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CMA

CHEMICAL MANUFACTURERS ASSOCIATION

November 1, 1988

TO: VDC Panel

FROM: Elizabeth J. Moran EJM

SUBJECT: Comments on OSHA's Proposed Air Contaminants Rule

Enclosed is a copy of the comments filed by CMA on OSHA's Proposed Air Contaminants Rule. The section relating to VDC begins on page 40.

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BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

POST-HEARING BRIEF OF THE CHEMICAL MANUFACTURERS ASSOCIATION ON OSHA'S PROPOSED AIR CONTAMINANTS RULE

Air Contaminants; Proposed Rule, 53 Fed. Reg. 20960 (June 7, 1988)	)	Docket No. H-020

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Executive Summary

In this Post-Hearing Brief on OSHA's Proposed Air Contaminants Rule, the Chemical Manufacturers Association reviews the written and testimonial evidence that has been presented on various issues in this proceeding since the filing of its Comments on July 22, 1988. Our Post-Hearing Brief addresses several generic issues and responds briefly to the suggestion made at the hearing that vinylidene chloride should be regulated as an occupational carcinogen. Our evaluation of the evidence leads to the following conclusions:

1. Given the outdated levels of many of the permissible exposure limits ("PELs") contained in the Z-Tables and the underinclusive nature of the Z-Table listings, we support OSHA's decision to conduct a generic multiple-substance rulemaking to

update the Z-Tables in order to reflect changes that have been made in the American Conference of Governmental Industrial Hygienists ("ACGIH") Threshold Limit Value ("TLV") list since 1968. As long as OSHA makes supportable findings regarding "significant risk" and "feasibility" for the affected substances, a multi-chemical proceeding can satisfy the requirements of the Occupational Safety and Health Act. The PELs established in this proceeding, however, should not be set below the levels at which a broad consensus exists regarding significant risk and feasibility. Moreover, OSHA should make an effort to update the Z-Tables on a regular basis, so that, in the future, it will not be necessary to conduct a massive and unwieldy rulemaking, such as the present one.

2. OSHA's decision to focus on setting permissible exposure limits for those substances that are included on the 1987-1988 TLV list represents a reasonable and sensible ordering of priorities designed to achieve a quick and substantial improvement in worker health protection. It may be desirable to regulate some substances more comprehensively and to establish generic monitoring and medical surveillance requirements for Z-Table air contaminants. Those matters, however, can properly be considered in subsequent rulemakings, a course of action that OSHA has already initiated.

3. TLVs established by ACGIH can appropriately be used as the basis for setting Z-Table PELs in this generic multi-chemical proceeding, where the evaluation of health risks and feasibility for individual chemicals is necessarily quite limited. Recommended Exposure Limits developed by the National Institute for Occupational Safety and Health ("NIOSH") should not, however, be used for this purpose, since they are more controversial than TLVs, less widely observed, and less likely to be feasible.

4. The short-term exposure limits ("STELs") that OSHA has proposed are not adequately supported by the Agency's independent evaluation of the health effects evidence. Accordingly, the question whether STELs are appropriate for some or all of the chemicals for which they have been proposed should be left for resolution in a later proceeding.

5. OSHA's proposal to phase-in (over a four-year period) the requirement to comply with the new PELs through the use of engineering controls is reasonable, given the scope of the present proceeding and the phase-in periods that OSHA has allowed in various single-substance standards. OSHA should be mindful, however, of developments in the separate proceeding that it has scheduled to consider whether the primacy of engineering controls should be reconsidered. Regardless of how that question is resolved, OSHA should expressly permit the use of respirators in

work operations where exposure to air contaminants is intermittent in nature and limited in duration, or where exposure occurs for less than 30 days per year.

6. OSHA should give priority to the development of analytical methods for the air contaminants for which adequate analytical methods do not presently exist. Until an adequate sampling and analytical method is developed for a particular air contaminant, OSHA should either postpone revising the PEL or defer implementing and enforcing the PEL until suitable sampling and analytical methods become available.

7. The computational formula in Section 1910.1000(f) of the proposed rule should be applied to multiple chemical exposures only when PELs for the chemicals involved have been set to protect against similar toxicological effects on the same organ(s).

8. Vinylidene chloride (" C") should not be regulated as an occupational carcinogen. NIOSH's contrary suggestion is not supported by the extensive toxicological data base on the potential carcinogenicity of VDC. In any event, action on the NIOSH recommendation would require OSHA to conduct a new rulemaking under Section 6(b) of the Occupational Safety and Health Act.

Introduction

On June 7, 1988, the Occupational Safety and Health Administration ("OSHA") published a notice of proposed rulemaking to revise the permissible exposure limits ("PELs") for the air contaminants listed in 29 C.F.R. § 1910.1000, Tables Z-1, Z-2, and Z-3, and to add additional chemicals to the Tables. 53 Fed. Reg. 20960. On July 22, 1988, the Chemical Manufacturers Association ("CMA") submitted Comments in response to the rulemaking notice (hereinafter referred to as the "CMA (or "CMA's") Comments"). CMA is a non-profit trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. Since many chemical industry employees are potentially exposed to one or more of the substances covered by the proposed rule, the rulemaking is of great interest to CMA's members.

CMA's Comments focused on a number of generic issues raised by the rulemaking proposal, rather than on the actions that OSHA proposed to take with respect to individual chemicals. Our Post-Hearing Brief also focuses on generic issues. However, we also will address the question whether vinylidene chloride ("VDC") should be regulated as as human carcinogen. This issue was not discussed in CMA's Comments (or, as far as we are aware, in anyone else's comments), since OSHA did not propose to regulate VDC on the basis of carcinogenicity. While we believe that the compound cannot lawfully be regulated as an occupational

carcinogen unless OSHA issues a new (or revised) rulemaking proposal and provides an opportunity to comment thereon, our Post-Hearing Brief responds to the recommendation made by the National Institute for Occupational Safety and Health ("NIOSH") on August 1, 1988 that VDC be designated a carcinogen and controlled in the same manner as vinyl chloride.

Our opening Comments addressed a variety of generic issues in considerable detail, and we do not propose to duplicate the discussion of those issues here. Instead, we will summarize the principal points made in our Comments on various generic issues and will discuss new material bearing on those issues that has been added to the record since our Comments were filed on July 22, 1988.

I. Under the Circumstances, OSHA's Proposal To Set Permissible Exposure Limits for Multiple Substances in a Single Rulemaking Is Desirable, but Efforts Should Be Made To Avoid Creating a Similar Situation in the Future.

In CMA's Comments, we argued that OSHA can lawfully revise the PELs for multiple Z-Table air contaminants in a single proceeding, as long as it makes the required "significant risk" and "feasibility" findings for each affected chemical on the basis of substantial evidence in the record.[1/] Given the outdated nature of many of the PELs contained in the Z-Tables and

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1/ See CMA Comments at 4-10.

the fact that numerous air contaminants for which Threshold Limit Values ("TLVs") have been set by the American Conference of Governmental Industrial Hygienists ("ACGIH") presently are not covered by the Z-Tables, we agreed with OSHA that such a multiple-substance proceeding would be desirable. We also supported OSHA's decision to use the 1987-1988 TLV list as the basis for chemical coverage in this proceeding and to focus solely on the question of appropriate permissible exposure limits. We urged OSHA, however, to review and update the Z-Table PELs periodically, as significant new information becomes available, so that it will not be necessary to conduct such a massive and unwieldy proceeding in the future.[2/]

Information that has been provided since the filing of our Comments confirms our views on these matters.

A. While a Generic Approach Is Desirable Under the Circumstances, OSHA Should Update the Z-Tables on a Regular Basis in the Future.

