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Comments on Proposed Rule for
 Vinyl Chloride Emissions

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EPA

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Introduction

In a fine statement the EPA administrator, Russell Train, expounded a policy on health risks of suspected carcinogens:¹

"I believe that it is important to emphasize the two-step nature of the decision-making process with regard to the regulation of a potential carcinogen. Although different EPA statutory authorities have different requirements, in general two decisions must be made with regard to each potential carcinogen. The first decision is whether a particular substance constitutes a cancer risk. The second decision is what regulatory action, if any, should be taken to reduce that risk."

It is uncontested that vinyl chloride at high doses is a carcinogen. The first step of the decision making is clear. Dr. Train went on:

In other regulatory areas, for example those under the Clean Air Act, the Federal Water Pollution Control Act, or the Safe Drinking Water Act where a large number of suspect carcinogens may exist in the atmosphere or public water supplies, the detailed risk benefit assessment will, because of limited Agency resources, necessarily have to be carried out on a priority basis in terms of which agents appear to be the most important."

"Once the detailed risk and benefit analyses are available, I must consider the extent of the risk, the benefits conferred by the substance, the availability of substitutes and the costs of control of the substance. On the basis of careful review, I may determine that the risks are so small or the benefits so great that no action or only limited action is warranted. Conversely, I may decide that the risks of some or all uses exceed the benefits and that stronger action is essential."

It is useful to discuss the proposed changes of the vinyl chloride standard in the light of this policy statement.

The Risk Analysis

The EPA staff have made a fine risk analysis for vinyl chloride.² This gives a risk of 7×10^{-5} /year for a concentration of 1 part per million of vinyl chloride in air. This risk is based on an assumption of a linear relationship between cancer incidence and dose, and fits the animal data for Maltoni, and is somewhat greater than estimated from human data. I have gone over this calculation³ and agree with it. More recent data of Maltoni announced in September 1976 agree with the previous data and when plotted on figure 4 of my paper, fit the data well as shown. These new data require, therefore, in my view, no change in the risk assessment.⁴

In calculating the community exposure the EPA study uses somewhat old vinyl chloride emission data. An average PVC plant processing 150 million pounds/year is assumed to emit 4% of the vinyl chloride processed or 800 pounds/hour.⁵ If the emissions are reduced, so will the concentrations be reduced.

Already in my report I had noted the concentrations measured by EPA⁶ were 1/10 of those calculated by the diffusion models--presumably because of a reduction in emissions between the estimate and the concentration measurement.

The present standard, promulgated in the Federal Register on October 21, 1976, will reduce these emissions still further to about 36 pounds/hour for a PVC plant according to the EPA, and still less if industry is correct and fugitive emissions are not so great as EPA assume.

It is important to realize that those who advocate taking a linear relationship between cancer incidence and dose do so on the basis of a simple theory of cancer incidence, such as that of Armitage and Doll, without any repair mechanisms. Inherent in the theory is that the risk is proportional to the concentrations averaged over a long time--an appreciable fraction of a lifetime--and not the maximum in a short period or over a small distance.

It is also important to emphasize that although I use here the linear relationship between cancer incidence and dose, there may well be repair mechanisms giving a threshold below which no effect occurs. If a threshold exists, the risk is probably zero at the doses discussed here. I neither accept nor reject the idea of a threshold but maintain that it is unnecessary to accept it to establish an acceptable level of risk.

Approximate Diffusion Calculation

The standard is written as if diffusion calculations are complex. This is not true and indeed the EPA has an excellent manual for diffusion calculations.⁷

The basis for this calculation is Sutton's well-known formula.

Concentration (C) =

$$\frac{Q}{2 \pi U_x \sigma_y \sigma_z} \exp \left(\frac{-y^2}{2 \sigma_y^2} \right) \left[\exp \frac{-(z-h)^2}{\sigma_z^2} + \exp \frac{-(z+h)^2}{\sigma_z^2} \right]$$

where Q is the emission rate

U_x is the wind speed along the x direction.

