

Monsanto

ENVIRONMENT, SAFETY & HEALTH

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

May 7, 1987

Sir Richard Doll
University of Oxford
Clinical Trial Service Unit
Radcliffe Infirmary
Oxford OX2 6HE
United Kingdom

Dear Sir Richard:

I have reviewed your review of the effects of exposure to vinyl chloride and have no particular criticisms.

You mentioned that there might be a couple of points that I would either take issue with or wish to see modified, but I didn't see anything, except perhaps in the section on "Hazards to the General Population", which I will mention below.

I have some comments on the U.S. study that are informational. The Environmental Health Associates study that is one of the major studies in your review was an update of an earlier study by Tabershaw and me. In the earlier study, we used national data as a basis for comparison, so EHA, in updating the study, was stuck with either using the same standard or reanalyzing the earlier study as well. I agree that state or regional data would have been better. Tabershaw and I elected not to use them for reasons of expediency, and EHA had to either follow suit or ask for a lot more money from the Chemical Manufacturers Association.

Most of the sponsoring group in the CMA ignored the finding on emphysema because it didn't show any increase with interval since first exposure. However, one member company elected to inform EPA just to be on the safe side, and got a reply from EPA asking what they proposed to do about this newly discovered scourge. In their position, I would have been tempted to suggest that EPA perform an anatomically impossible act. What the company actually did I do not know.

In any case, we were all concerned about the excess of liver and biliary cancer over and above the ones that were stated on the death certificate to have been angiosarcomas. Your point that the angiosarcoma registry shows 29 American cases is reassuring,

RSV 0003915

Sir Richard Doll
University of Oxford
Oxford OX2 6HE
United Kingdom

but we will probably try to get some kind of independent verification of the causes of death for the deaths in this category.

I wonder about the usefulness of the studies quoted in the section on "Hazards to the General Population" for two reasons. First, if I understand the designs correctly, the studies appeared to look at the present residence of cases versus controls, and then looked at the cases to see whether they had lived near a plant long enough to have had sufficient latency of exposure. In other words, the relevant evidence was where the cases had lived a decade or two ago versus where the controls lived at present. Is it not possible that, if we looked at the residences of both cases and controls a decade or two ago, we would get a more meaningful, and possibly different answer?

The second point is that, at least for a number of common organic toxic air pollutants, body burden does not seem to be associated with proximity to the source of the pollutant. An undated report of something called the TEAM study (probably done around 1979) is enclosed, plus a handout of a talk given by the authors in mid-1984. I have highlighted the relevant conclusions. I think EPA wishes these results would go away, because they still go merrily on calculating air concentrations by dispersion models and predicting excess deaths as a function of proximity to a point source. However, that is another matter. The point is that if these results are true, as they appear to be, there is no reason to expect that the effects of general population exposure will be more evident close to the source of air pollution. I don't know if this holds true for vinyl chloride and angiosarcoma, but the possibility still has to be recognized.

I don't debate the presumption that vinyl chloride may cause a minute hazard to the general population, but for the above reasons I doubt that we can find evidence of that hazard by looking at the residences of cases.

In any case, I greatly appreciate the opportunity to see the report. I assume that I may talk about the findings to the CMA Vinyl Chloride Panel after June 1.

Yours sincerely,

Bill

William R. Gaffey, Ph.D.
Epidemiology Director

/ab

RSV 0003916