The notion of updating the PELs for a large number of Z-Table contaminants in a single proceeding received support from many quarters, even from parties who disagree with some of the specific PELs that OSHA has proposed. Thus, representatives of NIOSH agreed with OSHA "that there is an urgent need to update

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2/ See CMA Comments at 3.

the current air contaminant standards because they represent exposure limits based on data available prior to 1968."[3/] Although it questioned some of the specific PELs proposed by OSHA, NIOSH did "not question the wisdom of this rulemaking."[4/] It recognized that "[e]ven if some PELs are less productive than NIOSH might prefer, the overall impact of this Z-Table update represents a significant advance for worker safety and health."[5/] NIOSH also concurred "with OSHA that it is in the best interest of the worker to promptly provide such increased health protection as is indicated by the evidence in the record," while identifying particular substances that might require follow-up rulemaking for the possible establishment of more stringent exposure limits.[6/]

Other witnesses at the hearing echoed these sentiments. Thus, Professor Thomas O. McGarity testified that he could not "stress emphatically enough the simple proposition that if OSHA is to have any prospect at all of fulfilling its statutory mandate . . . it must seek innovative ways to remove some of these

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3/ Testimony of the National Institute for Occupational Safety and Health on OSHA's Proposed Rule on Air Contaminants, August 1, 1988 (hereinafter referred to as "NIOSH Testimony") at 1.

4/ Id.

5/ Id.

6/ Id. at 18.

debilitating impediments to effective regulation."[7/] In Professor McGarity's view: "The current rulemaking effort is a commendable attempt to move in that direction."[8/]

Like NIOSH, Professor McGarity acknowledged that there might be information justifying more stringent exposure levels than those reflected in the ACGIH TLVs. This possibility, however, did not concern him, since such information can serve as the basis for subsequent individual chemical rulemakings.[9/] The important issue, Professor McGarity stressed, is whether the information OSHA considered would justify reducing the existing PELs to the levels OSHA has proposed.[10/] In this respect, Professor McGarity observed, the current proceeding could be viewed as an interim measure.[11/]

7/ Transcript of Informal Public Hearing ("Tr.) at 2-18 (July 19, 1988).

8/ Tr. at 2-18.

9/ See Testimony of Thomas O. McGarity, (Ex. 19) at 11 (observing that the strategy of updating the Z-Tables to reflect current ACGIH TLVs, while remaining free to propose more stringent exposure levels and to write more comprehensive standards for individual substances, "appears to reflect the congressional plan of establishing a minimum level of protection for workers followed by the implementation of a stricter regulation"); see also Testimony of Dr. Isadore Rosenthal, Tr. at 3-17 (noting that "OSHA is not prevented from additional rulemaking on any of these substances in the future as new data and additional resources become available").

10/ See Tr. at 2-44.

11/ See Tr. at 2-69.

Even those witnesses who were critical of OSHA in various respects applauded the "generic" approach to dealing with many substances at one time. For example, Dr. Philip Landrigan stated that OSHA "is to be congratulated on this bold stroke."[12/] And Dr. Franklin Mirer of the United Auto Workers Expressed the Union's pleasure "that OSHA has recognized the need for a downward revision of our chemical exposure standards on a broad basis."[13/]

In short, there was widespread support for acting on a "generic" or multiple-substance basis to update the Z-Table PELs.[14/] As Jeremiah Lynch, testifying for CMA, stated, "the time has come to bring the Z-Tables up to date, and the comprehensive approach that OSHA has proposed seems to be the most efficient way to achieve that objective."[15/] At the same time, however, various witnesses emphasized that the unusual circumstances which necessitated such a comprehensive, multi-chemical

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12/ Testimony of Dr. Philip J. Landrigan, August 1, 1988 at 2.

13/ Tr. at 1-95.

14/ The generic nature of the rulemaking is something OSHA has recently described as being "perhaps the most fundamental [feature] if OSHA is to deal with the hundreds of potential workplace hazards that may exist." See Regulatory Program of the United States, Occupational Safety and Health Administration (September 1, 1988), reprinted in 18 BNA Occupational Safety and Health Reporter 906 (September 28, 1988).

15/ See Statement of Jermiah Lynch on Behalf of CMA (Ex. 64) at 2.

proceeding should be avoided in the future. For example, NIOSH stated that "it should be clearly understood by all that this rulemaking is an exceptional event made necessary by the passage of 20 years without significant reevaluation of the standards contained in the Z-Tables."[16/] And Jeremiah Lynch observed: "It would have been preferable to have reviewed the Z-Table PELs on an on-going basis over the years, as the corresponding TLVs were adjusted or as significant new scientific information became available."[17/]

To avoid creating a similar situation in the future, various witnesses urged OSHA to institute a process for reviewing and updating the PELs for Z-Table air contaminants on a regular basis.[18/] As Dr. Ernest Mastromatteo, Chair of the ACGIH TLV Committee, stated, if TLVs are used for regulatory purposes, "provisions should be made to keep the list current."[19/] We are

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16/ NIOSH Testimony at 1.

17/ Statement of Jeremiah Lynch on Behalf of CMA (Ex. 64) at 1.

18/ See, e.g., Statement of Dr. Marcus M. Key (Ex. 17) at 11 (recommending that the Z-Tables be updated and expanded every three to five years); Testimony of Earle W. Arp, Jr. on OSHA's Proposed Standard for Air Contaminants (Ex. 8-60) at 4 (expressing the hope that "this is a one-time only proceeding, and that in the future OSHA will make a systematic effort to keep pace with scientific developments on these substances on a more regular basis"); Testimony of Dr. Isadore Rosenthal, Tr. at 3-17 (urging OSHA to develop a "mechanism for the more timely incorporation of the latest scientific information into its exposure standards").

19/ Testimony of Dr. Ernest Mastromatteo on Permissible Exposure Limits Project (Ex. 22) at 8.

encouraged to learn that OSHA plans to explore "ways in which to make this standard organic, that is, how the PELs can more easily be updated in the future to keep them current,"[20/] and we look forward to working with OSHA to achieve this objective.

B. OSHA Must Make Supportable Significant Risk and Feasibility Findings for the Chemicals Covered by the Rulemaking.

While the generic feature of the current rulemaking was applauded by many parties as being an effective means to break what one witness described as "the health standards log jam,"[21/] various witnesses emphasized that in revising PELs for air contaminants, OSHA must comply with the requirements applicable to standard setting under Section 6(b) of the Occupational Safety and Health Act. As Dr. Marcus M. Key put it: "OSHA must demonstrate the need for these new and revised limits in terms of reduction of significant risks and [must] show that these proposed limits are feasible, both technologically and economically."[22/]

20/ Regulatory Program of the United States, Occupational Safety and Health Administration (September 1, 1988), reprinted at 18 BNA Occupational Safety and Health Reporter 907 (September 28, 1988).

21/ Testimony of Richard Boggs, Vice President of Organization Resources Counselors, Tr. at 3-263.

22/ Statement of Dr. Marcus M. Key (Ex. 17) at 4.

NIOSH made a similar point when its representative stated that "NIOSH knows of no . . . method to develop reliable exposure limit standards that is consistent with NIOSH's responsibility from the OSHA Act" other than to evaluate all of the data relating to estimated human risk at specific exposures, the availability of adequate measurement and analytical methods, the feasibility of various exposure levels, and similar information.[23/] OSHA claims to have done this by considering health effects, significant risk, risk reduction, economic feasibility, and technological feasibility for each individual substance covered by the proposed rule.[24/] To the extent this has been done, OSHA can lawfully adopt new PELs for the multiple chemicals covered by the proposed rule. Where this has not been done on a supportable basis, however, OSHA's actions in setting PELs or short-term exposure limits will be subject to challenge.[25/]

C. OSHA's Decision To Focus on PELs for Substances on the 1987-1988 TLV List Was Reasonable.

The support of some participants for OSHA's overall generic approach was tempered by criticism of the Agency's selection of chemicals to be considered in the proceeding and of

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23/ See Tr. at 3-120.

24/ See Public Hearing Testimony of Charles E. Adkins (Ex. 15) at 3.

25/ See pp. 32 - 34, infra.

OSHA's decision to limit the rulemaking to adjustments of existing PELs and the establishment of new PELs. Several representatives of organized labor expressed reservations over the fact that certain chemicals were not included in the present proceeding, and they criticized OSHA for failing to establish comprehensive exposure monitoring and medical surveillance requirements for all of the Z-Table chemicals. As discussed in CMA's Comments,[26/] these criticisms are unwarranted.