σ_y and σ_z are dispersion constants in the y and z directions respectively (the Gifford coefficients)

h is the (effective) stack height = actual height + plume rise

For our purposes, we want an average over a long time and I assume all directions of wind, averaged over a year, are equally probable. Then I integrate over the y direction and average the concentration around a circle of radius x and center at the emission source.. Then I find

$$\bar{C} = \frac{Q}{4\pi^2 U_x \sigma_z \sigma_y x} \int_{-\infty}^{+\infty} \exp \left(\frac{-y^2}{2 \sigma_y^2} \right) dy \left[\exp \frac{-(z-h)^2}{2 \sigma_z^2} + \exp \frac{-(z+h)^2}{2 \sigma_z^2} \right]$$

I also note that for moderate stack heights, h, σ_z exceeds (h) at small distances and h = 0 for fugitive emissions anyway. If I assume $h < \sigma_z$, $z = 0$ (ground level) then the square bracket equals 2. Then using the relation $\int \exp (-a^2 y^2) dy = \frac{\sqrt{\pi}}{2a}$, we find

$$\int \exp\left(-\frac{y^2}{2\sigma_y^2}\right) dy = \frac{\sigma_y \sqrt{\pi/2}}{2} = \sigma_y \sqrt{\pi/2}$$

$$\bar{C} = \frac{Q}{\pi^{3/2} 2^{3/2}} \cdot \frac{1}{U_x \sigma_z X}$$

As a rough approximation I take values for U_x and σ_z which are correct about half the time.⁸ $U_x = 7$ meters/sec, $\sigma_z = 18$ m, $X = 500$ m. EPA estimate for a typical suspension plant under the present standard, $Q = 36$ pounds/hour = 4.55 gms/sec.⁹ I take this although industry believe it to be high. We then find

$$\begin{aligned} \bar{C} &= \frac{4.55}{(2\pi)^{3/2}} \cdot \frac{1}{7 \times 18 \times 500} \frac{\text{gms}}{\text{m}^3} \text{ at } 500 \text{ m.} \\ &= 1.15 \times 10^{-5} \text{ gms/m}^3 = 1.5 \times 10^{-11} \text{ gms/cm}^3 \end{aligned}$$

The density of air is well known to be 1.20×10^{-3} gm/cm³. So the concentration $\sim 10^{-8}$ or 10 parts/billion at 500 meters. σ_z increases less than linearly with X , so the concentration falls at about $1/X^{1.8}$ as already noted in the EPA risk assessment.

Taking this meteorological air condition alone gives a low result; according to Rogers and Gamertsfelder,⁸ 8% of the time we can expect Pasquill G conditions, a steady wind at 1 meter/sec and $\sigma_z = 5.5$ m and the concentration is $18/5.5 \times 7/1 = 20$ times greater. I average over the weather classes in Rogers and Gamertsfelder's paper⁸ tabulated here (Table 1) and find that 36 lbs/hr corresponds to an average concentration at 500 m of about 40 parts per billion, about what I took in August 1976, at 1/10 of the EPA 1975 risk assessment.²

Table 1

Meteorological Data for Atmospheric Release Calculations*

Weather type	A	B	C	D	E	F	G
Probability of weather condition	0.019	0.081	0.136	0.44	0.121	0.122	0.08
Wind velocity, u_x (m/sec)	2	3	5	7	3	2	1
Distance, x (m)	σ_z (m)						
200	28.8	20.3	14	8.4	6.3	4.05	2.63
500	100	51	32	18	13	8.4	5.5
1000	470	110	59	32	21.5	14	9.2
2000	3000	350	111	51	34	21.5	13.7
5000	-	1900	230	90	57	35	23
10,000	-	-	400	140	80	47	31
20,000	-	-	650	200	110	58	37
50,000	-	-	1200	310	150	75	48
100,000	-	-	1800	420	180	90	55

* Table adapted from 8.

