

Interoffice Communication

To F. Kennedy, Chemicals Research, Ponca City
 From W. R. Sorenson
 Date September 8, 1975
 Subject PPI Meeting on VCM in Piping, September 3, 1975, Washington, D.C.

RECEIVED

SEP 18 1975

The PPI meeting on VCM in Piping met on September 3 in Washington, D. C. This meeting was called to discuss the newly issued proposal from the FDA on uses of PVC, a copy of which you have received independently. Those in attendance were:

Bill Nesbeitt (Petrochemicals), Chairman of the Committee
 Rod Becker (Diamond Shamrock)
 John Madden (Clow)
 Randy Prust (Johns-Manville, R&D)
 Dick Carter (Johns-Manville, Legal)
 Dick Tannehill (Goodrich)
 Bart Hodges (President of the SPI)
 Bob Wilging (B. F. Goodrich)
 Joe Richard (Ethyl)
 Stan Mruk (PPI)
 Ray Durazo (PPI)
 Jerry Heckman (K&H)
 Dan Dixler (K&H)

Heckman summed up the proposal. He pointed out that we have to come up with test methodology that will support FDA's conclusion that pipe doesn't pose a likelihood of VCM migration to water; therefore, it seems necessary to do field test work. The conclusion should hopefully be that there is "no detectable" VCM that can get into the diet. This is going to require test methods sensitive to the vicinity of two ppb, although he stressed not to get hung up over just exactly what that sensitivity is. Something in the 2-15 level might be satisfactory. It was pointed out in the proposal that theoretical calculations show two ppb as the maximum that could get into food from flexible film, but that in practice less than this would actually be present. Heckman feels, therefore, that we should establish the same data for VCM extracted from the pipe.

Within 60 days of the publication in the Federal Register of the proposal, someone, presumably this committee, will have to say that there is a method under development (protocol) for getting the information sought by the FDA at the bottom of page 30 of the proposal. That is, studies must be underway to determine whether VCM may reasonably be expected to be present in water drawn from a PVC pipe. Failure to do so will lead to revocation of the regulation permitting continued use of PVC water pipe.

To this end, Bill Nesbeitt got unanimous approval to appoint a subcommittee to develop such a protocol. I was asked to be chairman and accepted.

UEV-200461

F. Kennedy
September 8, 1975
Page 2

Other members are: Dixler, Becker, Mruk, Wilging, Prust. The group is to be called the FDA Action Subcommittee. The mandate is essentially as follows:

Develop a protocol for determining the presence of VCM in water drawn from PVC piping systems. Submit this protocol to the full VCM Piping Committee. (This is to be done as a mail-out with a request for a reply or comment in two or three days. It is felt there is not time enough for a full meeting nor any extensive debate.) Then, go ~~the~~ FDA for discussion and to get their concurrence that the protocol will satisfy their needs. We will then prepare a report to the full PPI membership at the meeting the week of October 13 (New Orleans). This is not to be a "for approval" presentation but rather a "what is being done."

The Subcommittee will meet September 15 and 16 at the J-M Research Center in Denver. J-M has done extensive protocol planning work with both FDA and EPA up to now and has some written outlines in this area which they will submit to the Subcommittee members prior to the meeting. Heckman's conversations with Ronk and Shapiro of the FDA led the latter to suggest that a statistician be involved. J-M has had their biostatistician as a participant in their protocol work, and he will be available.

Jerry Heckman wants to attack FDA jurisdiction over water pipe as a matter of principle for fear that, if it stands, every ingredient in pipe will have to be cleared by a food additive petition. FDA takes the position, obviously, that they do have water pipe jurisdiction and, under the law, they do. Heckman will try to get them to reaffirm the PVC prior sanction and not impose a regulation on pipe. He says that the odds cannot be more than 10 percent that this will be successful. Heckman would rather see the EPA with such jurisdiction to avoid the matter of a food additive petition for everything that extracts from pipe.

Ray Durazo raised the question as to whether it was wise for PPI-SPI to be challenging FDA jurisdiction. For one thing, it could have adverse public relations effects and, secondly, could stiffen the back of FDA and lose us some sympathy that may exist there now. Heckman stressed that his would be a low-keyed, behind the scenes approach.

As you know, there will be a meeting September 10 in Washington for all members of the SPI. Heckman described his game plan for this as the formation of task groups to attack the question of: (1) bottles, (2) sheet and blister pack, (3) pipes, (4) possibly a group for lawyers in order to pursue how to handle the data gathering and corresponding with FDA. The goal in all the groups would be to demonstrate that VCM is not present up to two ppm as a sensitivity target but not a limitation, as noted earlier. We have, of course, formed a pipe group. For this reason I don't plan to attend the September 10 meeting, although Bill Nesbeitt will do so for the entire Pipe Committee. Mruk will also be there.