At the hearing, Charles E. Adkins, Director of Health Standards for OSHA, explained:

> "There are thousands of chemicals in commerce. There are different ancillary provisions which are relevant. There are several different sectors which are covered under current OSHA regulations. To successfully complete rulemaking covering all these aspects would be an impossible task."[27/]

Mr. Adkins emphasized that "OSHA is aware that additional chemicals should eventually be considered" and that "ancillary requirements are important and must be addressed."[28/] He pointed out, however, that

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26/ See CMA Comments at 6-10.

27/ Public Hearing Testimony of Charles E. Adkins (Ex. 15) at 6.

28/ Id. at 7.

> "these can be resolved in follow-on separate rulemaking in the near future. OSHA believes that it is most important to complete this first effort [reduction of the PELs] to provide appropriate protection against airborne contaminants present in the workplace."[29/]

As the courts have made clear, an agency rule is not invalid simply because the agency might have regulated more comprehensively than it did.[30/] An agency may "take one step at a time,"[31/] and, "[u]nless the agency's first step takes it down a path that forecloses more comprehensive regulation, the first step is not assailable merely because the agency failed to take a second."[32/] Clearly, OSHA's decision to focus on reducing PELs for the Z-Table air contaminants in this proceeding does not foreclose more comprehensive regulation of the Z-Table air contaminants in subsequent proceedings. Indeed, just recently, OSHA provided evidence of its resolve to regulate the Z-Table air contaminants more comprehensively by publishing advance notices of proposed rulemaking to establish generic standards for exposure monitoring and medical surveillance.[33/]

29/ Id.

30/ See, e.g., Hazardous Waste Treatment Council v. U.S. Environmental Protection Agency, No. 86-1143 (D.C. Cir. October 7, 1988), slip op. at 20.

31/ United States Brewers Ass'n v. EPA, 600 F.2d 974, 982 (D.C. Cir. 1979).

32/ Hazardous Waste Treatment Council v. U.S. Environmental Protection Agency, No. 86-1143 (D.C. Cir. October 7, 1988), slip op. at 20.

33/ See 53 Fed. Reg. at 37591, 37595 (September 27, 1988).

Certain representatives of organized labor expressed th· ·iew that "it would be more beneficial for OSHA to focus on 50 - 100 priority chemicals . . . rather than using a scatter-gun approach which treats all chemicals as equal concerns."[34/] But OSHA's decision to address the chemicals on the 1987-1988 TLV List and to focus on adjusting PELs was widely supported. Thus, Dr. Marcus Key applauded

> "the approach that OSHA has taken in using the ACGIH TLVs as a practical universe of chemical substances to be considered in their review. The TLVs have several attributes which commend them as a reference or starting point for the review; one, most of the limits in the Z-tables were originally derived from the 1969 TLVs; two, the TLVs constitute the most comprehensive database available; three, they are reviewed periodically, if necessary; four, documentation is published; and, five, they are applicable to the U.S. work places."[35/]

When questioned as to whether other air contaminants should be added to the rulemaking, Dr. Key replied, "No. . . . I would not want to see anything slow up the rulemaking process for these 400-odd chemicals, such as adding new ones back in for consideration."[36/]

34/ Testimony of Margaret Seminario (AFL-CIO), August 4, 1988 at 21.

35/ Testimony of Dr. Marcus M. Key, Tr. at 1-220.

36/ Testimony of Dr. Marcus M. Key, Tr. at 1-250. Earle Arp, Jr., speaking for API, also testified that "OSHA made a good

[Footnote continued next page]

OSHA's decision to limit the focus of the present proceeding to permissible exposure limits, while postponing consideration of ancillary requirements to later proceedings, also was widely supported. Thus, Dr. Marcus Key expressed the hope that

> "this rule making is not delayed because of the perceived necessity for ancillary provisions, such as the prescribing of acceptable work practices, methods of industrial hygiene monitoring, medical surveillance, training, etc . . . . Comprehensive standards may be necessary for a few of the substances we are considering but these can be dealt with in future rulemaking. Let us not hold up these urgently needed Z-table revisions for this reason. I repeat, the updating and expansion of the Z-tables should be OSHA's highest priority."37/

When questioned about his views on this point, Dr. Key explained that "OSHA cannot do everything at once. And . . . I certainly agree with their approach of going ahead and reducing the Permissible Exposure Limits and then at a later time consider[ing] those substances that need to be augmented with . . . medical examinations, and everything else."38/

[Footnote continued from preceding page]

choice in selecting the ACGIH TLVs as the principal starting point for updating the Z-Table PELs." Testimony of Earle W. Arp, Jr. (Ex. 8-60) at 8.

37/ Statement of Dr. Marcus M. Key at 14. See also Testimony of Dr. Marcus M. Key, Tr. at 1-233.

38/ Testimony of Dr. Marcus M. Key, Tr. at 1-265. See also id. at 1-266 (emphasizing the time and resource constraints that OSHA faces).

Professor Thomas McGarity echoed these sentiments, noting that the "overall strategy of taking a generic approach to updating the PELs appears to reflect a congressional plan of establishing a minimum level of protection for workers followed by the implementation of stricter regulation."[39/] And Richard Boggs, Vice President of Organization Resources Counselors, observed that

> "promulgation of PELs in a timely manner with . . . comprehensive occupational health standard evaluation later is appropriate not only because it is good industrial hygiene practice but because it is a cost-effective use of the Agency's and the public's limited resources."[40/]

In sum, OSHA's decision to focus on the current TLV list and to postpone consideration of ancillary requirements to subsequent proceedings was widely supported. Indeed, while criticizing OSHA's approach, the AFL-CIO itself appeared to recognize the desirability of reducing PELs quickly in a generic rulemaking, while developing more comprehensive standards in subsequent proceedings.[41/] Jeremiah Lynch summed the point up well

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39/ Testimony of Thomas McGarity, Tr. at 2-20.

40/ Testimony of Dr. Richard Boggs, Tr. at 3-263.

41/ See Testimony of Margaret Seminario (AFL-CIO), August 4, 1988 at 14 (urging OSHA to include the nine chemicals in the present proceeding, "so that reductions in exposure can be achieved while comprehensive rules are pending").

by stating that "OSHA . . . got its priorities straight" when it "concluded that adjusting the permissible exposure limits for chemicals on the TLV list should be its first order of business."[42/]

D. In this Truncated, Generic Proceeding, OSHA Should Act Only to the Extent that a Consensus Exists.

Finally, testimony from a variety of interests stressed the importance of limiting the actions taken in this highly accelerated generic proceeding to areas in which a substantial consensus exists. The Administrative Conference, whose recommendation is one of the major predicates for this proceeding, urged OSHA to update the Z-Table PELs on a generic basis "when consensus recommendations are available, which are generally accepted by employers and workers in the affected industry . . . ."[43/] Professor Thomas McGarity, one of the authors of the Administrative Conference report, stated that "it would be difficult to adopt a generic approach" if there is no consensus within the regulated community and no consensus within the scientific community, a situation that might be evidenced by a divergence between the ACGIH TLV and the NIOSH recommended exposure limit for a substance.[44/]

42/ Statement of Jeremiah Lynch on Behalf of CMA (Ex. 64) at 2-3.

43/ See 53 Fed. Reg. at 20964, col. 3.

44/ See Testimony of Thomas McGarity, Tr. at 2-77 and 2-78.

Similarly, Earle Arp, Jr., testifying for API, observed that if this

> "sort of rapid 'catch-up' procedure [represented by the present proceeding] is to be workable in a scientific and legal sense, the . . . rule should be confined to exclude complex or controversial questions and to focus on the issues for which there is already a broad consensus."45/

Any attempt "to reach beyond the scope of the consensus," Mr. Arp explained, "inevitably introduces additional scientific complexity and potential controversy that can only be addressed properly through full Section 6(b) rulemaking."46/

Perhaps this point was expressed most forcefully by Dr. Franklin E. Mirer, testifying for the United Auto Workers. Dr. Mirer pointed to "three notable features" of past OSHA rulemakings that have been "unique and effective" in producing protective, feasible, and efficient standards. These are:

> "(1) An informal rulemaking hearing in which all parties, including the Agency must present their evidence and be available for questioning;
>
> (2) A complete, on-the-record analysis of the evidence and explanation of the reasons for setting of a standard;

45/ Testimony of Earle W. Arp, Jr. (Ex. 8-60) at 4-5.

