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The attached is NOT a TSCA matter. It is related, however, in that it deals with a proposed rule-making action by OSHA to regulate carcinogens in the workplace. A long and detailed proposal issued in the Federal Register on October 3. The attached summary will give an overview of OSHA's intended action.

We can expect vigorous reaction to this proposal. Note also that carcinogens and their regulation are not confined to EPA under TSCA.

C. E. Blades

CEB:sk
Encl.

Carcinogens

GENERIC POLICY FOR CANCER AGENTS ISSUED BY OSHA AS PROPOSED RULEMAKING

With little substantive change from an earlier draft, a "generic" policy for regulating carcinogens was announced as a proposed rulemaking by the Occupational Safety and Health Administration October 3.

The proposal provides for the identification, classification, and regulation of cancer-causing substances in the workplace and, according to OSHA, will facilitate the agency's rulemaking by treating carcinogens as a class rather than substance by substance.

Public hearings were scheduled for March 14, 1978, a deadline for written comments was set for December 8, and a deadline for notifying OSHA of intention to appear at the hearings was set for January 9, 1978.

The proposed new 29 CFR 1990 contains three model standards.

Adopted Within a Year

An OSHA spokesman said there were no major changes from the draft regulations first described by the agency Janaury 24. However, a new category for foreign toxic substances not found in U.S. workplaces was added, and some arguments justifying OSHA's system of classifying substances were modified, the spokesman said.

Assistant Secretary of Labor Eula Bingham said at a news conference October 3 she hoped the new rule would be adopted in less than a year. She added that if there were legal challenges, it could take another one to two years.

The OSHA administrator told reporters that about two years would be needed by the agency to "catch up" in applying the new policy to the 2,000 suspected occupational carcinogens.

Categories of Carcinogens

At the heart of the proposal is the classification of a toxic substance into one of several categories based on the conclusiveness of data on its carcinogenicity. OSHA would classify as Category I a substance which was shown scientifically to have caused cancer in humans, or in two mammalian test species such as mice or rats, or in one species if the results had been replicated.

Category II substances would be those which were reported to be carcinogens but for which the evidence was only "suggestive," such as positive results of carcinogenicity in a single species which had not yet been replicated.

Category III would be reserved for all other toxic substances which deserve to be studied further, and Category IV, the new category, for foreign carcinogens which would be regulated if they were ever introduced into American workplaces.

OSHA Deputy Director of Health Standards Grover Wrenn, who appeared at the news conference with Bingham and Labor Secretary Ray Marshall, said examples of Category I substances would be acrylonitrile, kepone, dibromochloropropane, arsenic, benzene, beryllium, asbestos, and vinyl chloride.

Certain chlorinated hydrocarbon solvents, including perchloroethylene and trichloroethylene, might be considered Category II carcinogens, he said.

Bingham stressed that the present proposal would not interfere with any current rulemaking OSHA is conducting on particular carcinogens, nor would the agency "tread water" with regard to any new substances while the policy is in the process of being adopted.

Wrenn estimated that of the 2,000 suspected carcinogens identified by the National Institute for Occupational Safety and Health, about 100 would fall into Category I, 300 to 400 into Category II, and the remaining number into Category III of the OSHA scheme.

Lowest Feasible Level

Prescribed regulatory actions would be triggered by the categorization, including immediate issuance of an emergency rule for substances classified in Category I and the commencement of a permanent rule. Models for both standards, as well as a model standard for Category II substances, are contained in the proposed rulemaking.

Wrenn said the policy decisions which went into the present proposal, particularly those affecting Category I substances, recently had "helped to resolve questions about when it was appropriate for OSHA to issue an emergency temporary standard." He cited the issuance of an ETS for DBCP September 9.

Exposure to a Category I substance, in both the ETS and permanent rules, would have to be reduced to the lowest level feasible, which Bingham explained referred to "engineering feasibility that's actually available."

For Category II substances worker exposure would be reduced to a "level low enough to prevent acute or chronic toxic effects," Bingham said.

The OSHA director expressed the hope the new rulemaking approach would end the "exhaustive" scientific and medical debate over the extent "available data could be considered as evidence of cancer hazard in man." She called it imprudent to debate those questions each time a new substance is the subject of proposed regulation.

Only a limited number of major issues would be open for debate in rulemaking of specific substances if the proposal is adopted, the OSHA announcement said. Examples would be the selection of an appropriate exposure limit and determination whether OSHA had appropriately classified a substance.

Praise from Marshall

Bingham praised the OSHA staff for its work in preparing the proposal. Marshall said the announcement marked "another step in trying to redirect OSHA and concentrate on the important problems."

