



DOW CHEMICAL U.S.A.

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February 3, 1978 RECEIVED
FEB 8 1978
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Dear Harry:

Among the many challenges facing the chemical industry and its customers in 1978 is a new set of generic carcinogen procedures proposed by the Occupational Safety and Health Administration (OSHA).

The enclosed position paper pretty well spells out the issues at hand. We are passing it along to you for two reasons: 1) we want you to be informed about this issue; and 2) we hope you will actively involve your company in helping OSHA to arrive at more workable and rational solutions to the problem of carcinogens in the U.S. workplace.

This is an issue filled with emotion, misinformation and, unfortunately, the potential for the chemical industry to suffer unnecessarily if we do not get involved now.

We encourage you to bring this to the attention of your management and employees. If we can help in any way, we stand ready to do so.

Thank you for your interest.

Sincerely,

J. H. Morgan
Account Manager
Organic Chemicals

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FEB - 9 1978
J. C. NOVAK

AN OPERATING UNIT OF THE DOW CHEMICAL COMPANY

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Legislative Update

A summary of public issues or pending legislation of interest to the Organic Chemicals Department and its employees.

#4, January 19, 1978

The Occupational Safety and Health Administration (OSHA) has published proposed regulations for the identification, classification and regulation of toxic substances posing a potential risk of occupational exposure to cancer-causing agents.

The proposal is so far-reaching and potentially counterproductive that some observers consider the OSHA plan as the single most serious threat ever laid at the door of the chemical industry.

OSHA was formed in 1970 to devise and enforce rules related to worker safety. During a lackluster first seven years, OSHA gained notoriety for its preoccupation with the height of fire extinguishers and the proper methods of anchoring a step ladder. Now the agency finds itself under substantial Congressional criticism because of its failure to make meaningful progress. This has become especially sensitive as OSHA has singled out the industrial carcinogen issue for its highest priority in 1978.

Abandoning its previous substance-by-substance approach to regulating carcinogens, which has resulted in completed carcinogen rulemakings on only some 16 or 17 products to date, OSHA now proposes a vehicle and framework for future rulemakings which will enable it to move more expeditiously against suspect carcinogens. The regulations set forth criteria for determining whether a substance is a carcinogen, establish a classification scheme for such carcinogens and require certain regulatory consequences to automatically flow from the classifications. Once adopted the proposed regulation will undoubtedly lead to a flurry of regulatory activity with major emphasis on the National Institute for Occupational Safety and Health (NIOSH) list of some 2,400 "suspect carcinogens."

The regulations establish four categories for toxic chemicals which are potentially carcinogenic:

- Category I, confirmed carcinogens
- Category II, suspect carcinogens
- Category III, substances for which there is insufficient information to reach a conclusion on carcinogenicity
- Category IV substances with carcinogenic potential but not found in the American workplace.

There is no category for those substances found to be non-carcinogenic (cleared" or "acquitted" list.)

Upon receipt of information on a potentially carcinogenic substance from any interested person, or upon its own initiative, OSHA must publish within 30 days a notice of receipt in the Federal Register and provide an opportunity for public comment thereon. Within 90 days of publication, OSHA must classify the substance.

CATEGORY I -- CONFIRMED CARCINOGENS

The regulations create a presumption that a toxic material is a Category I substance if it causes an increased incidence of tumors, or decreases the latency period between exposure and onset in humans, or two mammalian species, or a single mammalian species if the test is replicated or if supported by short-term in vitro tests. OSHA may also create a Category I presumption if it determines there is any other evidence which it believes is sufficient.

The presumption may be rebutted if OSHA determines that the animal carcinogen data are the result of physical rather than chemical induction, that the route of exposure is "grossly" inappropriate to occupational exposure, that the data relied upon fit the

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Category II or III criteria, or for some other reason the animal data are not scientifically relevant.

For Category I substances, an Emergency Temporary Standard (ETS) must immediately be issued pending development of a permanent standard. The permanent standard will require exposure to be reduced to the "lowest level feasible" or, if OSHA determines there to be a "suitable" substitute, the substance may, in effect, be banned.

CATEGORY II -- SUSPECT CARCINOGENS

If OSHA determines that a Category I presumption should be rebutted because the evidence is only "suggestive" of carcinogenicity, i.e., scientific concern is raised but the evidence is not persuasive or statistically significant, OSHA must classify the substance Category II.

In addition, a Category II presumption is raised if the substance, without regard generally to dose or route of exposure, causes an increased incidence of tumors, benign or malignant, or decreases the latency period in a single experiment in a single mammalian species of if there is other evidence to convince OSHA that the substance should be in Category II.

