PB91-212688

NIOSH Comments to DOL

August 14, 1986

Mr. Tom Hall
U.S. Department of Labor
Occupational Safety and Health Administration
Division of Consumer Affairs
Docket No. H-225A
Room N-3662
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Enclosures and/or attachments that are not included are available free of charge from the NIOSH Docket Office (513/533-8450).

Dear Mr. Hall:

Posthearing comments submitted to the Occupational Safety and Health Administration (OSHA) by various parties following the regulatory hearing on formaldehyde have been reviewed by the NIOSH testimony team, and the following comments are submitted by specific docket document number:

1. In the testimony submitted by Dr. Philip Cole [Document No. 118], it is argued that Stayner has used an unconventional criteria of statistical significance, and that confidence limits and p-values should not be used for making public policy, but instead public policy should be based on "coherent patterns in data." The Stayner et al. (1986) report used a one-sided statistical test to evaluate study results. As indicated in NIOSH's review of the Blair et al. study, it is recognized that scientists debate the appropriateness of using a one-sided versus a two-sided statistical test. The NIOSH review quoted the recent text by Kleinbaum, Kupper, and Morgenstern where it is indicated that, "In most applications, one is interested in determining whether an exposure is detrimental, and that is why the one-sided alternative is used. . . ." Further, the NIOSH review indicated that the use of a one-sided statistical test seemed to provide the greatest reassurance against missing an exposure-related effect, especially when evaluating the effects of a suspected carcinogen on a suspected target organ system, i.e., the "a priori" hypothesis. These considerations led Stayner, et al. to use a one-sided statistical criterion.

   Additionally, while it is agreed that "coherent patterns in data" are reassuring for developing public policy, the characteristics of the data influence the ability to deduce coherent patterns. Some of the studies of formaldehyde-exposed individuals were relatively small, included relatively brief time for observation of latent diseases,

involved quite varied exposure scenarios (e.g. confounding exposures from other agents, variable patterns of formaldehyde exposure, and exposure to low, possibly nonreliably quantifiable concentrations of exposure) and were conducted in diverse geographical locations. In such situations, it is necessary to consider the relative merits of the available studies and to weigh the evidence which can be obtained from the individual studies in addition to just the overall coherent patterns.

2. The memorandum from Edward Zimowski to Susan Sherman and John Martonik [Document No. 125] presents OSHA test data from 1982-1984 on passive monitors for formaldehyde, and are consistent with the NIOSH findings on these devices.

3. With regard to the information submitted by Burlington Industries, Inc. [Document No. 136], it would be helpful to know the type of production processes (i.e. textile treating process or garment manufacture) which are represented in the various exposure levels for the numerous plants as reported for the years 1984, 1982, and 1980. It would be informative to know the number of workers potentially exposed in each plant, the sampling method employed in each plant, the number of samples obtained to place a plant in each category, the range and mean of sample results, and whether these results represent 8-hour exposure determinations vs. short-term exposure results.

4. With regard to the Formaldehyde Institute (FI) submission [Document No. 139] on page 34, relative to Dr. Emmett's testimony concerning formaldehyde exposure levels and post-cure treatment processes in apparel manufacture, it is probably true that post-cure processes result in higher exposures than pre-cure processes. It is also probably true that the improved resin systems have substantially reduced formaldehyde exposures from both types of processes. Since the industry is changing from the post-curing to pre-curing process, and improving the formaldehyde resin system to reduce free formaldehyde, it appears likely that lower exposure levels are feasible.

   It would be helpful in evaluating statements made in the FI submission if the references were included which document other chemicals in garment manufacturing thought to be associated (bottom of page 36) with symptoms similar to those of formaldehyde exposure.

5. There were several points in the information from the Motor Vehicle Manufacturers Association (MVMA) submitted by the FI [Document No. 139-A] which should be responded to:

   a. Attachment II from the MVMA information includes data on 982 measurements in nine foundries. These data are presented in the form of a histogram and indicate that 70% of the sampling results were above 0.5 ppm and 35% above 1 ppm. This data analysis assumes that there were no differences in the level of control between

individual companies and plants within those companies. To support this assumption, the data should be further analyzed to ascertain the levels of control achieved in each plant and to determine which were the "best" of these foundries.

b. Attachment III from the MVMA information lists an item by item response to the United Automobile, Aerospace and Agricultural Implement Worker's International Union (UAW) recommendations. The MVMA responses are based on their analysis of the summary data presented in their Attachment II cited above. Only in response to UAW recommendation No. 2 for a supply air system does the MVMA have specific data cited; this control reduced exposure by a factor of two (Reference MVMA Attachment IV). In response to recommendation No. 5, MVMA notes that the curing cycle is process-dependent; adding an off-gassing period to the curing cycle may decrease productivity but would not change product quality. MVMA states, in response to recommendation No. 9, that low formaldehyde hot-box resins have been used but have not reduced levels below 0.5 ppm. Does this response mean to imply that the low resin technology has reached a plateau? It is quite possible that further improvements are possible which could reduce exposure levels even further.