We should note that this simple calculation should be fairly good for a long term average and probably overstates the ground level concentrations at 500 m and more because we expect the air to be broken up in a populated area more than suggested by the diffusion constant σ_z of 18 meters.. The number is twice that given by the more precise diffusion calculations in the EPA risk study adjusted downwards by the ratio 36 bls/hr./800 lbs/hr. I also note as have others, that most of the assumed emissions come, and always have come, from PVC plants (which are more numerous) and not VCM plants. Therefore, using the adjustment for PVC plants alone is accurate enough..

My calculation is rough and intended solely to give some quick idea of how the concentrations vary. I take the numbers in the EPA risk study adjusted downward by the factor 1/20 noted above for what follows.

The EPA diffusion calculation when so normalized leads to a concentration averaged over all persons within 5 miles of a PVC plant and averaged over a year's time is less than 1 part in 1 billion given an average risk, on the EPA's linear basis of 5×10^{-8} /year averaged over the 5 million people who reside within 5 miles of PVC plants in the U.S. Multiplying the 5×10^{-8} by 5 million gives 1 hypothetical cancer case every 4 years out of 300,000 cancer cases/year from all causes in the whole U.S. population or 20,000 cancer cases/year from all causes within 5 miles of the plants.

Meaning of the Risk

The risk appears to be 5×10^{-8} /year averaged over all persons within 5 miles of the source. This is a low number and its meaning can only be grasped by a comparison with other risks; preferably risks similarly calculated. I listed some of these in my paper on vinyl chloride.³

In Table 2 I list some risks of 5×10^{-8} --which corresponds to a year's exposure to vinyl chloride with the October 21, 1976 standard--and some risks of 10^{-8} which correspond to the maximum change that could be caused by the proposed June 22, 1977 standard.

To explain one entry in this table: the proposed standard will reduce the average risk for one year by no more than reducing cigarette smoking by 1/75 of a cigarette, or alternatively, smoking one cigarette is worse than living near a PVC plant for 75 years.

The data came from many sources including a paper (attached) by Sir Edward Pechin.¹⁴

1. Cigarette smoking is a well measured and certain hazard. Doll's study of the smoking habits of British physicians show that the risk is proportional to the number of cigarettes, at least over the range 4-40/day. The estimate of the pollution from other smokers is based on the relative cigarette smoke concentrations. I note that even nonsmokers are subjected to a hazard far greater than from vinyl chloride.

2. This comes from a WHO¹⁵ study comparing incidence of cirrhosis of the liver in various countries and relating it to

Table 2
Maximum Effect of the Proposed Standard

Risk of 5×10^{-8} Oct. 21, 1976 Standard	Risk (or change in risk) of 10^{-8} June 22, 1977 Standard	
(1) 1/15 50 hours	1/75 10 hours	of a cigarette (cancer heart disease) of being in a room with cigarette smokers
(2) 1/3 oz.	1/15 oz.	wine (cirrhosis of the liver)
(3) 1/2 tablespoon	1/10 tablespoon	peanut butter (aflatoxin in mold causes cancer)
(4) 1/5 pint	1/25 pint	heavily chlorinated drinking water (chloroform water causes cancer; Orleans or Miami filter)
(5) 1.5	1/3	diet sodas (saccharin causes cancer)
(6) 30 miles	6 miles	flying in commercial aircraft
(7) 1 hour	15 minutes	air pollution (Boston Washington)
(8) 3 days	15 hours	inside brick or stone building (radioactivity causes cancer)
(9) 3 days	15 hours	visit to Denver, CO cosmic radiation causes cancer)
(10) 1.5 days	8 hours	fraction of average diagnostic radiation causing cancer
(11) 150 miles	30 miles	jet flying at 30,000 cosmic rays causing
(12) 1 year	1 year	average exposure with 5 miles of PVC pipe

the alcohol consumption. The incidence of cirrhosis is proportional to the alcohol consumption.

3. This comes primarily from the FDA report in the Federal Register,¹⁶ and I assume that the cancer hazard for man is related to that for animals for the same mg/kg intake. I take the average concentration of aflatoxin in the U.S. peanut butter to be about 1.5 parts per billion and the total consumption of peanuts from the Statistical Abstract of the U.S.