VEV-200462

F. Kennedy
September 8, 1975
Page 3

There was a lot of general background provided by Jerry Heckman about the goings on that preceded the regulations. He said, for example, that the Bureau of Foods was very mad at one of the assistant commissioners who is mainly responsible for the form of the current proposal. Bureau of Foods as of mid-June said that PVC would be dealt with as a no-migration situation with a method sensitive to 50 ppb. This is clearly not the way it was done. The Health Research Group via its Dr. Wolfe has taken the approach that there has got to be some VCM in PVC, no matter how little, hence some must, no matter how little, enter the diet via extraction. Heckman believes there is no chance that the FDA will give in to Wolfe's route. There is a comment in the proposal on page 32 saying that the HRG petition will get a reply. According to Heckman, it will be to deny the petition because all subjects which were addressed in it are properly answered in the proposal just issued.

We discussed the matter of how fast a protocol and data could be developed. Heckman was asking for this all in 60 days. He said he could probably get a 60-day extension. Dick Carter of J-M said that since last May EPA has not been able to decide a protocol, and likewise FDA has reversed itself at least a couple of times on protocols (first, a lab test, then to field testing as now). We discussed some of the problems involved in adequately testing for VCM extraction in the field. That is, there are so many different communities where the piping systems are not known in any detail, where the temperatures of the water may be very high or very low as a routine, and where sampling would be difficult to do without creating some kind of panic. There are a great many technical details that could come up wherein the number of variables that could be covered would be staggering. Heckman and Bart Hodges made the point repeatedly, and I think correctly, that a protocol should not allow itself to get hung up on the mass of technical details, that it should select communities and sampling points with the best obvious information available, that it should strive for relatively new piping systems where the VCM is not likely to be so high, that the FDA is looking for support for its current conclusions and a PhD thesis is definitely not called for. In other words, there should not be technical overkill. We should not strive to do everything that it is possible to think of in terms of technical detail and experimental design. However, this is where the statistician will come in to provide at least some guidance.

Pages 42 and 43 spell out what the protocol has to involve as a minimum: (1) determination of the lowest attainable level of residual vinyl chloride in potable water pipe, (2) investigation of the relationship between residual VCM in pipe and the amount of VCM that may be present in water in such pipe under static conditions, (3) investigation into the level of VCM that may be present in water drawn from such a system. The first point will be an assessment of the industry attitudes on how low VCM will go in resin and then dry blend. The second probably already exists in the data submitted by J-M, ourselves, and possibly others. This is already alluded

VEV-200463

F. Kennedy
September 8, 1975
Page 4

to in the proposal and asking for it in the specification of what is sought seems to be redundant. Point three will be the principal substance of the field investigation by the FDA Action Subcommittee. Not so incidentally, a survey of the Committee members present seemed to be that there will be a continued push to very low VCM levels in resin ensuring the lowest possible level in pipe and everything else, in that the industry will go to one ppm or less in resin. The general sense was that the industry would be below one ppm in pipe compounds by January 1977.

There was some comment about how much VCM there was currently in resin. A letter was shown from Hooker to the FDA in which their pipe grade of resin 303B was cited as having 11.9 ppm average during the month of July. Prust told me privately that he took serious exception to that; they had never seen Hooker resin anywhere near that low. Jerry Heckman commented at this point that he thinks that FDA will ultimately raise the question of the amount in pipe wall even if there is none detectable in water. He reminded us all that some six or eight companies have said that there would be less than one ppm in resin. (I can't recall that there have been that many that have stated a figure that low, but BFG via Wilging noted that the latter has had a press release in the last five days that their process will reduce any resin to less than one ppm.)

The question of feeding studies was raised. Heckman stated categorically that no feeding studies will be done or would have relevance. FDA accepts that VCM will be carcinogenic by injection. If we got no feeding cancers, it wouldn't invalidate Maltoni for FDA purposes. The only tack open, therefore, is that there is no reasonable likelihood of migration. Ray Durazo said that PPI will publish a position paper on the VCM question along the lines of J-M's position paper on asbestos in past times. Durazo wants PPI to do an aggressive, positive PR job on the matter and will be putting out more press releases. They have issued one press release now, a copy of which is attached, that was designed for the plumbing trade magazines rather than the general public.

W. R. Sorenson
W. R. Sorenson

rh
Enc

CC: HJH PAS KLS
DAK CJS WRBe

UEV-200464