4-98

*For Mr. Harding
3 pages

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210

Office of the Assistant Secretary

NOV 22 1977

Robert C. Barnard, Esq.
Cleary, Gottlieb, Steen
& Hamilton
1250 Connecticut Avenue, N.W.
Washington, D. C. 20036

Dear Mr. Barnard:

In response to your letter of November 1, 1977, both Secretary Marshall and I have carefully considered the requests made by your clients and by other interested persons for the release of certain information and for additional time to respond to the notice of proposed rulemaking published on October 4, 1977.

Specifically, you have requested that "(1) OSHA make available an up-to-date list of substances targeted for Category I or Category II classification and that OSHA extend for a period of 75 days, from the date such list is made available, the date for submission of written comments and notice to appear at the hearing and the date for submission of written testimony; (2) in the event OSHA is unable to provide such a list, the above mentioned dates be extended for a minimum of 90 days; and (3) OSHA allow a period of 45 days after the statements of OSHA's witnesses are filed for additional comment and proffer of testimony, and that the commencement of the public hearing on the proposed regulation be deferred accordingly."

As to your first request, OSHA does not have a list of substances "targeted for Category I or Category II classification." The agency, however, has contracted for an assessment of the probable categorization of substances listed on the NIOSH List of Suspect Carcinogens. When such information is received by the agency, we will, of course, make it available to you and any other interested persons. More fundamentally, however, the proposal is aimed at establishing minimum protective requirements which will ultimately protect American workers from the hazard of exposure to potential carcinogens in general, and no specific number of toxic substances are planned for regulation.

You also state that: "identification of these substances is essential in order to be able to evaluate the far reaching environmental and economic impact and the feasibility of the proposal." The proposal provides that environmental and economic impact and feasibility are to be determined, where required and where applicable, in the individual rulemakings conducted pursuant to the proposed set of regulations. This would provide your clients with opportunity, at that stage, to

AP00048068

fully participate in the hearing of those issues. In addition OSHA has prepared, to the extent possible, and included in the October 4 proposal, a draft programmatic environmental impact assessment. We invite your comments concerning this document.

As to your requests for extensions of time, your clients had signiffcant opportunity to review the agency's policies incorporated in the October 4 proposal and supporting data, before the actual publication date of October 4, 1977. An earlier but little changed draft of the proposed regulations has been made public since January 1977 and was the subject of public meetings of the National Advisory Committee on Safety and Health which were duly announced in the Federal Register. Also, the supporting data has long been available to the public. The NIOSH list, in major part, was first published in 1971 and most, if not all, of the references exist in the public domain and in the literature in this country. Because, however, of the fact that we wish to encourage persons to submit relevant information and views and because we recognize the importance of the issues involved, OSHA intends to extend the time requirements by notice to be published in the Federal Register, as follows:

1. January 30, 1978 will be the consolidated deadline for submission of both notices of intention to appear and written comments by the public, and for filing documentary evidence and testimony of public witnesses at the hearing. The new date will provide to your clients and others four months from the Federal Register publication of the proposal and over one year from the public presentation to NACOSH of a similar draft set of regulations, to respond to the proposal.

2. OSHA will file the testimony and written comment of witnesses to be called by the agency on or before March 15, 1978.

3. The hearing, presently scheduled to commence March 14, 1978, will commence April 4, 1978.

While the hearing date will be extended for three weeks, you will note that the time for your clients to file written comments has been extended from December 8, 1977, to January 30, 1978, a period of almost two months, thus substantially complying with part of your request in your letter.

As stated above, the major policy and factual bases of the proposed OSHA cancer policy have been available to you since January 1977 and in proposal form since October 4, 1977. This has provided you and

AP00048069

your witnesses a lengthy opportunity to prepare your comments and testimony. In addition, a minimum of two and one-half weeks will be available for you and others to prepare questions to ask witnesses invited to testify by OSHA and you will have an additional period from the availability of those witnesses' statements to prepare post-hearing comments in response. It also is permissible for witnesses at OSHA hearings to summarize their written material orally and use time made available to respond to points which have come up in other witnesses' statements. Therefore, interested persons, including your clients, will have sufficient opportunity to respond to the factual and policy points presented by OSHA.

