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VC - EPA

AUG 18 1980

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To (Name) F. D. Bess - 511
Division M. E. Eisenhour - 515
Location ~~100 Park Avenue, New York, NY 10017~~
Floor Number

Date August 14, 1980

Originating Dept. HS&EA

Floor Number 22

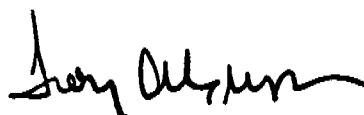
Answering letter date

Subject Vinyl ChlorideFILE COPY
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Copy to

Attached is a copy of a recent report prepared by the EPA Carcinogen Assessment Group (CAG) on vinyl chloride. The report and summary conclusion was directed to both Air and Water EPA officials.

Please note the report concludes that exposure to 1 ug/m³ of vinyl chloride will result in the risk from lifetime exposure of 4.1×10^{-6} . It has been my understanding that the EPA has set acceptable risks at a 1×10^{-6} level.


L. A. Crisorio

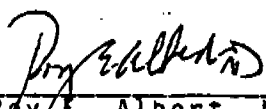
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Attachment

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Summary and Conclusions Regarding
Carcinogenicity of Vinyl Chloride

Vinyl chloride is a recognized human and animal carcinogen. Several occupational epidemiology studies in highly exposed workers have reported excess rates of liver angiosarcoma and tumors at other organ sites. Animal experiments using both inhalation and oral routes of exposure have also induced liver angiosarcoma.

A water quality criterion based on a lifetime excess cancer risk of 10^{-5} is calculated using the tumor incidence data from chronic rat inhalation studies. The validity of these incidence rates for humans was established by evaluating the cancer incidence in workers after accounting for their exposure. The vinyl chloride intake was assumed to consist of only drinking water, and the bioaccumulation factor in fish was assumed to be 1.0. With these assumptions, along with the assumptions common to other risk assessments, the concentration of vinyl chloride in surface waters must be less than 0.53 mg/l in order to result in an individual lifetime risk of less than 10^{-5} .


Roy E. Albert, M.D.
Chairman

Participating Members

Elizabeth L. Anderson, Ph.D.
Warren Hercules, B.S.E.E.
Kristine Hess, B.S.
Charalingayya Hiremath, Ph.D.
Robert McGaughey, Ph.D.
Steven Miller, M.S.
Wade T. Richardson, J.D.
Gharm Singh, D.V.M., Ph.D.
Ruth Pertel, Ph.D.
Todd Thorslund, Sc.D.
Adrienne Zahner, Ph.D.

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16 JAN 1978

SUBJECT: Amendments to the Vinyl Chloride Standard

FROM: *for Roy R. Albert*
Roy R. Albert, Chairman
Carcinogen Assessment Group

TO: David Hawkins, Assistant Administrator
for Air and Waste Management (AW-443)

With regards to your proposed amendments to the vinyl chloride standard, I believe that it is useful to keep two things in mind concerning the possible human health risk.

The first is that the average lifetime risk associated with the standard as currently set of 1×10^{-5} is relatively low with regards to lifetime risk associated with exposure to carcinogens for which regulatory actions have been taken (see Table I). While it is certainly desirable to reduce the risk from exposure to carcinogens to the lowest level possible, it will not always be possible to remove all risks completely. Therefore, I believe it serves a useful purpose to take a look at the relative lifetime risk from exposure to different carcinogens.

The second point is that an "adequate margin of safety" might possibly be viewed as an extremely low probability that a person exposed to the standard for a full lifetime might possibly get cancer from this exposure. A similar approach to this has been adopted by the FDA, in defining a "safe" level for residues for suspected carcinogens in animal food stuffs as an average lifetime risk of 1×10^{-6} (or one chance in a million of getting cancer from a lifetime exposure to the residue (see attached copy of FDA Guidelines).

Attachments

cc: S. Gage
M. James
T. Just

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

15 AUG 1978

SUBJECT: Vinyl Chloride Unit Risk Estimation

FROM: Elizabeth L. Anderson, Executive Director
Carcinogen Assessment Group

TO: Jack McGinnity
Strategies and Air Standards Division

This memorandum is written in response to your May 19, 1978 request for our comments concerning the vinyl chloride unit risk estimation by George Wahl. We apologize for our delay.

With minor differences we agree with Mr. Wahl's calculation that the risk from lifetime exposure to 1 ug/m^3 of vinyl chloride is about 4.1×10^{-6} , with all the caveats necessary in explaining such estimates. However, we disagree with the calculation of relative risks on a ppb basis, as we explain below.

In our previous memoranda we have arbitrarily used the density of dry air at 20°C and 760 mm Hg pressure rather than at 25° , as Mr. Wahl has done. For future reference the following table lists the ug/m^3 equivalent of 1 part per billion of vinyl chloride and ethylene dichloride, where $D(T)$ is the density of dry air and $M_a=28.8$ is the molecular weight of air.

T($^\circ\text{C}$)	$D(T) \times 10^{-9}$ (ug/m^3)	ug/m^3 Equivalent of 1 ppb*	
		VC ($M=62.5$)	EDC ($M=99$)
20	1.205	2.615	4.142
25	1.184	2.569	4.070

* Using the formula $\text{ug/m}^3 = 10^{-9} D(T) M/M_a$

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We have no reason to prefer 20° other than the inconvenience of changing our previous estimates for other compounds.

Using the 20°C temperature as the standard, the lifetime risk from breathing 1 ug/m³ of vinyl chloride is $1.5 \times 10^{-4} \times 70/2615 = 4.02 \times 10^{-6}$, whereas for EDC the corresponding risk was found to be 7.2×10^{-6} or 1.2×10^{-5} , depending on the method of calculation. Taking the higher of the two EDC risk values, the ratio of EDC to VC risks on a ug/m³ basis is therefore $1.2/0.402 = 2.99$.

To find the relative risks on a ppb basis, we note that for EDC the risk to 1 ppb is the same as the risk to 4.142 ug/m³, or $4.142 \times 1.2 \times 10^{-5}$. Similarly for VC the risk to 1 ppb is the same as the risk to 2.615 ug/m³, or $2.615 \times 4.02 \times 10^{-6}$. Therefore the ratio of EDC to VC risks on a ppb basis is $4.142/2.615 \times 2.99 = 1.58 \times 2.99 = 4.74$. This is larger than the relative risk on a ug/m³ basis rather than smaller, as Mr. Wahl's memorandum states.

We would be happy to discuss this further if you wish.

cc: W. Barber
J. Padgett
M. James

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