4. For this I take the report by the National Academy of Science on health effects of drinking water¹⁷ and note that Miami and New Orleans have 100-parts per billion of chloroform in their water. I have confirmed this by my own calculation using data on cancer induction by chloroform in mice and rats^{17, 18} and relating to human exposure for the same mg/kg intake as for the vinyl chloride.

5. I take the procedure as outlined by FDA for saccharin in April 15, 1977 Federal Register. I take the linear extrapolation and this is equivalent to the procedure in (4) above.

6. This comes from average of accidents over the last several years. Accidents happen mostly at take-off and landing and this number is clearly low for a long flight. Also recent improvements (last five years) in air traffic control reduces this markedly in the U.S.¹⁹

7. Air pollution is controversial. There seems little doubt that it is serious, but the active agent is uncertain. Ten years ago sulphur dioxide was blamed; three years ago sulphate particulates; now it is thought that any cation may be harmful. The

number here is my own average of several data sources and assigning the problem all to sulphate concentrations²⁰⁻²³ with a linear plot of health effect versus concentration. There are many press reports in July 1977 that a recent National Academy of Science report has similar numbers.

Finklea²³ may have found a threshold for the effect, but even if true, it is below the present Boston and Washington concentrations. The risk calculated here is much more reliable than its attribution to any particular chemical or source of air pollution since SO₂, SO_x, NO_x and particulates all tend to vary together.

8, 9, 10, 11. For all cases involving radiation I refer to the risk calculations using the report of the National Academy of Sciences/National Research Council Committee on Biological Effects of Ionizing Radiation, relevant pages enclosed.

The four cases cited are for different sources of radiation. The first is from uranium and other radioactive ores in the brick. It is largely due to breathing the released radon gas, and can be, but isn't, reduced by at some expense of painting with an epoxy paint sealer.¹¹

The risk of a visit to Denver, Colorado is taken here as the increased cosmic ray risk at the increased altitude, although in Colorado there is also an increased radioactivity in the ground and in drinking water which I here neglect. The increased activity is taken from the report of the UN Subcommittee for Effects of Atomic Radiation and the relevant pages are attached.¹² It is relevant that half this increase is due to cosmic ray neutrons where there is less likely to be a threshold effect.

Finally, the average whole body diagnostic x-ray dose is taken from a Public Health Service report listed in BEIR.

Many ideas of carcinogenesis have come from studying radiation effects. The International Committee on Radiological Protection (ICRP)--set up in 1926--espoused the linear concept for prudent public policy decisions and proposed that no unnecessary risk be taken, and no risk unaccompanied by a corresponding benefit. This is very relevant to a discussion of vinyl chloride.

The idea of linearity of cancer incidence and dose has its origins in the behavior of a single cell. It seems much more likely to hold for radiation than for chemical insults. For chemical insults, there are metabolic processes and repair processes before the cell is reached. Nonetheless, animal experiments involving millions of mice suggest a non-linear (quadratic) term in the dose response curve at low dose rates. These data are reviewed and used in the reactor safety study²⁴ to show the risk is less than 1/5 of the linear curve at low dose rates. At a recent conference¹³ Sir Edward Pochin, summarizing, said:

"It is very important, therefore, that the evidence is strengthening for the presence of a quadratic term "(threshold effect)" in the dose-effect relationship and hence for the increasing likelihood that, for protection purposes, the purely linear extrapolation from the frequency of effects at high doses will maximize the estimate of risk at very low doses."

This may apply with more force to chemical effects, but may not apply to the second and third of my chosen radiation effects. Neutrons present in the cosmic rays and responsible for half the dose may not show this non-linearity and diagnostic x-rays taken

in one sudden exposure will not. Therefore, the comparison here shows that the "natural" or non-industrial radiation effects are more serious than vinyl chloride by a large factor.