OSHA intends to proceed with this rulemaking as expeditiously as possible due to the serious nature of the risks posed to the health of the American worker. As pointed out in the proposal, we believe that such a system for regulation of exposure to potential occupational carcinogens is long overdue. We have reluctantly extended the already ample time requirements found in the proposal in order to accomodate you and others. Under the circumstances we do not believe that a further extension of time is warranted.

Sincerely,

Eula Bingham
Assistant Secretary
Occupational Safety and Health

AP00048070

News
United States Department of Labor
Office of Information
Washington, D.C. 20210

4.485

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION
Contact: James Foster
Office : (202) 523-8151
After Hours: (703) 941-6798

USDL-- 77-75
FOR RELEASE: Immediate
Monday, January 24, 1977

RECEIVED
FEB 14 1977
RICHARD FLEMING

OSHA ANNOUNCES PROPOSED CANCER POLICY

A draft of proposed regulations on worker exposure to cancer-causing chemicals that would speed the rulemaking process was made public today by the U.S. Department of Labor.

Bert Concklin, deputy assistant secretary of labor for the Department's Occupational Safety and Health Administration (OSHA), said the proposed rules are intended to identify, classify and regulate potential carcinogens in American workplaces. If adopted, the rules would provide three uniform job health standards to be used under differing circumstances as OSHA moves to regulate potential carcinogens.

The three uniform standards would each contain provisions OSHA has learned are common to most job health standards. By using these uniform standards, rulemaking could be speeded for each carcinogen being dealt with.

Concklin said the proposed rules are based on three propositions:

--That the term "carcinogen" must be defined for purposes of regulatory activity;

--That, as a policy matter, a toxic material confirmed as a carcinogen in a mammalian test animal species is to be treated as posing a carcinogenic risk to humans.

--That when OSHA is dealing with an identified carcionogen, the permissible worker exposure level would be set as low as feasible, or in certain cases would not be permitted at all. This is based on the general policy that there is

-MORE-

AP00048071

presently no means to determine a safe exposure level to a known carcinogen.

In dealing with a specific carcinogen, Concklin added, OSHA would rely on evidence from human epidemiological studies, animal studies, or both. The extent to which such data are conclusive would permit OSHA to classify the substance as a "confirmed" carcinogen (classification I), a "suspect" carcinogen (classification II), or neither (classification III). Classification III agents would require further analysis of available data.

The classification of a carcinogen would then trigger appropriate regulatory action. Classification I agents would be regulated by an emergency temporary standard.

A category II classification would result in developing a permanent health standard following normal rulemaking procedures. Classification III agents would cause OSHA to request from other federal agencies, including NIOSH, EPA, and NCI, any additional information which could have a bearing on reconsideration of the classification.

Each of the three approaches would include certain provisions common to job health standards issued by OSHA in the past. These would include, among others, rules on monitoring and measuring workplace concentrations of the carcinogen, medical surveillance requirements, personal protective measures, recordkeeping requirements, personal hygiene, sanitation and housekeeping measures and employee training.

Concklin noted that with these uniform measures in effect, rulemaking for a specific carcinogen would thus be limited to such issues as the lowest feasible exposure level, whether the substance was properly classified, and environmental impact issues.

"We recognize that this approach marks a departure from OSHA's usual pattern of setting job health standards on a substance-by-substance basis," Concklin said.

-MORE-

AP00048072

"However, we believe this new system will better enable us to protect the worker by effectively grouping hazards of a similar nature to facilitate standards setting in a more timely and consistent manner."

Cancklin said the proposed regulations will be presented later this week to the National Advisory Committee for Occupational Safety and Health (NACOSH) for review and recommendations.

NACOSH is a 12-member group made up of representatives of employees, employer the safety and health professions and the public. Its purpose is to advise and recommend to the Secretaries of Labor and Health, Education, and Welfare national policy on job safety and health matters.

Additional details are contained in the attached summary sheet.

