

11c

SEP 12 1976

JOSEPH E KELLER
JEROME H HECKMAN
CHARLES M MEEHAN
WILLIAM H BORGHESE, JR
ROBERT R TIERNAN
WAYNE V BLACK
DAVID L HILL
MARTIN W BERCOVICI
PETER M NEMKOV
JOSEPH E. HADLEY
CAROLE C HARRIS
PETER THOMAS SMITH
MICHAEL F MORRONE
LARRY S. SOLOMON

LAW OFFICES
KELLER AND HECKMAN
1150 17th STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS KELMAN

September 8, 1976

No. 26

TO: All Members of the VCM/PVC Mailing Lists

Letter Highlights

This letter contains a lengthy summary report on an ACS Symposium held in San Francisco last week to "record" essentially all that has happened as a PVC situation case history. On the basis of remarks made by Mr. Ronk of FDA at the Symposium it now appears that final FDA action on its proposals is unlikely for at least another month or two. Regarding compliance with the OSHA Standard, the deadline for use of canister and cartridge respirators without end-of-service-life indicators is September 30, 1976. Thus, we are requesting comments about the possible necessity for asking MESA for another time extension. It now appears that the EPA Standard may be approved earlier than anticipated, possibly almost immediately.

Ladies and Gentlemen:

We are writing again to bring you up to date about the latest vinyl chloride and polyvinyl chloride activities of interest, especially with regard to the American Chemical Society Symposium just held in San Francisco to discuss the entire history of the vinyl chloride "problem;" to note the revival of the canister and cartridge respirator non-availability issue with the Occupational Safety and Health Administration (OSHA); and to pass along the latest report we have

PRIVILEGED
AND
CONFIDENTIAL

GENC016829

*cc - VCM
Geneltt
Mudd
W. Hill
C. Hill
9/2/76*
*Collected
by
Mr. H. H. H.
R. H. H.*

September 8, 1976
Page Two

on the status of the proposed Environmental Protection Agency (EPA) air emission standard for vinyl chloride.

San Francisco Symposium

As many of you know, last week a two day Symposium on "Vinyl Chloride: A Case History" was held in San Francisco under the auspices of the Division of Environmental Chemistry of the American Chemical Society (ACS). The Symposium was organized by Dr. Nina McClelland of the National Sanitation Foundation, Program Chairman for the Division of Environmental Chemistry. Dr. Daniel Dixler of our office aided Dr. McClelland with the program; both of them are most grateful to the participants in the Symposium who were called upon and did respond on very short notice. It is anticipated that the proceedings will be published within a very short time to provide a ready and timely reference on the subjects covered. We will advise you when the publication becomes available.

The Symposium was organized around the general theme that here was a mature chemical industry that suddenly discovered it had a major problem. It responded promptly and most effectively; the ACS program was an effort to "put on the record" what the responses were so that other elements in the chemical industry might have this guidance should it ever be necessary in the future. With this in mind, the Symposium was organized to present first a general overview of the problem, the industry, and the analytical and physical chemistry concerns the solution of which was essential to develop a sound scientific approach for dealing with the situation to protect the public and industry interests affected.

Treatment of these areas was followed by government representatives who presented the Occupational Safety and Health Administration responses to the problem, and those of the Food and Drug Administration and the Environmental Protection Agency.

After the government positions were presented, a review of the basic parts of the PVC production industry followed, including discussion of suspension and dispersion

PRIVILEGED
AND
CONFIDENTIAL

GENC016830

September 8, 1976
Page Three

resin plants; specialty resin plants, including solution and other specialty polymerization procedures; and bulk polymerization plants. Attention was also directed to the PVC processing plants where little or no problems have ever been found.

The Symposium concluded with a review of the consumer industries, i.e. the PVC pipe industry, the PVC bottle industry, the PVC rigid and semi-rigid sheet industry, and the PVC plastics packaging materials industry.

The introductory lecture was given by Richard Wilson of Harvard University who presented a risk-benefit analysis vis-a-vis the PVC industry and exposure to vinyl chloride monomer. The conclusions presented showed that compared with many major socially accepted hazards, the risks associated with vinyl chloride exposure at present levels appear to be orders of magnitude lower.

A review of the European PVC industry was presented by John Stafford; it appeared that with some differences due to varying governmental structures and philosophies, industries, labor and public roles, procedures were not the same but the net results were similar, and somewhat similar to those reached in the United States. Basically, wherever PVC is manufactured, exposure of employees has been drastically reduced to levels far, far lower than had existed in the pre-1974 operations and orders of magnitude lower than those experienced by employees in plants that were characteristic of the early days of the industry. Likewise, the resin products shipped for use in consumer products now have far lower residual monomer levels than were characteristic of earlier products.

