

October 11, 1977

Attached is a marked copy of OSHA's proposed rule on occupational cancer which appeared in the Federal Register of October 4, 1977. While the notice contains no surprises and in fact represents a partial retreat from the position advanced by OSHA in earlier drafts it nevertheless should be studied carefully and some of its implications viewed with serious concern. It seems appropriate to group these concerns, based on initial reading, into those relating to legal duties and system administration and to separately consider scientific objections which might be raised as follows:

A. Legal and Administrative considerations.

1. The thrust of the regulation is to adopt three pattern standards, an Emergency Temporary Standard, and one each for Category I (proved) and Category II (suspected) carcinogens. OSHA anticipates that when a compound is identified as belonging to a particular category the appropriate pattern standard will be promulgated verbatim. By promulgating these pattern standards in this proceeding OSHA hopes to preclude future challenges to the classification system, and to the standard itself when it is applied, and thus to leave open for challenge, or for the taking of evidence at a 6(b) proceeding, only the question of whether a compound was properly categorized. This approach would also preclude, OSHA hopes, challenges to such policy matters as whether, for a particular chemical labeled as carcinogenic, the exposure levels should be set at other than the lowest feasible limit.

2. The document repeatedly asserts as a basis for pattern standards that a hierarchy of control be employed with primary emphasis on "feasible engineering changes" and minimum reliance on personnel protective equipment. As in the past OSHA has not defined its terms; consequently, it is left to the employer to demonstrate lack of feasibility on a case by case basis.
3. The pattern standards prescribe new duties on the part of employers to assure that personnel wash hands and face before smoking or eating and take showers at the end of the work day, and perform certain other acts. These have either not been mentioned in previous standards, or have been written to describe the duties of the employee.

Heretofore, our obligation has been to make such facilities available and to instruct employees in their proper use, not to literally see to it that the employee complies in each and every instance.

4. The pattern standard includes the concept that occupational exposure to certain materials may be prohibited if the Secretary determines that suitable substitutes exist. Nowhere in the proposal is there a discussion as to the basis on which the Secretary will make such a determination, or the procedures for contest or rebuttal.
5. Though it may be an error in draftsmanship, both the preamble and pattern standards can certainly be read to require on-site laundry services. This situation, at least, requires clarification since on-site laundries are the exception rather than the rule.
6. The proposal calls for labeling with the notation "carcinogenic risk" on containers leaving the premises, if the substance is so classified. Thus the Secretary would appear to be in conflict with the labeling authority of other agencies, who might very well have differing standards of proof of carcinogenicity. The effect on customer acceptance of products, or on third-party liabilities, needs to be carefully considered.
7. The proposal, for the first time allows the individual employee access to his own medical record for purposes of inspection and copying. In previous standards and proposals the employee's right

has been limited to an authorizing release of said information to a designated physician.

B. Technical and Scientific considerations.

Although the present draft represents in some respects a softening of OSHA's earlier positions, the classification scheme and basis for classification in reality make it easy; indeed it almost compels the Secretary to declare that a substance represent a carcinogenic risk in the work place even in situations which are not recognized by FDA except with respect to intentional food additives under the Delaney amendment. The recitation mentions and then almost contemptuously dismisses some of the long standing and recognized problems involved in interpreting rodent studies. It also establishes as primary criteria, certain interpretive rules which heretofore have been considered supportive in nature. Some scientific considerations are enumerated below:

1. In the evaluation of animal test results benign tumors (so described without further definition; does it include warts or fatty cysts?) are to be given equal weight to malignant tumors.
2. A malignant tumor is defined as one that invades, metastasizes, and or has a capacity for doing so, thus threatening the life of the host (emphasis supplied, paraphrased in part). OSHA thus adopts the position espoused by EPA, which in turn is based primarily on Dr. Reuber's assertions that tumors that are morphologically similar to non-invasive cancer should be classified as malignant. This viewpoint is vigorously contested by other eminent pathologists, among them Drs. Newburne and Butler. It will be recalled that this diagnostic criterion was the basis for EPA's attempted classification of Kepone as a carcinogen, and was the basis for FDA's refusal to concur with EPA on this issue.
3. It is asserted that a decrease in the latency period for cancer in test animals would be a basis for classification as a carcinogen, even if the frequency of such tumors was no different than from the control population. This flies in the face of repeated observations that stress factors including those related to unnatural diets or toxic stress are capable of shortening the induction time in sensitive strains of animals.

4. OSHA asserts that injection and gavage are appropriate means of administration in establishing industrial hazards even though neither route of administration is at all likely in the occupational setting. There is a hint that the Secretary's decision might be rebutted in a 6(b) proceeding, without any clear definition as to what the appropriate grounds for rebuttal would be.
5. It is asserted that a single positive study, "when properly conducted", takes precedence over all previous negative studies. This assertion is dogmatic rather than scientific, since it is possible in any given study for confounding factors to be introduced which lead to false positive findings. This is especially true of epidemiology studies, in which a multiplicity of potential agents and off the job environmental factors are the rule and not the exception.
6. OSHA continues to maintain "no threshold", "one-hit" concepts on the argument that they have not been proven to be untrue. Our own study on carbon tetrachloride, and Dr. Jandl's study on benzene both very clearly indicate that both in man and test animals a series of biological events must first transpire before a cancerous condition develops. The work recently completed by Dow on vinyl chloride yields similar conclusions.

I have been informed that ORC as well as some other trade associations intend to submit a request for a delayed hearing date to allow adequate time for preparation of hearing testimony. In addition, ORC plans to convene two separate task groups--one to address the legal issues and the other composed of physicians and other health specialists to address the scientific issues. Their initial evaluation is consistent with our first reaction, namely, that the proposal as written sets no real bounds on the discretion of the Secretary and provides him with no insulation against political pressures from public interest groups. It also seriously restricts the opportunity for employers affected by such standards to successfully rebut a decision of the Secretary no matter how arbitrary or politically inspired it might be.

We also need to examine the effects of decisions by the Secretary to characterize a material as a carcinogen on our Workmen's Compensation exposures, our product liability exposures, and our relations with EPA under the Toxic Substances Control

Act. I believe we should prepare now to vigorously support efforts on the part of trade associations and/or ad hoc groups in devising an industry position consistent with the intent of the statute which is more acceptable both technically and legally than the OSHA proposal.

I also believe that Divisional Occupational Health managers should immediately inventory their processes so that we can identify the areas of greatest vulnerability within Allied thus gaining a sounder appraisal of the overall impact on the lines of business. Divisional Health managers should also assume the personal obligation of informing their divisional management as to the products or product lines that would be jeopardized by this development.