- MORE-

AP00048073

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 killed a reported 358,400 U.S. citizens in 1974--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.

AP00048074

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 approac in regulating carcinogens, a speedy approach and an approach which will limit th size of OSHA's rulemakings which have grown far beyond the ability of OSHA's sta to handle by the present case-by-case approach.

III. Summary of Proposed Regulatory Policy

OSHA has drafted for review by its National Advisory Committee for Occupational Safety and Health, a proposed set of regulations to identify, classify, and regulate potential carcinogens in American workplaces. The proposal incorporates several policy considerations derived from OSHA's experience to date in applying its regulatory obligations to the issue of carcinogens. These policy considerations include:

1. That the term "carcinogen," although perhaps difficult to define precisely as a matter of science, must be defined for purposes of regulatory activity.

2. That a toxic material confirmed as a carcinogen in animal tests must be treated, as a policy matter, as posing a carcinogenic risk to man.

3. That there is presently no means to determine a "safe" exposure level to a carcinogen; hence, for regulatory purposes, it will be assumed that no safe level exists.

4. That in regulating employee exposure to a carcinogen, OSHA will set the permissible exposure limit as low as feasible.

5. That where suitable substitutes for a carcinogen are found to be less hazardous to the worker, no occupational exposure to the carcinogen will be permitted.

AP00048075

The proposal would permit any interested party to submit information from human or animal studies to establish the carcinogenicity of a toxic material. OSHA would then be required, within a specified brief period, to classify the toxic material as to its carcinogenicity based on the criteria set forth. The degree of conclusiveness of such data will permit classification of the substance as a "confirmed" (Category I Toxic Material) or a "suspect" (Category II Toxic Material) carcinogen, or neither (Category III Toxic Material) where further data is needed. Classification of a "confirmed" or "suspect" carcinogen would be followed immediately by specific regulatory action as provided in this proposal.

IV. Classification of Carcinogens

Receipt of information concerning a potential occupational carcinogen will be noted in the Federal Register and public comment invited. Within 30 days from the close of the comment period, OSHA in consultation with NIOSH will classify the substance and announce that classification in the Federal Register. The following criteria are proposed to be used in classifying carcinogens.

A. Category I Toxic Materials

A substance will be classified as a Category I Toxic Material ("confirmed" carcinogen) based on positive evidence found in any of the following:

1. Humans

2. Two mammalian test species

3. One mammalian species, if the results are replicated in the same species in a separate study

4. A single mammalian species if the results are supported by multi-test evidence of mutagenicity

B. Category II Toxic Materials

A substance will be classified as a Category II Toxic Material ("suspect" carcinogen) if the evidence of carcinogenicity in humans or one or more mammalian species is found by OSHA to be only "suggestive" as opposed to confirming. Such a distinction would be based on generally accepted standards of review for such scientific studies.

AP00048076

C. Category III Toxic Materials

A substance for which the evidence of carcinogenicity is found inadequate to classify as Category I or II will be classified as Category III.

V. Regulatory Actions

The proposal provides that at the time of or immediately following classification, regulatory action shall be initiated as follows:

A. Category I Toxic Material

1. Issue an Emergency Temporary Standard--a model standard is proposed for this purpose.

2. Issue a proposed permanent standard--a model permanent standard for a confirmed carcinogen is proposed for this purpose.

3. Simplify and reduce the time required for rulemaking by limiting the public hearing to certain specified issues, including feasibility.

4. Issue a final standard within six months.

5. Prohibit occupational exposure in specific applications where suitable substitutes are found which are less hazardous to workers.

B. Category II Toxic Material

1. Issue a proposed permanent standard--a model permanent standard for a "suspect" carcinogen is proposed.

2. Notify other federal agencies including NIOSH, EPA, and NCI of the determination that the evidence of carcinogenicity is only "suggestive" and request that those agencies consider such evidence in priorities for further research.

3. Complete the rulemaking proceeding and issue a final standard.

C. Category III Toxic Material

Advise other federal agencies including NIOSH, EPA, and NCI of classification and request any additional information which could have a bearing on reconsideration of the Category III classification.

AP00048077