Richard Laramie of Conoco Chemicals reviewed the extensive advances achieved in the analytical chemistry relative to vinyl chloride which have made it possible for plant and environmental plastic product controls to be instituted. He also reviewed the analytical chemistry with relation to foods, drugs and cosmetics packaged in plastics. In all cases, methods with extremely low level of reliable sensitivities are available.

PRIVILEGED
AND
CONFIDENTIAL

GENC016831

September 8, 1976
Page Four

This was followed by a review of the diffusion of vinyl chloride from PVC resin and plastics presented by A. R. Berens of B. F. Goodrich Chemical Company. The diffusion of vinyl chloride from PVC resins and plastics is responsible for the possible presence of vinyl chloride in products packaged in PVC or in the atmosphere where PVC resins are stored. The Berens paper provided a review of the diffusion characteristics, an understanding of which led to the impressive engineering achievements which have allowed reduction of vinyl chloride levels all through the entire chain.

Grover Wrenn of OSHA reviewed the events leading to the final OSHA standard for vinyl chloride exposure of employees; Susan Wyatt reviewed the EPA concerns and discussed briefly some of the reasons behind the EPA proposed standards. She indicated that a final standard could be expected in October in line with our present expectations.

Of considerable interest was the review of the FDA position presented by Richard Ronk, Director of the Division of Food and Color Additives. Mr. Ronk read a prepared but as yet unavailable paper which reviewed the events leading to the proposed regulations to govern the use of PVC plastics for food contact applications. He presented a brief summary of the more substantive comments that have been received and stated that these would all be answered in the preamble to the final regulations which, he suggested, might be promulgated "some time in the fall".

After his formal statement, Mr. Ronk then spoke extemporaneously on the general question of how FDA might deal with extremely low levels of carcinogens that might enter the food supply as contaminants or indirect additives, pointing out that he personally feels the Delaney Clause is inappropriate and should not be applied to indirect additives. He suggested that ultimately a rational approach might be to develop sufficient animal data so that biostatisticians using extremely conservative approaches such as the "one-hit model" could set a level of population exposure sufficiently low so that all reasonable people could conclude that there

PRIVILEGED
AND
CONFIDENTIAL

GENC016832

September 8, 1976
Page Five

was no risk. This level of exposure might then be set as an acceptable level for regulating indirect additives.

He went on to state that, in the case of vinyl chloride exposure, biostatisticians working with available data have informed him that a level of 2 parts per billion (ppb) in food is such a "safe" level with respect to vinyl chloride. Nevertheless, he cautioned that no regulation could set a "tolerance" in the conventional sense even at the 2 ppb level since doing so would violate the Delaney Clause as presently interpreted by some attorneys at the Food and Drug Administration. He implied, without stating explicitly, that the staff at the Bureau of Foods was wrestling with the problem of how to permit by appropriate regulation materials which are recognized to be safe without at the same time setting any explicit number which could be interpreted as a tolerance. He also pointed out that the advances in analytical chemistry are such that no matter how low a figure might be set, the analytical chemists will ultimately define a list of research procedures to a point where they can find anything in anything.

Messrs. Holbrook of B. F. Goodrich, Wheeler of Union Carbide and Abramowitz of Hooker Chemical reviewed in some detail industry progress in analyzing the sources of emissions of vinyl chloride into the plant atmosphere and the steps taken to eliminate or minimize these emissions. Although the speakers generally directed most of their specific attention to processing and operations within their own companies, it was understood that similar results are being achieved by all producers on similar types of resins using similar plant processes.

This phase of the program was then completed by a review of levels of vinyl chloride found in PVC processing plants, as presented by Ed Muhall of Diamond Shamrock. He presented measurements in a variety of PVC plants taken before the new low RVCM resins were available to show that in PVC processing plants, even as they were previously operated, in most operations and plant locations exposures above the OSHA "action level" will not occur and, if adequate ventilation is introduced into those areas found above the action

PRIVILEGED
AND
CONFIDENTIAL

GENC016833

September 8, 1976
Page Six

level, this level need not be exceeded in any plant. Furthermore, whatever levels of exposure might have existed in the past, the low residual vinyl chloride resins now being provided still further lower possible employee exposure in the processing industries.

The final portion of the program was opened with introductory remarks by Dr. Seymour Gilbert of Rutgers University who reviewed some of the questions which had been raised in connection with PVC packaging materials.