The Society of the Plastics Industry, Inc., criticized the proposal as a "quick fix method." Society President Ralph L. Harding, Jr., said the agency was placing undue reliance on limited animal tests to demonstrate carcinogenesis.

"OSHA assumes that there is no safe threshold for potential carcinogens — a premise with which we totally disagree," Harding asserted. The society urged establishment of a medical review board to examine animal test data before any enforcement action is taken.

Comments Asked

OSHA raised 11 issues concerning the proposed regulation and invited public comment. Submissions should be sent to the OSHA Docket Officer, Docket H-090, Room S6212, Department of Labor, Third St. and Constitution Ave., N.W., Washington, D.C. 20210, postmarked no later than December 8.

Notice of requests to appear at the public hearing, which is scheduled to begin at 9:30 a.m. March 14, 1978, in the Department of Labor auditorium, should be sent to the OSHA Division of Consumer Affairs, Room N3633, Department of Labor, Third St. and Constitution Ave., N.W., Washington, D.C. 20210, postmarked no later than January 9, 1978.

The OSHA notice of proposed rulemaking on occupational carcinogens appears in Part II of this Current Report.

BNA

CHEMICAL REGULATION REPORTER

A weekly review of activity affecting chemical users and manufacturers

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Part II

OSHA SUMMARY SHEET: IDENTIFICATION, CLASSIFICATION, AND REGULATION OF OCCUPATIONAL CARCINOGENS

I. Background

Heart disease and cancer — the fourth and eighth leading causes of death, respectively, in 1900 — now lead the nation's list of killers. In 1900, these two diseases were responsible for only 12 percent of deaths; today, they account for more than one-half of U.S. mortality. Annual death rates from cancer rose from 64 percent per 100,000 population in 1900 to 168 in 1970.

Cancer kills a reported 370,000 U.S. citizens per year — over 1,000 persons per day. Over one million are under treatment for the disease, and each year 900,000 new cases are diagnosed. Of these, about one-third are skin cancers — usually treatable, and with no significant impact on life expectancy; the other 600,000, however, are serious and are potentially fatal. The American Cancer Society now estimates that 25 percent of the United States population will ultimately develop some form of cancer.

The economic and social impacts of cancer in the United States are massive and hard to estimate. An estimated $1.8 billion per year is spent solely for hospital care of cancer patients. To these direct expenditures must be added indirect costs, such as the estimated 1.8 million work years lost to the national economy and to family income by unemployed or underemployed cancer victims. One estimate cited by the General Accounting Office of the United States Congress is that the annual cost of cancer is $15 billion, of which $3-5 billion is attributable to direct care and treatment and the remainder attributed to the loss of earning power and productivity.

Most prominent of the causes of cancer are believed to be genetic and environmental factors. Today, there is growing recognition that 60 to 90 percent of all cancer may be related to environmental factors. Cancer rates vary significantly through the United States. In general, however, states with high rates are the industrial states. It has long been known that densely populated and industrialized areas have higher death rates from many causes than nearby rural areas.

The extent to which the observed incidence and rise in incidence of cancer are attributable to manmade chemicals cannot be estimated with any precision, however, but the tragic effects are. Recognition by cancer specialists that the majority of human cancers are influenced by environmental factors is of extraordinary significance to OSHA — *it means that most human occupational cancers may be preventable* if the causative agents can be identified and human exposure to them eliminated or minimized.

II. The Regulatory Dilemma

Any decision to regulate carcinogens is obviously complex. And with the increasing number of environmental chemicals, the number of carcinogens also increase, together with the size and complexity of OSHA's rulemakings. In its five year history, OSHA has concluded only 4 rulemaking proceedings concerning carcinogens, namely the asbestos standard in 1972, the carcinogen standard in January 1974 (regulating 14 substances), the vinyl chloride standard in October 1974 and the coke oven emissions standard in October 1976. At the outset OSHA notes that 1,500 agents have been identified by the National Institute for Occupational Safety and Health ("NIOSH") as being "suspect carcinogens." In other words, NIOSH has found some scientific evidence, admittedly of varying quality, identifying those substances as having potential carcinogenic activity in humans or in laboratory test animals. Yet, OSHA has completed regulatory activity for only 17 of those substances. Thus, we believe it is necessary to devise a system for regulatory action which will assure a consistency of approach in regulating carcinogens, a speedy approach and an approach which will limit the size of OSHA's rulemakings which have grown far beyond the ability of OSHA's staff to handle by the present case-by-case approach.