46/ Id. at 8.

(3) Combining analysis of health effects (risk assessment) with feasibility (risk management) in a single proceeding."[47]

Dr. Mirer contrasted these features of individual substance rulemakings with the much more truncated approach that necessarily is followed when hundreds of substances are considered in a single proceeding.[48] The truncated nature of the proceeding, Dr. Mirer pointed out, severely limits consideration of both risk and feasibility evidence for individual substances.[49]

For these reasons, any actions taken in the present proceeding should reflect a broad consensus. When the consensus for reducing a PEL does not extend below a specified level, that level should be as far as OSHA goes in the absence of a more comprehensive substance-specific proceeding.[50] As Margaret

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47/ Testimony of Dr. Franklin E. Mirer on OSHA's PEL Update Proposal, August 5, 1988 at 13.

48/ See id. at 13-14.

49/ See id.

50/ The fact that some parties (e.g., organized labor) believe that a PEL should be set at a lower level than OSHA has proposed does not mean that the TLV level selected by OSHA does not represent a "consensus." As long as the primary interested parties (including representatives of labor and industry) agree that the TLV level responds to a significant health risk and is feasible, it can be considered a consensus level, even though some participants do not consider the TLV level to be adequate as an OSHA standard. See Testimony of Marc Stepp (UAW) on OSHA's Proposed Standard for Lockout (Docket No. S-012A), October 13,

[Footnote continued next page]

Seminario of the AFL-CIO observed: "Studies which address major hazards and require significant changes in industry practices and operations can only be effectively set through a comprehensive rulemaking," not in a compressed and truncated generic proceeding.[51/]

OSHA appears to recognize these points. Thus, Charles Adkins acknowledged that the Agency's "[a]ssessment of health data was based on a . . . limited analysis" of the primary literature.[52/] Such a "limited analysis," Mr. Adkins stated, "is appropriate in light of the general scientific support and applicablity of the allowable limits" being considered by OSHA in this proceeding.[53/] A limited analysis does not, however, provide an appropriate basis for setting exposure limits whose scientific justification or feasibility is disputed by parties who would be significantly affected by the new PELs. Accordingly, in

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[Footnote continued from preceding page]

1988 at 4 (emphasizing that the lockout/tagout standard developed by the ANSI Committee on which organized labor and industry were represented was a "consensus standard," even though the unions did not consider it adequate as an OSHA standard).

51/ Testimony of Margaret Seminario (AFL-CIO), August 4, 1988 at 22.

52/ Testimony of Charles E. Adkins, Tr. at 1-45. Harry Ettinger, OSHA's Project Officer for this proceeding, explained that the Agency only reviewed summaries of the studies cited by ACGIH. Tr. at 1-145 and 1-146.

53/ Id.

the present proceeding, OSHA should set PELs only when there is a broad consensus that the proposed PEL responds to a significant health risk and is feasible.

II. TLVs, Rather than NIOSH Recommended Exposure Limits, Should Be Used as the Basis for Setting Z-Table PELs.

In our opening Comments, we argued that, while it is reasonble to use TLVs as the basis for revising Z-Table PELs, NIOSH recommended exposure limits ("RELs") should not be used for this purpose.[54/] We took this position for two principal reasons: First, because NIOSH RELs are more controversial and far less widely accepted and observed in practice than TLVs, and thus do not constitute consensus recommendations; second because the feasibility of RELs is much more questionable than the feasibility of TLVs, thus making it inappropriate to use RELs as the basis for setting standards in a massive multi-chemical proceeding in which evaluations of feasibility for individual chemicals are necessarily superficial. Additional support for this position was provided in written statements and at the hearing.

54/ See CMA Comments at 11-13.

A. TLVs Are More Comprehensive, Widely Respected, and Broadly Accepted than RELs.

At the outset of the hearing, Charles Adkins explained that this multi-chemical generic proceeding "represents an effort to bridge a 20 year gap in maintaining PEL's current, while at the same time satisfying all of the legal requirements OSHA must follow."[55/] To accomplish this objective, Mr. Adkins acknowledged, OSHA must rely

> "on well established, and generally accepted guidelines and recommendations regarding allowable airborne contaminant limits as a 'starting point' for the proposed OSHA PEL. By using these data as a foundation it was possible to avoid the need for detailed development of each proposed PEL on an ad hoc basis."[56/]

We agree that "well established and generally accepted" guidelines should be used as the basis for setting PELs in this generic proceeding. We also agree that ACGIH TLVs fit this description. NOISH RELs, however, do not.

Numerous participants in the rulemaking testified to the fact that ACGIH TLVs are comprehensive, widely respected, and broadly accepted -- all of which provides evidence of their validity and feasibility. As stated by Dr. Marcus M. Key, "TLVs

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55/ Public Hearing Testimony of Charles E. Adkins (Ex. 15) at 5.

56/ Id at 5-6.

constitute the most comprehensive set of limits available anywhere, and . . . as a group of practical limits the ACGIH TLVs remain unparalleled."[57/] Similarly, Dr. Isadore Rosenthal observed that "ACGIH TLV values are recognized as the standard of good practice by most health professionals around the world . . . . There is no other organization's work on exposure standards that has had as much impact and recognition as those of the ACGIH."[58/] Moreover, as Dr. Rosenthal points out, even though feasibility is not specifically taken into account in setting TLVs, "the use of ACGIH-TLVs as de facto control limits by significant sectors of industry backed up by the Agency's own study on the issue of feasibility gives OSHA reasonable grounds to assume general feasibility" of TLV-based PELs.[59/]

Dr. Ernest Mastomatteo, Chair of the ACGIH TLV Committee, also emphasized the wide acceptance of TLVs, not only in the United States, but throughout the world. He explained that his work at the International Labor Organization demonstrated to him that ACGIH TLVs are widely respected, accepted, and used on a global basis, which "must give some indication of their

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57/ Statement of Dr. Marcus M. Key (Ex. 17) at 8; Tr. at 1-225.

58/ Testimony of Dr. Isadore Rosenthal (Ex. 25) at 6.

59/ Id. at 7. See also Tr. at 3-28 (pointing to the wide use of TLVs throughout industry and by other governments as an indicator of their feasibility).

feasibility and validity."[60/] Similar views were expressed by other parties.[61/]

Many witnesses contrasted the wide acceptance and observance of ACGIH TLVs with the much more limited acceptance (or even awareness) that NIOSH RELs enjoy. Thus, in arguing against the use of RELs as the basis for expedited revision of Z-Table PELs, Earle Arp, Jr. emphasized the fact that RELs "do not have the broad acceptance that the TLVs enjoy. Quite the contrary, in many cases the RELs have proven to be quite controversial."[62/] Dr. Richard Olson also contrasted the widespread awareness of TLVs among small and medium sized companies as a result of their inclusion on MSDSs with the relative

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60/ See Testimony of Dr. Ernest Mastromatteo (Ex. 22) at 2-3; Tr. at 2-125.

61/ See, e.g., Testimony of Earle Arp, Jr. (Ex. 8-60) at 2 (observing that ACGIH TLVs "are widely accepted by employers, employees, and government regulators both here and abroad, as appropriate goals for protecting worker health"); Testimony of Dr. Richard Olson, Manager of Regulatory Compliance for the Dow Chemical Company, Tr. at 3-249 (pointing out that "[m]any, if not most, . . . small and medium-sized companies are already aware of TLVs because they are on material safety data sheets from industry"); Testimony of Richard Boggs (noting that "TLVs are known by virtually every employer and many employees in this country . . . . Because of the hazard communication standard requirements, the TLVs have, in many ways, become de facto standards for much of the industrial world"); Testimony of Lawrence Birkner, Manager of Safety and Industrial Hygiene of ARCO Petroleum and Chemical Company, Tr. at 3-230 (stating that "ARCO's 20 industial hygienists currently use the ACGIH TLVs as benchmarks for evaluating and controlling exposures to our workers").

