

A matter of major concern to the industry is the quality of the conclusions reached and presented in the support documents which are subsequently used to justify the need for a standard, and the unwarranted and unsubstantiated inferences drawn from this inaccurate and misleading data base. The information alleged as evidence on adverse health effects and the existing ambient air levels and extent of human exposure have been grossly overstated. As the result, the Preamble to the proposed standard contains many erroneous statements, unjustified conclusions and incorporates obsolete and misleading data. Much of the justification for the need of a standard is based on emission data supplied by industry or gathered by the Agency. The requests to industry for information on emissions were made in the Spring of 1974, when little was known on how to determine emissions, and when full attention was being given to OSHA problems. The data supplied were a combination of estimates and rapidly measured rates, often on a spot basis. The interpretation of the questions varied greatly from company to company, and thus the replies were inconsistent. Industry believed that the unaccounted for losses were divided between vinyl chloride gas losses and polyvinyl chloride solid losses, and so informed the Agency. But in its treatment of the data all such losses were assumed to be vinyl chloride gas. The preamble speaks lightly of the results of the changes made to attempt to comply with the OSHA requirements; these have had a substantial effect on emissions while reducing the vinyl chloride in the

workplace and in resins by one to two orders of magnitude.

Even more blatant is the use of the emission data gathered by the Agency. There has been repeated reference in all of the documents to "some occasional peak concentrations as high as 33 ppm" when the truth is that only one such measurement was made; the next highest concentration found was 3 ppm; and no other figure within an order of magnitude of this has been found despite thousands of additional tests. This tendency to exaggerate and bend facts to fit the wishes of the writer permeates the preface, the Standard Support Document, the Star Document, and the Risk Assessment Document.

As an example the preamble states that the results of the extensive environmental test program in three anions "conducted --from November 1974 to June 1975 are not discussed in detail because they are still being analyzed." The Star Document dated June 1975 contains a brief summary of a part of this test program, and these data show that the concentrations found at that time are less than those predicted to prevail after the standard is enforced. The arithmetic average of 1903 24-hour measurements was 5ppb, and no sample taken 1,000m or more from the source was about 0.1 ppm.

The preface and the supporting document continue to refer to non-occupational cases of angiosarcoma even though the CDC angiosarcoma case test has now dropped all but the occupational cases.

The "reasonable extrapolations" and assumptions made in one section became fact in another section and then are used to demonstrate the need for a standard, with no admission made for the tenuous line of reasoning which led to the judgment. The tone is that of a decision looking for support, rather than a demonstrated progression of facts leading to a decision.

These documents contain so many errors of fact that their credibility is damaged. Some examples of those found so far are:

(1) Incorrect conversion factor was used to convert from liters to gallons throughout the documents;

(2) An error was made in calculating the residual vinyl chloride vapor in a reactor leading to a standard only 50 percent of the proper value;

(3) The very interesting statement is made that operator error is preventable. This is unenforceable, as well as being unconstitutional to enforce penalties against one person for the actions of another, but more important, no way has been found yet to avoid human error, as the two examples above show;

(4) The statement is made that the decision by the Agency to promulgate a standard for asbestos requiring work practices has not been tested in the courts, when in fact it has been tested in six cases in three courts, and five of these found against the Agency;

(5) Efforts to determine the source of the statement that occupational responses to vinyl chloride cause "tumors in many different sites" looks to the Tabershaw-Cooper report presented by Industry at the OSHA hearing, in which the authors specified that this finding is not statistically significant. These are several parallel studies which show no such suggestion. This is exemplary of many other statements which are not supportable upon examination. For example, vinyl chloride is not a mutagen for reproductive cells, and thus cannot cause defects in the offspring of exposed persons (this also has been shown by epidemiological studies) and PVC tests have been shown not to cause pneumonocosis in test animals;

(6) The concern that there will be an increase in water use or in its vinyl chloride content in the effluent is not supported by internal evidence in the Support Document, or by proper consideration of the proposed control methods;

(7) Similarly, the use of ventilation to control worker exposure per se, does not increase emissions. If it has any effect, it would be to increase dispersion not reduce any potential effect.

It is very disappointing to have such a critical document so poorly done and resting on such a flimsy basis. The regulatory agencies must be impartial and dispassionate in their decision making, as well as technically correct. Political pressure and emotion have no place in such proceedings.