CATEGORY III -- POSSIBLE CARCINOGENS

Any substance which is not classified Category I or II is to be classified by OSHA as Category III. Category III is intended to include those substances for which there are insufficient data to make a finding of carcinogenicity. This includes those substances for which there are no data to suggest carcinogenicity.

OSHA must transmit to other federal agencies its findings with respect to a Category III determination along with a request that such agencies determine whether they have additional information which might bear on reclassification of the substance.

CATEGORY IV -- FOREIGN SUBSTANCES

If OSHA determines that a substance would be a potential occupational carcinogen but for the fact that it is not found in an American workplace, it must publish appropriate notices in the Federal Register and, upon receipt of information that the substance is, has been, or will be in the American workplace, initiate standard-setting procedures.

THE IMPLICATIONS

Perhaps a normal reaction to the OSHA proposal is that "it won't be as bad as it sounds". Unfortunately the OSHA program has implications of major importance to the chemical industry, and the potential harm is greatest among the chemical industry's small and medium sized companies. If the OSHA proposals are adopted unchanged, many companies in the 50-500 million dollar/year sales range will simply be forced to drop products because they lack the resources to defend the materials with appropriate and needed scientific data. There is no exemption for small companies, many of whom are good Dow customers.

In addition, the regulations represent OSHA's resolution of complex scientific and legal issues which, once resolved in this rulemaking, will not be open to further question in subsequent rulemakings on individual carcinogens. Thus, if OSHA decides that there is no safe threshold for a carcinogen, that principle is established and may not be challenged in subsequent rulemakings on individual substances. The criteria, classification scheme, and regulatory consequences in this proposal will apply to all subsequent OSHA rulemakings on suspect carcinogens. Indeed, given recent public pronouncements on the need for cooperation between federal agencies on toxic substances, the OSHA proposal may serve as the basis for a national approach to regulating suspect carcinogens for all federal agencies.

The OSHA proposal is presently being scrutinized by an abundance of environmentalists, academicians, consumerists and bureaucrats whose well-meaning (and often conflicting) approaches to regulation often fail to take into account common sense, economic realities and the misinformation that abounds about cancer.

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Ralph L. Harding Jr., president of The Society of the Plastics Industry, Inc., recently wrote to SPI members about one of his encounters with the pro-OSHA forces:

"On the Friday afternoon preceding OSHA's Monday press conference, SPI's Washington public relations man received a call from a reporter who asked for our industry's reaction for the story he was already writing. Our answer: 'OSHA won't release a copy to us until Monday.' The reporter said he'd had a copy for several days. Upon checking we learned that, as usual, copies had been given to several reporters and, apparently, to several environmental groups.

"When confronted with the evidence, OSHA's press office reluctantly gave us a copy of the proposal -- the first and only one known to have been given out to anyone from industry prior to the press conference.

"This has been the pattern all too often. Government officials, with very little experience in -- and less understanding of -- the industries to be regulated, draft regulations after little or no consultation with the industries involved. Outside advisors are more likely to be environmentalists or academicians whose zeal is unquestioned but whose knowledge of industry is limited. Then, in order to achieve favorable publicity, the officials call in their friends in the press for an advance briefing. No wonder industry often looks bad in these situations. How do you comment on a 278-page proposal if you haven't even seen it?"

THE ISSUES

A leading issue in this controversy is whether or not the United States is, in fact, in the midst of a cancer epidemic. Anyone would agree that a single death from cancer is unfortunate, but few would advocate an overreaction when modern medicine knows so little about the causes of the disease.

Dr. Hugh Farber, a Dow environmental affairs authority, has written:

"Let's explore the emerging national cancer policy and the basis for it. Several federal officials have described it to me personally and it has been manifested in many of their public comments and proposed regulatory programs. Basically the policy states, 'any chemical found to cause cancer in any animal species under any conditions of exposure route or dose will be considered a human carcinogen and banned or restricted to the lowest feasible exposures using the best available technology'.

"This action appears to be directed toward industrial chemicals only, not the natural chemical carcinogens, such as cigarettes, eggs (found to cause cancer in mice) and saliva (contains a precursor to nitrosamines that form in our stomachs and are potent carcinogens in test animals.)

"The basis for the unwarranted over-emphasis on industrial chemicals is an often-quoted and misinterpreted statement that 80 to 90 percent of human cancer is due to "environmental effects" over which we have some control.

"What is not explained is that probably less than one to two percent -- and perhaps considerably less -- of human cancer is due to industrial chemicals, and that 80 to 90 percent is due to life style effects such as smoking, diet, sunlight and so forth.