62/ Testimony of Earle W. Arp, Jr. (Ex. 8-60) at 9.

unfamiliarity that small and medium sized companies have with RELs.[63/] Richard Boggs of Organization Resources Counselors, made a similar observation, pointing out that NIOSH RELs, in contrast to ACGIH TLVs, "are not consensus values, nor are they widely known, used, or accepted."[64/] And Jeremiah Lynch testified that RELs "are more controversial than TLVs from a health standpoint; they are less widely observed in practice; and they are less likely to be feasible."[65/]

B. The Process for Adopting TLVs Is More Open to Public Input than the Process for Adopting RELs.

Part of the reason why NIOSH RELs are less widely accepted and observed than TLVs is the difference in the process by which they are adopted. As described by the Chair of the ACGIH TLV Committee:

> "TLVs are derived in an open process. Recommended additions or amendments to current TLVs are placed in a provisional list, the Notice of Intended Changes (NICs), for a minimum period of two years to allow for input by all interested parties. NICs are given public notice in professional publications. The TLV Committee meets with interested groups wishing to present a point of view. Finally, . . . the recommendations of the TLV Committee are published in a special

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63/ Testimony of Dr. Richard Olson, Tr. at 3-249 and 3-250.

64/ Testimony of Richard Boggs, Tr. at 3-267.

65/ Statement of Jeremiah Lynch on Behalf of CMA (Ex. 64) at 3.

documentation which provides the scientific basis for the judgment by the Committee."[66]/

Furthermore: "The TLV Committee publishes an Appendix, 'Chemical Substances and Other Issues Under Study,' which lists the substances and areas it is interested in and requests input by interested groups."[67]/ All of the input that the Committee receives as a result of the publication of these notices is considered before a final decision is made.[68]/ Moreover: "People who request an opportunity to make input [at meetings of the TLV Committee] are invited to come, and they would be welcome to come to such meetings."[69]/ In addition, "TLVs are subject to regular review and revision," a point that is underscored by the fact that approximately 200 of the current TLVs represent reductions from the levels that were originally adopted by OSHA.[70]/

66/ E. Mastromatteo, "TLVs: Changes in Philosophy," 3 Applied Industrial Hygiene F-12, F-14 (March 1988). A copy of this article was submitted as Attachment I to CMA's Post-Hearing Evidence.

67/ Id. at F-16.

68/ See Testimony of Dr. Ernest Mastromatteo (Ex. 22) at 14-15.

69/ Testimony of Dr. Ernest Mastromatteo, Tr. at 2-141.

70/ Testimony of Dr. Ernest Mastromatteo, Tr. at 2-123. While not all of the TLVs are reviewed and updated every year, a significant number are reviewed annually on the basis of priority evaluations. See id. at 2-132.

Because of the broad opportunity for public input to Committee deliberations and the periodic review that occurs, many witnesses described the setting of TLVs as being an open process that takes account of new scientific developments.[71/] By contrast, the process by which NIOSH develops RELs was said by many witnesses to be less open to public input and participation. For example, Dr. Isadore Rosenthal expressed the view that RELs are derived in "a relatively closed process."[72/] When questioned as to the basis for his belief, Dr. Rosenthal replied that while he has been aware of potential or intended changes in TLVs and has offered comments and documentation to ACGIH on potential changes, he has not been aware of a similar opportunity to offer documentation and comments regarding the development of NIOSH RELs.[73/] Similarly, Dr. Richard Olson observed that "[s]ome of the RELs have not been set in an atmosphere where outside occupational health experts generally knew that the review of the REL was

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71/ See, e.g., Testimony of Dr. Marcus M. Key, Tr. 1-222 ("TLV Committee conducts a continuing review of the scientific literature and other documentable data sources" and engages in a process that allows "for input from all sectors including the public"); Testimony of Dr. Isadore Rosenthal (Ex. 25) at 6, Tr. at 3-11 (process used to arrive at TLVs "offers the opportunity for comment by organizations and individuals outside ACGIH"); Testimony of Dr. Richard Olson (Dow), Tr. at 3-249 (emphasizing that the TLV Committee provides two-years' advance notice of proposed changes "during which time any scientific and factual data and analyses can be submitted and is utilized and evaluated").

72/ Testimony of Dr. Isadore Rosenthal, Tr. at 3-12.

73/ See Testimony of Dr. Isadore Rosenthal, Tr. at 3-25 and 3-26.

occurring and could take part in the process."[74/]

NIOSH RELs are subjected to limited review, but that is not the same as widely soliciting input and comments from the public at large. Moreover, as Dr. Marcus Key, a former Director of NIOSH, testified, in his experience, review of NIOSH RELs is not of the same nature as the peer review that is conducted by many scientific journals.[75/] For example, NIOSH did not convene formal panels of peer reviewers and thus sacrificed the quality of review that is achieved when all of the peer reviewers "sit[] down in the same room and discuss[] their views."[76/]

In short, the review process associated with the development of NIOSH RELs does not substitute for the opportunity of broad-based public comment that characterizes the development of TLVs. Indeed, a spokesman for organized labor stated that his union "doesn't believe that peer review is a necessary or even useful part of the rulemaking process."[77/]

74/ Testimony of Dr. Richard Olson, Tr. at 3-248 and 3-249. When questioned, Dr. Olson pointed to carbon tetrachloride and chloroform as examples of cases in which NIOSH revised the Criteria Documents without Dow being aware that the revision was in progress. See id. at 3-260. See also Testimony of John Hinshaw (representing the National Association of Manufacturers), Tr. at 3-331 (noting that "NIOSH RELs must go through very little review outside NIOSH before they are recommended by the Agency").

75/ See Testimony of Dr. Marcus M. Key, Tr. at 1-243.

76/ Id. at 1-244.

77/ Testimony of Dr. Franklin E. Mirer (United Auto Workers) on OSHA's PEL Update Proposal, August 5, 1988 at 18.

C. There Is More Evidence for the Feasibility of TLVs than for the Feasibility of RELs.

As noted above, the fact that TLVs are widely accepted and observed provides reassuring evidence of their general feasibility. Evidence of the feasibility of RELs, by contrast, is sorely lacking. While NIOSH does consider technological feasibility in other documents, feasibility is not reflected in the RELs themselves. Moreover, NIOSH takes the position that the Occupational Safety and Health Act specifically prohibits it from considering economic feasibility at all.[78/] Thus, RELs reflect only health effects, with a possible limitation being the lower limit of detectability.[79/]

In short, RELs, like TLVs, are set without specifically considering feasibility. Unlike TLVs, however, RELs are not widely accepted and observed in practice. Consequently, while it may be reasonable to presume that most TLVs are feasible, it is not reasonable to indulge such a presumption for RELs. Given the limited feasibility analysis that OSHA has performed for individual substances in this proceeding, the fact that the feasibility

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78/ Testimony of Richard Lemen, Tr. at 3-141 and 3-142.

79/ See 53 Fed. Reg. at 20978, cols. 1 & 3; Testimony of Dr. Richard Olson (Dow), Tr. at 3-249. Moreover, for potential carcinogens, NIOSH recommends that exposures be restricted to the lowest feasible level, even if there is no evidence of a significant risk above that level. See NIOSH Testimony at 7.

of RELs cannot be presumed is an independ nt reason not to u RELs as the basis for setting permissible exposure limits for the Z-Table air contaminants, particularly since NIOSH has not attempted to provide OSHA with data demonstrating the feasibility of its RELs.[80/]

D. The Charge that the TLV Committee Is Unduly Influenced by Industry Is Unjustified.

Despite the advantages TLVs have over RELs as a basis for setting PELs for Z-Table air contaminants, they have been criticized by some as being unduly unfluenced by industry. This is said to result from the fact that the ACGIH TLV Committee has made use of unpublished industry studies and has used industry-related consultants in the past. These criticisms are unjustified.

It is true that the ACGIH TLV Committee uses some consultants. At present, the TLV Committee has 21 members and four consultants, 3 from industry and 1 from labor.[81/] As the Chair of the TLV Committee points out: "Members and consultants are appointed on the basis of their scientific qualifications and expertise, as well as for their experience as practicing industrial hygienists employed in governmental agencies."[82/] Even a

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80/ See NIOSH Testimony at 11.

