdermal dosage form utilizing Estane 5702. Under the terms of a secrecy agreement, we have sent to Rhône-Poulenc copies of our original polyurethane food additive petition, U.S.P. Class VI tests and other relevant tests and data from our FDA Estane Drug Masterfile.

19. We have received and reviewed the galley prints for the manuscript by Hinderer and Kaplan (SWRI) entitled "Assessment of the Inhalation Toxicity of Hydrogen Chloride Gas to Man". This article has been developed to communicate new data showing that primates can tolerate high levels of HCl.

20. Medical exam schedules were generated for nine locations. Oneida was added to the program and it is hoped that this will encourage them to correct their employee job histories.

21. Mrs. Wallace entered 4,463 records into the system this month including all death certificates, disabilities, Metpath tape corrections and PMIS race code corrections received during the month. We are behind schedule entering Metpath tapes due to vacations and holidays. The situation will be corrected without difficulty during January.

H. W. Dietz

jjp

B.F.Goodrich

The BFGoodrich Company
500 South Main Street
Akron, Ohio 44318

Address Reply To:
Dept. 0020
Bldg. 24-B

February 17, 1986

Dr. B. Bennett
Imperial Chemical Industries
Hillhouse Site
P.O. Box No.4 Thornton - Cleveleys
Blackpool FY5 4QD
England

Dear Dr. Bennett:

Although BFGoodrich is in the midst of extensive reorganizations, the one product line which has not been involved in discussion of disposal has been VCM/PVC. To the best of my knowledge Goodrich plans to remain in VCM/PVC; in fact one of our most recent acquisitions has been in that area.

I look forward to receiving the ASL Register and would be greatly pleased to meet with you if you do visit the States.

Sincerely,

Harold W. Dietz, M.D.
Director
Health and Environmental Services

jp