12. I note that this figure uses EPA numbers in EPA calculations and is probably pessimistic, particularly since it uses a linear, non-threshold, theory. It is dominated by fugitive emissions from PVC plants, and EPA assume that any vinyl chloride not accounted for in the mass balance is a fugitive gaseous emission, whereas a proportion--maybe half--is probably solid. Also, it takes little or no account of the plume rise for ordinary emissions; the reducible emissions are at 50 feet ($h = 16$ m) with air at 150°F. If preliminary industry measurements are correct, the risk is one-fifth of that discussed here.

The Reduction by the Proposed Standard

... In one and only one respect the proposed standard is well presented; it is not to apply immediately to all plants, but is to be introduced on new plants only to avoid excessive perturbation of the industry. But there are many other problems.

The Federal Register of June 2, 1977 gives little data or references to data on how these emission standards can reduce concentrations and none at all about the effect on public health in spite of the claim that the whole purpose is to improve health (Federal Register 42, 106, page 28154, column 2: "the standards be set at the level which in the judgment of the administrator provides an ample margin of safety to protect the public health from such hazardous air pollutants.")

Accordingly we must rely on industry sources, memos of EPA staff,²⁵ and transcript of a meeting between EPA staff and industry. The reduction in emissions from 10 ppm to 5 ppm at a PVC plant will change less than 0.1 lb/hr or 3/10% of all emissions. The increased stripping of resins can only reduce by 6 lbs/hr or 20% of emissions and it is not always possible. Those from a vinyl chloride plant are already low.

Thus the effect of the proposed standard will be to reduce the hypothetical cancer hazard from 1 in 4 years by 20%, or to save 1 hypothetical cancer every 20 years at a maximum.

Fugitive emissions are not controlled by this standard. If they are not as great as EPA claims (and there is disagreement on this point, since at a PVC plant a lot of the losses (fugitive emissions) come out as solids and not as gas) or they can be

reduced, risk can be reduced. But that is nothing to do with the proposed new standard.

Cost of Proposed Standard

This is hard to identify since there is a certain nebulous nature to the standard. It appears

1. that the production of some resins will not be able to be done at some locations
2. plant expansions will be curtailed
3. where possible to manufacture PVC will be more expensive;

Industry reckon that the cost of a new plant with these extra requirements will be greater by 2.1 cents per pound of PVC. The total industry output is 6 billion lbs/year, so that if the whole industry were to convert, the cost will rise to \$120 million per year, which corresponds to a cost of \$4 billion for each hypothetical cancer case. It is true that the industry is only being asked to install new equipment for new plants. But it is also true that the reduction in vinyl chloride emissions will only arise as these plants come in. The ratio--over \$4 billion for each hypothetical cancer case--remains correct.

Indirect Risks

The list of risks above are direct- (first order) effects of the pollutant or action concerned. It is, however, clear that when the risk is small, as in this case, indirect (second order) risks may be more important. The number of these indirect risks is huge and I can only outline a procedure here.

There are ignored in the document for the proposed standard. This is clearly incorrect. There is a risk to life for every action involving capital expense. The classic, oft-quoted, case is that three people died building Brooklyn Bridge. One person died in building the Cambridge Electron Accelerator (\$12 million capital cost). At the present time, about one person dies in an accident for every \$30 million spent (average over industries). Thus to implement the proposed standard, industry would have to cause 4 deaths by accident every year to save one hypothetical cancer case every twenty years. The accident risk is well defined and not merely an upper limit. Moreover, these lives lost indirectly by accident will be in the prime of life whereas cancer cases arise later in life.

Thus the proposed standard will by this means alone be a cost to human life 80 times what it can possible save. It is therefore clear that the indirect risks introduced by the proposed standard could well outweigh the minute, hypothetical, reduction.

How Has the EPA Gotten Into This Administrative Mess?