81/ See Testimony of Dr. Ernest Mastromatteo (Ex. 22) at 9.

82/ Id. at 10.

quick perusal of the list of its current members shows an impressive mix of experience and practice that "brings an expert balance to the deliberations of the TLV Committee."[83/]

While industry has provided more consultants to the TLV Committee than organized labor, the fact is that consultants "are added for their own particular expertise" and "do not have a vote."[84/] Moreover, ACGIH "receives no subsidies from governments, industries, or unions."[85/] As Dr. Mastromatteo explained: "All recommendations for TLVs are based on the Committee's professional assessment of the published literature and other information made available to it."[86/]

Some of the "other information made available to it" may consist of unpublished industry studies. But this does not result in a tainted process and does not justify "casting aspersions on the professional integrity of the TLV Committee . . . and implying some sort of collusion between the TLV Committee and industry over the years."[87/] As Dr. Marcus M. Key (former Chairman of the ACGIH) reminds us, only industry toxicologists and

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83/ Id. at 11.

84/ Id. at 16.

85/ E. Mastromatteo, "TLVs: Changes in Philosophy," 3 Applied Industrial Hygiene F-12 (March 1988).

86/ Testimony of Dr. Ernest Mastromatteo (Ex. 22) at 15.

87/ Testimony of Dr. Marcus M. Key (Ex. 17) at 7.

industrial hygienists "were in a position to do these studies and gain this experience . . . ."[88/] Thus, rather than being criticized "for sharing their information with us for the purposes of developing safe limits," these industry toxicologists and industrial hygienists "should be complimented . . . ."[89/] Since the TLV Committee's recommendations were published as intended changes for two years before final adoption, anyone interested could have "asked for details of the personal communications cited from industry, academia, or government at that time . . . [and] the TLV Committee would have had them on hand and would have made them available."[90/]

In short, as Dr. Marcus M. Key emphasizes, "the ACGIH is a responsible, independent professional organization [that is] . . . not controlled by either labor or industry."[91/] Recommendations of the TLV Committee "are based on health consideration."[92/] Reflecting his experience as Chair of the TLV Committee, Vernon L. Carter notes:

88/ Id.

89/ Id. See also Vernon Carter, "Message from the Chair," 3 Applied Industrial Hygiene F-6 (March 1988) (noting that "it is to the committee's credit that it brought in industrial consultants to provide this source of information"). A copy of Vernon Carter's "Message" was submitted as Attachment I to CMA's Post-Hearing Evidence.

90/ Statement of Marcus M. Key (Ex. 17) at 7-8.

91/ Id. at 8.

92/ Testimony of Dr. Ernest Mastromatteo (Ex. 22) at 15.

> "Debate among and between members and consultants was many times very intense over the value of scientific data to be used in establishing a TLV . . . . However, without question, I can say that when debate had ended voting members based their decision upon valid scientific reasoning."93/

As the foregoing discussion indicates, the "charge that corporate consultants [to the TLV Committee] manipulated the available data to the perceived advantage of industry without regard to human health" is unjustified.94/ The ACGIH TLVs have been, and continue to be, "the most comprehensive set of limits available anywhere," and "as a group of practical limits . . . [they] remain unparalleled."95/ For the reasons discussed above and in CMA's Comments of July 22, 1988, this "unparalleled set of limits" should be used, in preference to the far more controversial and untested RELs, as the basis for adjusting permissible exposure limits in the present proceeding.

93/ Vernon Carter, "Message from the Chair," 3 Applied Industrial Hygiene F-6 (March 1988).

94/ Id.

95/ Statement of Marcus M. Key (Ex. 17) at 8.

III. Short-Term Exposure Limits Should Not Be Adopted in the Present Proceeding.

OSHA has proposed to adopt short-term exposure limits ("STELs") for 134 of the air contaminants that are currently listed, or are proposed to be listed, in the Z-Tables. The vast majority of these STELs are taken directly from ACGIH recommendations, although in some instances OSHA has ignored the fact that some of those recommendations have been (or are being) withdrawn.[96/] In our opening Comments, we argued that the proposed STELs have not been adequately supported.[97/] The limited evidence that has been adduced on this issue since we filed our Comments confirms our belief.

A STEL, like an 8-hour PEL, must be shown to serve a demonstrated health need. As we explained in our Comments, a STEL can serve a demonstrated health need in three situations:

1. Where there are recognized acute toxic effects that are independent of the total daily dose;
2. Where there is a demonstrated dose-rate response for a chronic health effect; or
3. Where a STEL is feasible and would further reduce a significant health risk that would remain even when compliance with the 8-hour daily limit is achieved.

In its testimony, NIOSH described the same three

96/ See CMA Comments at 16-17 & nn.44 & 45.

97/ See id. at 4-18.

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circumstances as justifying the imposition of a short-term ceiling value.[98/] NIOSH also emphasized that in selecting an appropriate ceiling value, "[a]n analysis of the data supporting the proposed limit must be conducted on a case-by-case basis . . . ."[99/] This same point was made by Earle W. Arp, Jr., who testified that

> "[t]he proposed STELs can be sustained . . . only if OSHA conducts an independent examination, on a chemical-by-chemical basis, of whether there is sufficient scientific support for a STEL."[100/]

In our Comments, we pointed out that OSHA has not made independent, supportable findings regarding the need for the proposed STELs. Instead, it has simply relied unquestioningly (and in some cases, mistakenly) on what it understood to be the ACGIH recommendations. This is not a statutorily sufficient basis for adopting STELs. As Jeremiah Lynch testified, "OSHA has a responsibility to perform its own analyses, to make its own evaluations, and to reach its own conclusions."[101/] It has not discharged that responsibility in the present case. Accordingly, the question whether STELs are appropriate for some or all of the

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98/ See NIOSH Testimony at 19.

99/ Id. See also Tr. at 3-117.

100/ Testimony of Earle W. Arp, Jr. (Ex. 8-60) at 3.

101/ Statement of Jeremiah Lynch on Behalf of CMA (Ex. 64) at 4.

chemicals for which they have been proposed should be left for resolution in a later proceeding.[102/]

IV. OSHA Should Phase-In the Requirement of Achieving the New PELs Through the Use of Engineering Controls.

In our Comments, we strongly supported the concept of phasing-in any requirement to comply with the new PELs through the use of engineering controls. Phasing-in such a requirement is particularly important in a proceeding where OSHA is establishing new PELs for hundreds of chemicals simultaneously, thereby requiring employers to assess multi-chemical exposures and to evaluate, design, install, and test engineering controls that will be adequate to achieve compliance with all of the applicable new PELs. This process may proceed relatively quickly in some workplaces, but is likely to take a great deal of time and effort in others. Accordingly, phasing-in the engineering control requirement over a period of years seems reasonable, particularly given the phase-in periods that OSHA has allowed in various single-substance standards.[103/]

102/ Cf. Testimony of Earle W. Arp, Jr. (Ex. 8-60) at 13-14; Oral Comments of the Synthetic Organic Chemical Manufacturers Association at 4.

103/ See CMA Comments at 19-20; Testimony of Charles Adkins, Tr. at 1-101, 1-102, and 1-308.

The concept of phasing-in engineering control requirements over a period of years was supported by various witnesses. Thus, Dr. Isadore Rosenthal expressed the belief that

> "OSHA's proposed strategy [of] staged implementation of control measures is appropriate. . . . [A]llowing companies to control exposures immediately with the best means readily available will provide for a substantial immediate increase in employee health protection while setting a future goal of a more structured control system.
>
> Staged implementation of engineering control measures will also allow companies to accumulate the knowledge needed to make the engineering changes and material substitutions needed for full compliance with the standard."104/

John Henshaw, testifying for the National Association of Manufacturers, also stressed that since the present rule "covers a vast number of chemicals . . ., a four-year phase-in period is the very least that should be allowed."105/

In short, phasing-in engineering control requirements over a period of four years is a reasonable approach to ensuring the feasibility of the broad-ranging reductions in permissible exposure limits that would be required under the proposed rule. As indicated in our Comments, however, OSHA should be mindful of

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104/ Testimony of Dr. Isadore Rosenthal, Tr. at 3-14 and 3-15.

