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To L. N. Vernon

From D. A. Kuhn

Date April 6, 1978

Subject Report of SPI PVC Safety Committee Meeting - 3/31/78

EPA CARCINOGEN POLICY HEARING - 3/23/78

SPI (John Barr) testified on behalf of the American Industrial Health Council with the assistance of AIHC staff, API, MCA and others. SPI testomony was reviewed extensively to make sure it was consistent with the position of both AIHC and SPI. It was presented before a panel of EPA representatives which included Walt Barber, Deputy Assistant Administrator for Air Quality, Planning and Standards, Dr. Roy Albert of the cancer assessment group, Joe Pageant and Dr. Elizabeth Anderson of the Interagency Liaison Group. The SPI/AIHC objective was to set the record straight on the EDF petition to EPA that they establish a generic cancer standard. The EDF (Rauch) represented their proposal as a compromise. He threatened EPA that EDF could force the agency in court to require a zero level for a material when a safe threshold cannot be established. EDF questioned how the standards-making process could be speeded up, and emphasized the legal aspects of the zero level. They also reached many misleading conclusions about environmental exposure to carcinogens.

SPI (Barr) had the impression that the EPA panel members were very disturbed by the EDF generic cancer proposal. They were very sensitive to charges they were "dragging their feet". They asked how the process should be speeded up and what should be an "acceptable level of risk". Apparently EPA still feels vulnerable to EDF criticism. Later, Barber (in conversation with Floros of Great American) said he couldn't understand why industry spent so much time on the "zero" goal. He said no Congressman would ever pass a law requiring zero. He said the activities in New Jersey (the ambient monitoring for carcinogens) required greater scrutiny by EPA and that it was obvious to him that industry wanted a slow, orderly procedure to regulate carcinogens. Maury Johnson of BFG said no medical questions arose in the hearing. He thought that EPA didn't let EDF off easily. He believe that EPA asked EDF all the questions industry would like to have asked. Gary Baise said EPA will mull over the results of the hearing and probably make a proposal in the fall. Baise added that everyone concentrating on the class 1 materials but he warned us that class 2 materials, which would be regulated under Section 111, might even be a bigger problem because there will be so many of them and they will require stiff, new source performance standards.

What do we do now as a result of this hearing? The consensus was to raise the 20 or so issues generated by the proposal with the agency. These would be the zero emissions goal and whether the Clean Air Act would allow promulgation of the EDF proposal, for example.

It was agreed that SPI will recommend to AIHC that they pick up the ball on answering the questions raised at the 3/23/78 hearing.

THE EPA VC AMENDMENT PROPOSAL

Currently, EPA is sitting tight on final promulgation of the VC Standard Amendments until after they have proposed their generic cancer standard. They will probably do nothing unless EDF takes them to court and it's believed that EDF is involved in so many issues that they don't have time. Best guess now is that there will be a reproposal at some future time which will not require offsets to be retroactive to 6/2/77. However, stripping levels will very likely be lowered to less than 50 ppm because several companies have already submitted information to EPA that they can accomplish this currently.

WHAT HAPPENS IF WE MISS THE 10/21/78 DEADLINE?

Rumblings at EPA indicate that they will impose fines and injunctions to firms not in compliance with the current VC standard by the deadline. Baise indicates he is preparing a memo to be issued about 4/15, which will detail all the expected action. We've strongly urged him to issue that opinion sooner if he could. We don't know whether EPA will take a company missing deadline to court or whether charges will be civil or criminal.

The whole issue has now been complicated by a recent Supreme Court decision in favor of Adamo Construction. This case was brought under the asbestos standard, also promulgated under Section 112 of the Clean Air Act. Asbestos is also a hazardous air pollutant. The asbestos standard also specifies engineering and work practice controls. The court ruled that the Clean Air Act allowed only ambient air quality standards, so that the asbestos standard was unenforceable. The Clean Air Amendments of 1977 tried to mend this deficiency but Congress just forgot or overlooked mending the language in the enforcement section of the amendment. This means that EPA can promulgate engineering and work practice control standards, but they may not be able to enforce them. Baise said he thought EPA would "go to the mat" to demonstrate to Congress that they need the authority to enforce engineering control and work practice standards.

WILL NEW OR EXPANDED SOURCES REQUIRE OFFSETS?

New or expanded sources can be permitted under the existing regulation if they meet existing requirements, with the provision that they must comply with the requirements, including offsets of the proposed amendment, including offsets after 6/2/77 if it's promulgated. Evidently EPA is giving approval to permits subject to that provision. However, the SPI attorney's contacts with EPA have revealed that it is EPA's intention to withdraw the amendments proposed on 6/2/77 and repropose them. If this happens, the cutoff date of 6/2/77 will disappear with substitution of a more recent date. This means that new sources and expansions can begin construction between now and the reproposal with a small but yet finite risk that offsets will be required.

FDA ACTIVITIES

Heckman indicates FDA is withholding any promulgation of PVC regs until the acrylonitrile issue is taken care of. Because of the activities with AN, the outlook for PVC in food packaging is improving. FDA would like to back down on banning plastics for rigid packaging and they are looking for a way. This is primarily because they have discovered the problem is much more wide spread including, as well as plastics, lead leaking into food from the solder on tin cans. FDA wants us to get all the VC oral toxicity studies completed and add them to all the other toxicity work now available. It was mentioned that Maltoni has a study nearing completion that may have demonstrated a no-effect level for VC at around 1.8 ppm or 3.3 ppm. Noone was quite sure of the actual results.

Using the animal toxicity, we would do a risk assessment study using appropriate statistical methods to develop dose-response information for both VC and other chemicals in food packaging. We would then compare these to the acceptable risk assessment for things like lead and aflatoxin. From what we know now, VC and other monomers would pass this risk assessment with flying colors.

FDA is still trying to give EPA the regulatory authority on plastic pipe. On 10/31/77, Kennedy of FDA wrote to Costle telling him he's got the regulatory authority for plastic pipe and that FDA has washed its hands of it.

EXPENDITURES OF THE PVC SAFETY COMMITTEE

For the six months ending in February, 1978, the Committee spent $437M. In the next six months, however, expenditures will be reduced. Legal costs will be $20-25M/month and Communications will be reduced to $11M/month. This means further solicitation of funds from the members will be deferred to November or December of 1978. It was agreed that the assessment, based on total production, would be updated. Each company's share will depend on total production volume of VC and PVC combined.

WHO'S BEING SUED?

It was indicated that Union Carbide, Pantasote, BFG(Avon Lake) and "Perth Amboy" are being sued for damages by employees who were exposed to vinyl chloride in the work place.

ETHYL STRIPS PVC TO A RESIDUAL VC CONTENT OF 2 PPB

Ethyl has informed FDA that they can strip PVC for food packaging as low as 2 ppb in the laboratory, and they developed a hypothesis that it could go no lower. Contact with an Ethyl representative at the meeting revealed that this has been accomplished only in the laboratory, but they are committed to FDA to work out a commercial process. To reach this level, stripping must occur well beyond the reactor or stripper in the plant, but exactly how they carry out the process was not revealed. I couldn't determine whether this information has been given to EPA or OSHA, but it wouldn't surprise me if it were.

David A. Kuhn

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