The good intentions expressed in the Federal Register on May 25, 1976 and October 21, 1976 have not been followed. In the preamble to the proposed standard there are several statements that lead to confusion:

"...it has not been possible to determine if there is a threshold level of effects for vinyl chloride and it is not certain that such a threshold may be determined in the near future. In the absence of strong evidence to the contrary, then, the only level of vinyl chloride which would appear to be absolutely protective of health is zero, which may be achievable only by banning vinyl chloride emissions completely. That, in turn, would require closing the entire industry. As explained in the earlier rulemaking it is not clear that Congress would have intended this result, so instead EPA required the lowest level achievable using technological means."

The first sentence is correct but only correct in the sense that a strict threshold effect cannot be determined for anything. No human cancer has been attributed to vinyl chloride at levels below 100 parts per million (10,000 times those discussed here) and for animals at levels below 10 parts per million lifetime dose. Does this mean that there is a threshold at 10 ppm? Some might argue that there is. It is a matter of definition. Is there zero cancer incidence at 10 ppm because we haven't found any cancers at this level, or is there a finite (but small) incidence because we haven't proved it to be identically zero? If we calculate assuming no thresholds in any effect (from alcohol to vitamin C or peanut butter) we must also assume there is a small but finite risk. It is not consistent to assume that there is no threshold in cancer incidence from vinyl chloride exposure merely because it is intrinsically unprovable in a rigorous way and to allow for a threshold in other matters equally unprovable--such as

pollution of the air by everyone in a hearing room breathing out. Then, as so well stated in the May 25, 1976 Federal Register, there must be a comparison of risks and benefits. Such a comparison is not made in the preamble to the proposed standard.

There is a second cause for the present confusion. The statement that an aim is "to encourage technology" to reduce emissions is not addressing the issue. The logical procedure in protecting public health is to minimize the product of the concentration of the pollutant and the population density at that concentration (ECP in units of parts per billion x persons). This, on a linear theory, minimizes the adverse effect on public health. In any case no one can change the dose effect relationship whatever it is (except for possible synergistic effects). It is just as reasonable, and I contend that it is more reasonable, to provide incentives to reduce population density around a plant, to place the plant in a low population zone, or downwind.

If the population density is uniform we could minimize the concentration by reducing emissions. Since emissions come from several places, including fugitive emissions, tank car accidents, etc., the best way of reducing emissions may be complex. In such a task, it is clear that industry, given the incentive, can better decide how to reduce emissions than the EPA. If the regulations are set to minimize the product of concentration and population density the aim is well achieved.

The distinction between emission controls and concentration controls was made in the legislative discussion of the Clean Air

Act. In particular, Senator Muskie made a very clear distinction in the U.S. Senate.

When concentrations can be measured, and assigned to a particular source, control of concentrations is preferred. In control of sulphur emissions, pollution from many sources overlaps and it is impossible, merely by measuring a concentration, to identify the polluter and take remedial action. Therefore emission controls are necessary. For radiation from nuclear power plants, concentrations are not easily separable from the large natural background, and emission controls are again used, but they are related by diffusion calculations to concentrations.

In the case of vinyl chloride concentrations have been, and can be, measured up to the site boundary and even beyond where sites are available, and diffusion calculations used beyond that. (The variation with distance is roughly vs. $\frac{1}{x U_x \sigma_z} > AV$ or $1/r^{1.8}$.) If not actually used for regulation, this procedure must be used in discussion of the effects of the regulation.

It might be possible to provide an incentive for an individual plant operator by demanding that the quantity (LCP in parts per billion x persons) be reduced if it can be done for a reasonable price, perhaps 50 cents per unit. It should be open to each plant operator to decide the best way to reduce this. This has been suggested in the radiation context by the Nuclear Regulatory Commission²⁶ who asked that power plant operators reduce radiation dose if it can be done for less than \$1,000/man rem, corresponding

roughly to \$10,000,000 per cancer projected on a linear theory.

I suggested²⁷ that a charge be made of this amount to simplify regulation.

This (or a similar) incentive procedure would encourage industry to:

- reduce emissions--including fugitive emissions as much as they can
- place plants in low population zones
- operate plants well

The proposed standard is too indirectly related to the problem (protection of public health) to give any incentive to industry.

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