105/ Testimony of John Henshaw, Tr. at 3-332.

developments in the separately scheduled proceeding to consider whether t preference given to engineering controls should be modified.[106] Furthermore, even if engine ing controls are generally afforded primacy, OSHA should expressly permit the use of respirators in those work operations (such as maintenance and repair, vessel cleaning, instrument calibration, and tank gauging) where exposure to air contaminants is intermittent in nature and limited in duration, or where exposure occurs for less than thirty days per year.[107]

V. OSHA Should Give Priority to the Development of Analytical Methods for Those Air Contaminants for which Adequate Analytical Methods Do Not Presently Exist.

In the notice of proposed rulemaking, OSHA indicated that it is not aware of adequate analytical or sampling methods for seven substances covered by the proposed rule.[108] Comments suggest that there may be other substances covered by the proposed rule which also do not have adequate analytical or sampling methods.[109] As we pointed out in our opening Comments, if an

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106/ See CMA Comments at 20-21.

107/ See CMA Comments at 21-23.

108/ See 53 Fed. Reg. at 20978, Table I-F-E; id. at 20979, col. 1.

109/ See, e.g., Comments of Inco United States, Inc. and Inco Ltd. on OSHA's Proposed Air Contaminants Rule, July 28, 1988.

adequate analytical method does not exist, employers cannot determine whether employee exposures are being maintained below the PELs, and OSHA cannot determine whether compliance with the standard is being achieved. Accordingly, we argued that if new PELs are adopted for these substances, OSHA should give priority to the development of appropriate analytical methods and should make clear that it will not enforce the PELs until an adequate analytical method has been identified.110/

Other participants in the rulemaking expressed similar views. For example, NIOSH stressed that

> "it is extremely important to note that for many substances listed in the update, there are no sampling and analytical methods available or the method given has not been validated by either NIOSH or OSHA. Also, many of the proposed methods are in-house OSHA methods which are not available to NIOSH or the general public for evaluation. Finally, there are methods whose Limit of Quantitation cannot support the proposed PEL or STEL. These problems are critical and must be corrected for proper enforcement of the regulation.
>
> Therefore, it is important that NIOSH and OSHA work together on a method development scheme that will allow the appropriate validated methods to be developed in a prioritized fashion . . . ."111/

110/ See CMA Comments at 36.

111/ NIOSH Testimony at 14; see Tr. at 3-107 and 3-108. At the hearing, Charles Gordon acknowledged that OSHA's "in-house" analytical methods have not been published or made available for public scrutiny and comment. See Tr. at 3-193 and 3-194.

Similarly, Dr. Isadore Rosenthal stated that "[a] determination of compliance with an exposure limit is not feasible if there is no method of determining exposures below the PEL value that OSHA proposes."[112/] Consequently, Dr. Rosenthal urged OSHA to "delay the start of the period when a firm must control exposures via its standard hierarchical approach for any Z Table substance until it has concluded that it has a suitable monitoring method for the substance in question."[113/] He pointed out that OSHA also "must provide a suitable period of time for the regulated community to master these analytical methods, carry out monitoring, and start to take corrective action if the proposed standards are exceeded."[114/] This period, Dr. Rosenthal stated, "should begin only after OSHA has certified a feasible analytical method."[115/]

A number of other witnesses also expressed the view that OSHA either should postpone revising PELs for those substances that do not have approved sampling or analytical methods, or at least should defer implementing and enforcing the PELs until suitable sampling and analytical methods become available.[116/] We believe that this is sound advice and that priority

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112/ Testimony of Dr. Isadore Rosenthal (Ex. 25) at 10.

113/ Id.

114/ Id.

115/ Id.

116/ See, e.g., Testimony of Richard Boggs, Vice President of Organization Resources Counselors, Tr. at 3-268; Testimony of

[Footnote continued next page]

should be given to developing adequate sampling and analytical methods for the substances at issue.

VI. The Computational Formula in Section 1910.1000(f) of the Proposed Rule Should Be Applied to Multiple Chemical Exposures only when PELs for the Chemicals Have Been Set To Protect Against Similar Toxicological Effects on the Same Organ(s).

In our opening Comments, we argued that the computational formula set forth in Section 1910.1000(f) of the proposed rule should be applied only when the employee is exposed to two or more substances whose PELs have been set to protect against similar toxicological effects on the same organ(s).[117/] Limiting application of the formula in this way makes sense from a toxicological standpoint and is consistent with the approach taken by ACGIH.[118/]

At the hearing, a spokesman for the American Industrial Hygiene Association expressed a similar view, recommending "that OSHA adopt the guidance of ACGIH . . . or similar wording" to describe the circumstances in which the computational formula is to be used.[119/] John Henshaw, testifying for the National

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[Footnote continued from preceding page]

John D. Yoder on Behalf of the American Industrial Hygiene Association, Tr. at 3-304; Testimony of John Hinshaw on behalf of the National Association of Manufacturers, Tr. at 3-332.

117/ See CMA Comments at 37-38.

118/ See id.

119/ Testimony of John D. Yoder, Tr. at 3-307 and 3-308.

Association of Manufacturers, also urged OSHA to amend the relevant regulatory provision to make clear that the computational formula should be used only "where there are exposures to two or more materials which have similar target organ effects at or near the control concentration . . . ."[120/] We trust OSHA will clarify the application of the computational formula along these lines in the final rule.

VII. Vinylidene Chloride Should Not Be Regulated as an Occupational Carcinogen.

In its testimony, NIOSH recommended that vinylidene chloride ("VDC") (also referred to as 1,1-dichloroethylene) be designated a carcinogen and be "controlled as specified for vinyl chloride in 29 CFR 1910.1017 with eventual goal of zero exposure."[121/] Since OSHA did not propose to regulate VDC on the basis of carcinogenicity, the NIOSH recommendation, even if it were properly supported, could not lawfully be adopted unless OSHA issues a new (or revised) rulemaking proposal, explains the basis for the proposed action, and provides an opportunity to comment thereon. In fact, however, the NIOSH recommendation is not supported by the scientific evidence, much of which was submitted for the record on October 7, 1988 as Attachment II to CMA's Post-Hearing Evidence.

120/ Testimony of John Henshaw, Tr. at 3-334 and 3-335.

1. NIOSH Testimony at 8-9 and NIOSH Table N6B.

The potential oncogenicity of VDC and the metabolic and pharmacokinetic differences among animal species have been studied extensively. Seventeen long-term studies have been negative for carcinogenicity. Only one of the eighteen studies reported showed a positive response, and that was only in the kidneys of male Swiss mice.[122/] As a result of pharmacokinetic/metabolism studies, a consensus has developed among scientists regarding the mechanism by which the tumors were produced in the single positive study. The oncogenic response, or lack thereof, in the various species studied correlates with the extent to which the species metabolizes VDC to its toxic metabolites. An increased production of toxic metabolites in the mouse causes an increase in several toxicity endpoints. The oncogenic response in the Swiss mouse correlates with a high level of toxicity. The absence of an oncogenic response in other species correlates with lower levels of toxicity, which in turn correlate with reduced production of toxic metabolites.

Attachment II to CMA's Post-Hearing Evidence includes a paper entitled "Interpretive Review of the Animal Toxicological, Pharmacokinetic/Metabolism, Biomolecular and In-Vitro Mutagenicity Studies on Vinylidene Chloride and the Significance

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122/ Maltoni, et al., "Experimental Research on Vinylidene Chloride Carcinogenesis," in Archives of Research on Industrial Carcinogenesis (Maltoni, C. and Mehlman, M.A., eds.) Vol. 3, Princeton Scientific Publishers, 1985.

of the Findings for Man" by J. M. Norris and R. H. Reitz ("Interpretive Review"). The Interpretive Review presents a comprehensive overview of data relevant to an effort to extrapolate from the existing animal data on VDC to the prediction of potential human cancer risk. It demonstrates that VDC is unlikely to pose an oncogenic risk to humans. While the Interpretive Review should be read in its entirety, the essence of the analysis is as follows.

