FOR25048

Vinyl chloride

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UNIROYAL CHEMICAL
Division of UNIROYAL, Inc.

Naugatuck, Connecticut
EMIC

September 12, 1975

To: W. D. Harris
Oxford E-G-1

From: R. J. Dowling

Subject: Carcinogens - "No Effect" Level

You are well aware of the background on VCM including the current FDA proposal to ban all PVC uses where "detectable" amounts of VCM may migrate into food or water. Methodology in the PVC proposal mentions 20 ppb sensitivity. Other references mention capability of detecting 2-4 ppb.

Applying "Delaney Clause" principles, a carcinogen would be banned from food if any amount can be detected. Carried to the ultimate, a method that showed one molecule could be legal justification for a food additive ban.

As I think about VCM, the Delaney Clause, and other exposure situations wherein constant reference is being made to prohibition of any contact at any level to any carcinogen it seems to me that a plan of action is needed to demonstrate the logical theory that there is a "no-effect" level for a carcinogen. The total VCM background suggests that this material represents an excellent candidate for a no-effect level experiment. If we don't begin to collect some hard data the question on no-effect level will haunt us forever.

URL 17407

You have many contacts with professional toxicologists (in and out of government). Dr. Maltoni of course would be an excellent contact to advise on the feasibility of a program - which although it would be lengthy and costly - could at least provide a data base for the future.

I will propose a rough outline of a specific program. I know an SPI task group (possibly MCA also) has considered this type of thing but I don't believe anything has actually started.

Discussed with RJD 9/15/75 No use to do more animal studies now. NCI agrees.

Rats would be the obvious test animal. The number to use would have to be arrived at statistically (it would be a large number but hopefully not ridiculous). Feeding level to be selected on a rational basis - e.g., if we assume methodology of 20 ppb sensitivity and apply an arbitrary 100 X factor we arrive at 2 ppm.

In any program of this type there is always the possibility that an adverse effect of a small numerical order might show up in the "treated" versus the "control" group. For example, if 1,000 animals were used and 2 liver cancers developed in the "treated" and only 1 in the "untreated" would this be considered significant?

The whole point here is that we need hard data to refute the "one-hit" and "no safe level" theorists. A rapid test technique would be ideal but I don't know of one that is dependable. Whether we work with VCM or something else is not as important as making plans to clarify this subject looking to the future.

How do you feel about this?

RJD:lads
CC: RJD-file
MJK-circ.