



National Association of Manufacturers

SUMMARY
PRE-HEARING COMMENTS OF
THE NATIONAL ASSOCIATION OF MANUFACTURERS
ON
PROPOSED RULEMAKING FOR
IDENTIFICATION, CLASSIFICATION, AND
REGULATION OF TOXIC SUBSTANCES
POSING A POTENTIAL
OCCUPATIONAL CARCINOGENIC RISK
BEFORE THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
U.S. DEPARTMENT OF LABOR
WASHINGTON, D.C.

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Generic
Standard



FILED
FEBRUARY 28, 1978

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On October 4, 1977, the Occupational Safety and Health Administration announced its proposed policy to identify, classify and regulate toxic substances posing a potential occupational carcinogenic risk and invited interested parties to comment on the proposal by February 28, 1978.

National Association of Manufacturers (NAM) filed pre-hearing comments in response to this notice. NAM's comments are presented in four Parts: Parts I and II set forth procedural and legal difficulties NAM has with respect to both the generic regulatory approach suggested by OSHA and the proposed rulemaking notice itself. In Part III we propose a reasonable alternative plan for the regulation of substances which may be carcinogenic. Finally, in Part IV NAM voices its objections, both legal and practical, to specific provisions of the proposed rules and model standards. In some instances in Part IV alternative compliance approaches are suggested in the event OSHA decides to promulgate the proposed policy and rules. A summary of NAM's comments is presented here.

The members of NAM are genuinely concerned about the occupational health and safety of their employees, and believe that substances known to produce cancer in man should be regulated. Similarly, because a long latency period may exist between exposure to a carcinogenic substance and the physical manifestation of detectable symptoms of the disease, OSHA should not wait until it has human data to commence regulatory action. Thus, we would agree that appropriately designed, sufficiently persuasive animal data would provide an appropriate basis for OSHA to engage in rulemaking.

However, NAM urges OSHA to reconsider its continuation of this proposed rulemaking because the approach taken is (1) unreasonable, (2) unworkable, (3) contrary to law, and (4) holds the potential for vast disruption of the national economy. The proposal is unreasonable and unworkable because

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it is overly broad and it treats all carcinogenic substances alike while, at the same time, OSHA recognizes that some cancers are usually treatable and do not materially impair health. OSHA has in part justified generic rulemaking on the grounds that it will increase OSHA's efficiency in generating regulations by preserving its resources. NAM submits, however, that the proposal is self-defeating in this respect for it creates many new issues the effect of which will be to protract rather than streamline rulemaking proceedings.

Part I:

NAM argues that OSHA's proceedings should be terminated because the Notice of Proposed Rulemaking itself is inadequate as a matter of fairness and law. Contrary to the requirements of the Occupational Safety and Health Act of 1970 as well as several past and proposed Executive Orders, OSHA fails, without explanation, to make any assessment of the potential economic impact of its proposal. Because the proposal calls for the automatic issuance of Emergency Temporary Standards (ETS), it quite clearly has a significant economic impact in the sense that employers will be required to expend large sums of money on ETS compliance without an evaluation of economic impact ever having been made.

The proposal's economic impact could have been evaluated at least in part had OSHA stated what substances it was targeting for automatic ETS (i.e., Category I) treatment. As recently as last November, an OSHA representative stated that approximately 100 substances might fall into Category I, thereby suggesting that many of these substances are indeed known to OSHA. Its failure to set these forth in the proposal effectively deprives the public of the opportunity to comment fully on the impact of the proposal, deprives OSHA of useful information, and will serve to effectively preclude reviewing courts from making a reasoned assessment of the need for generic rules against other perhaps less costly alternatives. Additionally, contrary to the National Environmental Policy Act, OSHA fails to adequately assess the environmental impact of its proposal.

Moreover, the proceedings as instituted and conducted by OSHA are arbitrary and unfair. Even a cursory review of preamble to OSHA's proposal strongly suggests that OSHA is not approaching this regulatory effort with a completely open mind. OSHA has cast the proceedings in litigation terms and erroneously attempts to shift the burden of proof onto employers requiring them to come forward with evidence sufficient to "convince" the Secretary of Labor that his general policy is incorrect. NAM submits that OSHA's posture in this matter ignores the fundamental objections of informal rulemaking, and further suggests that due process is not served by permitting public debate after the decision has been made.

Finally, NAM notes that the overwhelmingly broad scope of OSHA's proposal in terms of its potential coverage, the complexity of issues involved, the length of the proposal, the hearing procedures employed by OSHA, and the amount of time allowed for comment join to significantly deprive many

employers, and particularly small businessmen, of the opportunity to meaningfully participate in the proceedings. There are a number of things which OSHA could have done to ease this burden (e.g., schedule regional hearings as has been done in the past with other proposals) and its failure to do so, we submit, is unreasonable and contrary to Congressional intent.