A review of the PVC pipe industry which showed that there was no measurable vinyl chloride in water drawn from PVC distribution systems which had been made with pipe produced before 1974 was presented by R. S. Prust of Johns-Manville who also reviewed the present efforts underway and the achievements already attained by the PVC pipe industry in radically lowering residual vinyl chloride levels in PVC pipe and fittings.

A. J. Haefner of Ethyl Corporation reviewed the PVC bottle industry--where it had been and where it is today. The data he presented showed that bottles for foods, drugs and cosmetics are now available which will assure no reasonable expectation that vinyl chloride will become a component of packaged products. A similar conclusion was demonstrated with respect to now available PVC rigid and semi-rigid sheet. The paper on this subject was written by Mike Saggese of Tenneco Chemicals who could not present his paper personally. It was read for him by Dr. Gilbert.

The program then closed with a review of the prior sanctioned PVC plastics presented by E. N. Skeist of the Borden Chemical Company. He demonstrated that the plasticized PVC plastics, and PVC coatings, by the nature of their production and application never had measurable levels of residual vinyl chloride and, consequently, pose no opportunity for vinyl chloride to become a component of foods, or other regulated products. Even with these products, it was pointed

PRIVILEGED
AND
CONFIDENTIAL

GENC016834

September 8, 1976
Page Seven

out, the residual monomer level of the resins have in many cases been still further lowered as a result of compliance with OSHA and anticipated EPA regulations. Consequently, if the concept has any meaning, the products now being made are even safer than safe.

By and large the entire Symposium, as judged by audience comments and questions, appeared to confirm that from the point of view of labor, government and the public at large, there is a growing recognition that exposure to vinyl chloride has now become a "non-problem".

OSHA

Last fall we reported to you that, with the approach of the April 1 date upon which the Occupational Safety and Health Administration (OSHA) Standard went into full force and effect with regard to respirator usage, five of the Vinyl Chloride/Polyvinyl Chloride Producers Group had filed with OSHA seeking temporary variances based on the non-availability of certain types of respirators, insufficient time to complete engineering modifications, the effects of other regulatory action (viz., FDA and EPA activity), and other grounds.

We also reported that all of these temporary variance requests were mooted by the publication in the April 1 Federal Register by the Mining Enforcement and Safety Administration (MESA) of the Department of the Interior of its retroactive (to January 1, 1976) extension to September 30, 1976 of the previously established December 31, 1975 deadline for development of an "end-of-service-life indicator" for canister and cartridge respirators in vinyl chloride service. Prior to this, the failure to develop the requisite indicator had made use of canister and cartridge respirators inadequate for compliance with the OSHA Standard during 1976; only air-supplied respiratory protective devices were approved. With MESA on its own motion having extended the deadline for the end-of-service-life indicator requirements, the resultant canister and cartridge mask availability made it possible for OSHA to deny all requests for variances.

Of late, we have had occasion to be in touch with the responsible officials at OSHA, NIOSH and MESA concerning

PRIVILEGED
AND
CONFIDENTIAL

GENC016835

September 8, 1976
Page Eight

the status of an end-of-service-life indicator and to determine, were such indicator not approved by the deadline, whether an extension of the September 30, 1976 cutoff could be expected.

The NIOSH laboratories responsible for investigating the end-of-service-life indicator for vinyl chloride informed us that the only applicant device was rejected and had not been resubmitted. We were told that, as of this time, it would be impossible to approve any indicator device prior to the cutoff date.

Having already addressed ourselves to MESA and OSHA officials about a time extension with no success, we inquired of the NIOSH officials on whether they were going to take any action. We received something in the nature of a "no--that is your problem" response, so we thought it best now to inform those receiving copies hereof that these circumstances exist.

Only one company has expressed to us any desire for an extension of time, but we are nonetheless inquiring whether sufficient interest exists to support an extension of time request by the VCM/PVC Producers Group. If the Voting Representatives of that Group would care to comment on the situation or on the desirability of an extension, said views and arguments supportive of such a request should be directed to us promptly.

EPA

As we have often done in the past, we are attaching hereto a report received from our Associate Counsel, Beveridge, Fairbanks & Diamond, concerning the status of the proposed standard for emissions of vinyl chloride. The import of that letter is that the Standard could be promulgated very shortly, perhaps as early as the middle of September.

*

*

*

We shall continue to make every effort to keep you fully and promptly informed on all the various aspects of the PVC problem.

Cordially yours,

Enclosure

James H. Witherspoon
**PRIVILEGED
AND
CONFIDENTIAL**

GENC016836