Animal bioassays with VDC have been uniformly negative, with the one exception cited by NIOSH. Tumors were produced in the kidneys of male Swiss mice in the Maltoni inhalation study at VDC concentrations that were toxic and near the acutely lethal concentration.[123/] There is considerable evidence of the greater sensitivity of this strain of mouse to the toxic effects of VDC. The single positive oncogenicity study appears to be related to the significant tissue injury in male mice exposed to VDC.

The greater sensitivity of the mouse to the toxic effects of VDC can be attributed to physiological and biochemical factors. Studies have shown that the mouse has a greater capacity to metabolize VDC to the reactive metabolite(s) than does the

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123/ EPA Office of Health and Environmental Assessment, "Health Assessment Document for Vinylidene Chloride," August 1985. Maltoni, et al., 1977 reported a high degree of toxicity and mortality within one week at 200 ppm, 100 ppm and 50 ppm in the Swiss mouse (p. 19-91).

rat. Since the availability of the reactive metabolite(s) is greater in the mouse than in the rat, there is a much greater potential for these metabolite(s) to react with cellular macromolecules and cause toxicity. DNA repair, measured directly in mice exposed at the dose which resulted in kidney tumors, showed a small but significant increase only in the kidneys of the mice. Tissue damage in the kidneys of mice was observed immediately after cessation of exposure. Factors which support the conclusion that the mouse tumors arose by a non-genetic mechanism, namely, recurrent tissue damage, include the following: (1) the inability to demonstrate significant DNA alkylation at a tumorigenic dose, (2) the reported dose-related tissue damage, and (3) increased DNA replication in the kidneys of mice.[124/]

The following 17 long-term animal toxicity and/or oncogenicity studies involving VDC produced negative results:

(1) Inhalation study with Sprague-Dawley rats.

Negative results were reported by Maltoni, et al., 1985.

(2) Inhalation study with Chinese hamsters.

Negative results were reported by Maltoni, et al., 1985.

124/ See also U.S. Environmental Protection Agency, "Drinking Water Criteria Document for Dichloroethylenes (1,1-Dichloro-ethylene, cis-1,2-Dichloroethylene, and trans-1,2-Dichloroethylene) (Draft)," December 1984 ("EPA Criteria Document"), at VII-I.

(3) Gavage study with Sprague-Dawley rats.

Negative results were reported by Maltoni, et al., 1985.

(4) Inhalation study with Wistar rats.

Negative results were reported by Viola and Caputo, 1977.

(5) Inhalation study with Sprague-Dawley rats.

Negative results were reported by Viola and Caputo, 1977.

(6) Inhalation Study with CD-1 mice.

Negative results were reported by Lee, et al., 1978.

(7) Inhalation study with CD rats.

Negative results were reported by Lee, et al., 1978.

(8) Inhalation study with Sprague-Dawley rats.

Negative results were reported by McKenna, et al., 1982.125/

(9) Ingestion study with Sprague-Dawley rats.

Negative results were reported by Quast, et al., 1983.126/

(10) Inhalation Study with CD mice.

Negative results were reported by Hong, et al., 1981.

(11) Inhalation Study with CD rats.

Negative results were reported by Hong, et al., 1981.

(12) Skin application study with Ha:ICR Swiss mice.

125/ A copy of this study was submitted in Attachment II to CMA's Post-Hearing Evidence.

126/ A copy of this study was submitted in Attachment II to CMA's Post-Hearing Evidence.

Negative results were reported by Van Duuren, et al., 1979.

(13) Subcutaneous injection study with Ha:ICR Swiss mice.

Negative results were reported by Van Duuren, et al., 1979.

(14) Inhalation study with Sprague-Dawley rats.

Negative results were reported by Maltoni, et al., 1982.

(15) Gavage study with Sprague-Dawley rats.

Negative results were reported by Maltoni, et al., 1982.

(16) Gavage study with Fischer 344 rats.

Negative results were reported by NTP, 1982.127/

(17) Gavage study with B6C3F1 mice.

Negative results were reported by NTP, 1982.128/

Furthermore, the oncogenicity observed in the Swiss mouse in the single positive study is not considered applicable to man. The rate of oxidative metabolism for halogenated hydrocarbons such as VDC appears to be related to body surface area, rather than body mass. Thus metabolic activation would occur more slowly in man than in small laboratory animals. This observation is consistent with findings of Reitz, et al.

127/ A copy of this study was submitted in Attachment II to CMA's Post-Hearing Evidence.

128/ A copy of this study was submitted in Attachment II to CMA's Post-Hearing Evidence.

(1980),[129] and Jones and Hathway (1978)[130] who demonstrated that the rat metabolizes less VDC than the mouse; Anderson, et al. (1980),[131] who related the slower rate of metabolism of VDC in man versus the rat to the rate of pulmonary uptake; and Walker (1978),[132] who reported that significant metabolic dissimilarities exist between man and the mouse relative to the monooxygenases which catalyze the metabolism of VDC to the reactive metabolites.

In sum, the animal data do not provide a basis for concluding that VDC should be treated as an occupational carcinogen. The available human data also fail to support any such conclusion. Thus, an epidemiological study of employees working in a VDC facility has documented no adverse health effects or carcinogenic effects associated with VDC exposure.[133]

129/ Reitz, et al., "Effects of Vinylidene Chloride on DNA Synthesis and DNA Repair in the Rat and Mouse: A Comparative Study with Dimethyl Nitrosamine," 52 Toxicol. Appl. Pharmacol. 357-370 (1980).

130/ Jones and Hathway, "Differences in Metabolism of Vinylidene Chloride Between Mice and Rats," 37 Brit. J. Cancer 411-417 (1978).

131/ Anderson, et al., "Determination of the Kinetic Constants of Inhaled Toxicants In Vivo Using Gas Uptake Measurements," 54 Toxicol. Appl. Pharmacol. 100-116 (1980).

132/ Walker, "Species Differences in Microsomal Monooxigenase Activity and Their Relationship to Biological Halflife," 7 Drug Metab. Rev. 295-323 (1978).

133/ Ott et al., "A Health Study of Employees Exposed to Vinylidene Chloride," 18 J. Occupational Med. 735-738 (1976).

NIOSH's recommendation and the Current Intelligence Bulletin 28 on which it is based suggest that regulation of VDC is justified by the structural similarity between VDC and vinyl chloride. While it may be appropriate in some circumstances to consider structural relationships where there is no toxicity data for one of the "related" substances, it is entirely inappropriate to give any weight to structural similarity when actual test data demonstrate toxicological dissimilarities between the substances. Any significance placed on structural similarity between VDC and vinyl chloride is negated when the toxicity data for the two substances are considered. In view of the extensive toxicity data, evidence of structural similarity to vinyl chloride has no bearing on an assessment of VDC's potential risk.

In short, the available evidence does not justify regulating VDC as an occupational carcinogen, and NIOSH's contrary suggestion would have to be rejected even if it had been set forth in the rulemaking proposal. Since it was not, the question whether to treat VDC as an occupational carcinogen should not even be considered in this proceeding.

Conclusion

As indicated in our opening Comments, CMA strongly supports the concept of updating the Z-Table PELs to reflect advances that have been made since 1971 in the understanding of potential occupational health risks. We also believe that OSHA has acted reasonably and sensibly in seeking to reduce the PELs to consensus levels quickly, while scheduling ancillary matters for consideration in a separate rulemaking or series of rulemakings. For the reasons discussed above, however, we believe that ACGIH TLVs, rather than NIOSH RELs, should be used as the basis for updating the Z-Table limits and that the adoption of STELs at the present time is not adequately supported by the rulemaking record.

In our Comments and in this Post-Hearing Brief, we have made a number of suggestions which, if followed, would produce a final rule that provides significant improvements in employee health protection while respecting the statutory requirements that apply to the adoption of occupational health standards. Additional actions, such as the adoption of generic monitoring and/or medical surveillance requirements, can be considered in separate rulemakings. We look forward to working with OSHA to develop appropriate proposals to deal with those issues in the near future.