c. Attachment IV of the MVMA information discusses industrial hygiene aspects of formaldehyde use in the foundry. On page 3 of that attachment, MVMA acknowledges that other processes exist which release less formaldehyde, but states that new tooling is required. It should be noted that changes in product also require changes in tooling, and that many alternate processes require less costly tooling than that used with the hot-box system (in other words, the cost of tooling changes in the hot-box system should not be viewed in isolation from the cost of tooling changes for other systems which could be used to further reduce exposure). MVMA notes that some ventilation systems are similar to that depicted in ACGIH Design Specification VS-114. This specification is for shell type cores as was noted in NIOSH's earlier posthearing comments (June 27, 1986). Use of this design for hot-box cores would require larger air volumes due to increased quantity of sand/resin (resulting in greater release of heat and formaldehyde).

6. The posthearing comment submission from E.I. duPont de Nemours and Company [Document No. 140], summarized the Blair et al. (1986) study as showing a nonsignificant excess of lung cancer, unrelated to dose, and the Stayner et al. (1986) epidemiologic study as showing a similar excess of lung cancer with no relationship to dose. They further state on page 2, that "Despite the the [sic] fact that few chemicals have been as widely studied as formaldehyde there remains a lack of evidence indicating that formaldehyde is carcinogenic to man." As the NIOSH testimony indicates, we believe contrary to the E.I. duPont de Nemours interpretation and recommend that formaldehyde be regarded as a potential occupational carcinogen. DuPont's position does not

acknowledge the statistically significant excess of lung cancer among formaldehyde-exposed workers with at least 20 years since first exposure observed in the Blair et al. study, nor does it acknowledge that both the Blair et al. and the Stayner et al. studies observed statistically significant excesses in nasopharyngeal or buccal cavity cancers in formaldehyde-exposed workers. While these data do not demonstrate a dose-response relationship, they should not be described with the wording, "a lack of evidence indicating that formaldehyde is carcinogenic in man."

Additionally, the human evidence cannot be evaluated in isolation. Bioassay data released by Kerns et al. demonstrated significant excesses of squamous cell carcinomas in the nasal cavity of both male and female Fischer 344 rats and the observation of the same tumor in the nasal cavity of C57BL/6 X C3H F_1 male mice. Bioassay data released by Albert et al. demonstrated a significant excess of squamous cell carcinoma in the nasal cavity of male Sprague-Dawley rats. As indicated in the NIOSH testimony, the animal information alone is sufficient to classify formaldehyde as a category I carcinogen as described in the OSHA Carcinogen Policy (29 CFR 1990). The animal data emphasize the biological plausibility for an association between formaldehyde exposure and respiratory system cancers in humans as reported by Blair et al, Stayner et al., and others.

7. As reported in the study by Health and Hygiene, Inc., submitted by the American Apparel Manufacturer's Association [Document No. 143], the 14 facilities surveyed were not randomly selected by the consultants doing the study. As stated in the report, "These facilities were selected by the companies who volunteered to participate, companies which for the most part are large apparel companies with ventilation and other capabilities that probably exceed those available in the smaller apparel companies." It is noteworthy that the majority of the higher levels detected (0.54 ppm-1.00 ppm) were observed in post-cure process operations. These observations were short-term exposures (90 minutes), not 8-hour time-weighted averages. NIOSH believes that the last sentence of the report would be more accurate if it read, ". . . . a wide variety of post-cure operations which, ..."

8. In Dr. Blair's submission to OSHA on July 14, 1986 [Docket No. 156-A2], he observed on page 11 of the corrections and additions to his testimony that a summary statement of the discussion in the NIOSH epidemiologic report by Stayner et al. changed between the time he first reviewed the paper and the time the report was released to the public and at the OSHA hearing. NIOSH has a formal peer review procedure. This procedure includes internal scientific and administrative review, and external scientific review before a paper is released. Dr. Blair was one of several external peer reviewers for the report by Stayner et al. Mr. Stayner not only considered Dr. Blair's comments, but also those of the other external and internal peer reviewers in preparing the final paper which was publicly released.

The change which Dr. Blair refers to was a result of addressing comments received from the reviewers. These reviewers believed that the study should stand on its own and not rely on the weight of evidence from other studies to make interpretations of this study's findings. Mr. Stayner's revisions were approved within the Institute prior to the public release of the final report.

If there are any further questions or information that you require after receiving all of the posthearing comments, please feel free to contact NIOSH to assist you in preparing the final rulemaking.

Sincerely yours,

Richard A. Lemen
Director
Division of Standards Development
and Technology Transfer

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