"For example, the "official" contention that chemicals are the principal causes of cancer is refuted by both the American Cancer Society and the National Cancer Institute. These two groups, hardly advocates for industry, cite "life-style" factors such as cigarette smoking, improper diet, and alcohol consumption. In their opinion, no more than one in twenty cancer cases is caused by the environment or workplace."

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Of course, the political realities of this issue are that anyone opposing the OSHA plan will be branded as more interested in profits than in people's lives, etc. That oversimplifies a complex set of issues fueled by the OSHA proposal. Unfortunately, there is no unanimity even in the scientific community about the best way to protect the American worker from carcinogens.

Based on the best available data, however, the chemical industry has established a scientific position on the OSHA proposal. Among its most important points are the following:

- A) Although there is scientific dispute as to whether there are thresholds or "no effect" levels for carcinogens, there is a strong body of scientific opinion that there are thresholds. Further, there is evidence of a no effect level for many substances. Modern toxicology is based on experimental evidence demonstrating that toxic substances follow a dose-response relationship and that there is some level below which no response occurs.
- B) Attention should be focused on socially acceptable risks rather than only debating what is a "no effect". Absolute guarantees of safety are an impossibility. Careful assessment of the benefits is also necessary, since there are many valuable substances in everyday use which have produced tumors in animals but not in humans, e.g. egg yolks, vitamin D and calcium. Among the criteria to be suggested for evaluating risk and benefit will be the risk to the worker, the impact on employment, the economy and on consumers, the protection of life, the increase in knowledge and the reduction in waste.
- C) OSHA should exempt some mixtures containing carcinogenic substances from the scope of the regulation. Criteria to be applied in subsequent rule-makings on individual substances will be suggested for establishing the point below which mixtures containing carcinogenic substances should be exempted. Examples can be cited of the potentially disruptive impact of the failure to provide for such an exemption (e.g., many aerospace propellants and lubes contain trace amounts of carcinogenic substances which cannot be eliminated). OSHA has previously recognized the need for an exemption for mixtures containing carcinogens in its standards for the 17 carcinogens. This is a precedent on which OSHA should draw.
- D) OSHA's failure to distinguish between laboratory and non-laboratory workplaces is unreasonable. OSHA's proposal imposes many burdensome and unnecessary requirements on laboratory workplaces and may, indeed, have the unintended effect of impeding important research, including that being done on cancer.
- E) The inflexible procedures and automatic regulatory responses embodied in the OSHA proposal may result in irrational and unscientific rulemakings because the procedures will, in effect, take out of OSHA's hands the ability to rationally set its own regulatory priorities. For example, under the OSHA proposal, OSHA could, upon the filing of a "citizen petition", be required to give equal regulatory priority to such seemingly unequal problems as selenium and nickel (essential body nutrients), peanuts, asphalt and carbon tetrachloride.
- F) The permanent standard provides that if OSHA determines there to be a less hazardous "suitable" substitute, it can require no exposure to the suspect carcinogen. This may, in effect, amount to a ban for many substances. The term "suitable" is nowhere defined by OSHA. The permanent standard also mandates a preference for engineering and work practice controls over less costly personal protective controls (e.g., respirators) as methods for complying with the exposure limits. Engineering and work practice controls must be utilized first even if they do not bring exposures within the required limits. Although the term "feasible" is nowhere defined in the regulations, there is little reason to believe that OSHA intends the term to include economic as well as technical considerations.

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CHEMICAL INDUSTRY OPTIONS

It is quite apparent that the industry has a number of options. One is to do nothing about the OSHA proposal, another is to put forth a token effort (which is no better than the first).

The only acceptable option is to dive in head-first and participate in the rule-making process with OSHA. It is important to keep the cancer/OSHA discussion in the proper perspective. Despite some recent press accounts, the chemical industry is not "at war" with OSHA, nor is it "gearing up for battle" over cancer standards.

As Ralph Harding recently wrote:

"Nobody in chemicals is in favor of being soft on cancer. We want solutions just as much as anybody else. And we must keep on saying just that, loud and long and clear..We have to be prepared to go 75% of the way -- or more -- in proposing regulations and procedures which will work. All the industries involved have much of the information and the expertise needed, provided governmental agencies will join with us in some kind of cooperative efforts."

It is entirely possible-- even probable -- that industry working closely with OSHA could come up with a mutually acceptable strategy to protect America's workers from the perils of cancer. However, without the information, expertise, dedication and resources of the chemical companies being brought to bear, the only probable result will be "environmental overkill" which will mean lost jobs, plant shut-downs, unnecessary and frivolous overregulation and, ultimately a government-run chemical industry.

The choice to the chemical industry and its customers is fairly basic -- act or be acted upon.

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(Note: A subsequent mailing of "Legislative Update" will deal with specific alternatives to parts of the OSHA proposal).

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