



CHEMICAL MANUFACTURERS ASSOCIATION

July 1, 1992

TO: Health and Safety Committee
Health and Safety Contacts
State Affairs Contacts
Risk Assessment Task Group
Exposure Assessment Task Group
Existing Chemicals Testing Task Group

RE: Recent EPA View on the Human Relevance of Animal Carcinogens

Attached for your information is a recent letter from EPA articulating a policy view that not all findings of carcinogenicity in animal studies are relevant to humans. EPA has included this view in a letter to the National Toxicology Program in reaction to that organization's Annual Report on Carcinogens.

The Annual Report on Carcinogens is a federally mandated report that serves as an automatic trigger for numerous regulatory reporting requirements at both the federal and state levels. Most notable among such requirements include OSHA's Hazard Communication Standard and more than 20 different state Right-to-Know laws. CMA has objected to the use of the Annual Report as an automatic trigger for reporting, labeling and other regulatory requirements because NTP does not include an evaluation of all available data and information on a chemical as part of the evaluation included in the Annual Report.

This recent EPA letter enforces the importance of going beyond a simple evaluation of whether a material can cause tumors in animal models. EPA cites a number of examples where a tumor response observed in animals is not necessarily viewed as relevant to human carcinogenicity. This view has important implications not only to the Annual Report on Carcinogens, but to numerous other chemical lists that are based in part on NTP's Annual Report. These views are also relevant to the International Agency For Research on Cancer (IARC) Monograph series, which also does not include information relating to mechanism and exposure in evaluating animal cancer data.

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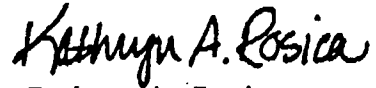
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This information may be helpful to you in understanding the limitations for some of the available chemical lists that are frequently incorporated into numerous different laws and regulations. If you have any questions, please contact me at 202-887-1282.

Sincerely,



Kathryn A. Rosica
Director
Health and Safety

Enclosure

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