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July 16, 1986

Roy T. Gottesman, Ph.D.
THE VINYL INSTITUTE
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Wayne, New Jersey 07470

Re: OSHA Regulation of PVC Resins and Compounds

Dear Roy:

As we discussed previously, on July 11, 1986 I met with John Miles, Director of the Occupational Safety and Health Administration's (OSHA) Directorate of Field Operations, to discuss the status of polyvinyl chloride (PVC) resin and compound under the OSHA vinyl chloride standard and the Hazard Communication Standard (HCS). Mr. Miles was accompanied by Roy Gibbs and Gail Brinkerhoff. Our objective is to obtain an opinion letter from OSHA indicating that PVC is not a hazardous chemical under the Hazard Communication Standard and that vinyl chloride homopolymer and copolymer resins and compounds do not trigger the labeling and training provisions of the vinyl chloride standard when no exposure to vinyl chloride monomer (VCM) at or above the action level of 0.5 parts per million (ppm) is anticipated.

The meeting was less than satisfying. Mr. Miles had just returned from travel and vacation and, although he was courteous enough to schedule a meeting promptly, he had not had the opportunity to review the prior correspondence or these issues in general. Messrs. Gibbs and Brinkerhoff took a "zero threshold" "one hit" position that PVC is inherently unsafe because some amount of VCM will remain in the resin. To say

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the least, I was quite distressed with this Neanderthal approach.

It is my recommendation that we develop some additional materials for submission to Mr. Miles and indicate that, if he is inclined to follow the preliminary views of Messrs. Gibbs and Brinkerhoff in resolving this question, we be granted a meeting with Mr. Miles, the Assistant Secretary for Occupational Safety and Health (John Prendergast) and the Associate Solicitor for Occupational Safety and Health (Frank White). Such a meeting should include representatives from the Vinyl Institute with health science, regulatory and management expertise to make the most persuasive presentation possible. Because a number of OSHA citations have already been issued, it is obvious that there is an important and immediate need to resolve this issue.

A. Meeting Summary

Before expanding on the nature of the meeting, I should note that Roy Gibbs has played an influential role within OSHA in describing the relationship between the Hazard Communication Standard and other Agency standards. For example, he was the author of the Agency material describing the relationship between HCS and the access to medical records rule.

The meeting began with my reviewing the information and materials in our letter of June 18, 1986. The first question that I attempted to review was whether OSHA viewed PVC itself as a hazardous chemical under the Hazard Communication Standard. Although the staff did not indicate any concern with PVC homopolymer, they considered the residual vinyl chloride monomer (RVCM) question to be "inseparable." At first, Mr. Brinkerhoff indicated that any of the subcutaneous particle insertion studies showing local tumor growth, in the absence of evidence to the contrary, would require carcinogen labeling. When I responded that this would require carcinogen labeling on wood, wool, glass and other materials, Mr. Gibbs indicated that what they meant was that since there is residual vinyl chloride monomer, OSHA must assume that the local growth around the particle is a result of the RVCM level in the PVC polymer. They also suggested that there was a relationship between the RVCM level in the particle and the likelihood of tumorigenic response.

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This led to their contention that there was no safe threshold for carcinogens. This means that any PVC resin or compound would be required to carry the carcinogen warning label due to the presence of vinyl chloride, however minute, and that the training requirements would also apply. In response, I noted that the Secretary of Labor had taken a contrary position in prior litigation and that imposing a training requirement would make no sense. Companies would be forced to advise workers about the health effects of vinyl chloride monomer and then inform them that exposure was so low there was nothing to do or worry about.

Mr. Gibbs went on to raise some extraneous issues on the Hazard Communication Standard. For example, he expressed the opinion that since injection heads may clog from time to time, that workers should be informed of the thermal decomposition products of PVC resins and compounds, including carbon monoxide and chlorine, which he assumed would create some significant exposure to hydrogen chloride. He also raised the question of meat wrappers' asthma from the hot wire melting of PVC film. I disagreed with his assessment on both. To forestall any precipitous and adverse response from OSHA, I indicated that I would supply additional information in response to the staff comments.

The only saving grace in this meeting was Mr. Miles' concluding remarks that the Agency had not reached a position and that we should not do anything "rash" until we had a further opportunity to discuss this issue.

B. Proposed Strategy

Because Mr. Miles has not taken a position or involved himself substantially in this matter, I recommend that we begin by preparing another submission to address the subcutaneous particle question, the meat wrappers' asthma allegation and whatever other materials we feel would strengthen our scientific argument on the safety of low RVCM resins. In addition, I propose including a section on the legal constraints within which OSHA must operate, with a clear indication that the Agency's current course is at odds with its statutory mandate.

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Our letter should request that, if Mr. Miles is inclined to follow the preliminary staff recommendation and require the carcinogen labeling regardless of the RVCN level, we meet with him, the Associate Solicitor and John Prendergast. At that meeting, we should be prepared to make a presentation on the practical effects of OSHA's position, the health science underlying our position and the supporting legal arguments. This would necessitate assembling a small group within the Vinyl Institute to prepare such a presentation. In the interim, I will contact some OSHA staff members who are more familiar with the history of the OSHA PVC standard and see whether they will pass favorable views along to Mr. Miles.

As you suggested, this whole topic is appropriate for the Health, Safety and Environment Committee meeting which we will be attending on July 17 and 18. In addition, I would appreciate hearing the views of others receiving a copy of this letter.

Sincerely,

Peter

Peter L. de la Cruz

cc: Robert D. Luss, Esq.
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