Part II:

OSHA has commenced this proceeding on three mistaken assumptions of law. In error it assumes that (1) the decided cases involving health hazards stand for the proposition that the determination of whether a substance poses a health hazard is solely a decision of policy; (2) the Act authorizes the regulation of toxic materials by class; and (3) the case authorities which have previously approved generic rulemaking provide authority for OSHA to engage in such rulemaking.

First, NAM argues that a single policy determination can not be made with regard to the regulation of all potential carcinogens, for to do so ignores many relevant factors which must be considered for each substance. To the extent that OSHA's proposal turns so heavily on policy determinations it goes far beyond the authorities relied on by OSHA. OSHA conveniently ignores the fact that most of the health cases relied on involved substance-by-substance regulation and its approach necessarily assumes that "policy" may be easily substituted for facts even when appropriate facts are available.

Second, generic rulemaking is not authorized by the Act. The legislative history and the Act itself strongly suggest a deliberate preference for substance-by-substance regulation. For example, the legislative history is replete with expressions of understanding that different industries would require different regulatory approaches. OSHA's present approach, by way of contrast, treats all industries alike. Congress, however, being concerned with economic problems as well as occupational health problems and being aware of the fact that standards would have differing impacts for different industries, approached the subject of regulating toxic materials on a substance-by-substance basis.

Finally, OSHA cites three cases to support the present proposal but none of them, and for that manner no other case that we are aware of, stands for the proposition that an agency may arrogate to itself the authority to require virtually all employers in the nation to obey the agency's dictates under pain of civil or criminal penalty while at the same time depriving them of the opportunity to be heard on the question of whether they should be regulated. The cited authorities do not deal with agency decisions made for purposes of law enforcement. Rather, they involved the establishment of conditions precedent for persons within specific identified industries who desire a governmental grant to enter into or continue in the specific businesses. Moreover, each of the cited decisions dealt with single, narrowly defined factual issues of limited applicability whereas OSHA's approach deals with many broad policy decisions of unlimited applicability.

Similarly, the many new complex issues which this proposal interjects into future rulemaking proceedings will offset any efficiencies which OSHA now seeks to realize.

Part III:

The NAM has considered the alternative carcinogen proposal offered by the American Industrial Health Council (AIHC) in this proceeding and is in general agreement with their proposal. Specifically, we agree that the only reasonable approach to regulation in this context is to establish standards on a substance-by-substance basis. Any regulatory activity must take into account the many variables that are involved such as the potency of individual substances, the uses to which they are put, the industries and products directly affected by the regulation of individual substances and the physiological effects of exposure, to mention just a few.

Furthermore, we agree that rulemaking may be initiated on an animal data base of acceptable experimental design or on a human data base, employing acceptable protocols. Although we would suggest a minor clarification, the AIHC has, we submit, suggested appropriate criteria for categorizing substances as confirmed animal oncogens and as known human carcinogens. Substance-by-substance rulemaking initiated on these criteria and involving a risk (hazard) vs. benefits including cost analysis as recommended by AIHC is, in our view, the approach the Act mandates for promulgating standards to regulate toxic substances.

We agree, also that a Data Evaluation and Classification Panel of the type proposed by AIHC should be established. Implicit in this suggestion is the concept that all concerned agencies, OSHA, EPA, FDA and the CPSC, will coordinate their rulemaking activities so that all of the environmental aspects of a potential health problem will be handled uniformly instead of according to the fragmented approach presently being employed.

Recognizing, however, that OSHA cannot for the interim yield its mandate to regulate occupational health hazards, it seems to us a reasonable alternative to create an evidentiary rebuttable presumption of carcinogenicity for rulemaking purposes where an appropriate data base exists.

As we view it OSHA could look to NIOSH, as is provided for by the statute, to develop criteria on a substance-by-substance basis. NIOSH's criteria could identify and categorize toxic substances as recommended by the AIHC thereby raising the presumption and allowing OSHA to focus its attention on the development of reasonable and appropriate performance standards tailored to the uses and effects of each substance.

Significantly, the alternative suggested by NAM would (1) require OSHA to specifically determine the existence of a "grave hazard" as to each substance; (2) not regulate substances where the evidence is only "suggestive"; and (3) eliminate category III as defined in OSHA's proposal.

Part IV:

Finally, NAM identifies specific provisions of the proposed rule and model standards to which it objects both legally and practically. In some instances we offer alternatives in the event OSHA decides to promulgate the policy and rules as proposed. Provisions addressed in NAM's comments include, issuance of Emergency Temporary Standards, substance bans and suitable substitutes, definitions, classification of substances, the proposed categories, monitoring, medical surveillance, and labeling.

NAM has requested time to appear and present testimony at the hearings scheduled to begin May 16, 1978 at the Department of Labor. Testimony presented at that time will specifically address the economic and practical implementation impact on small business as well as on a large international corporation. In addition, NAM witnesses will be available for cross examination on NAM's Pre-hearing Comments. If you would like to receive a copy of the full text of NAM's Pre-hearing Comments, please call or write:

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