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LAW DEPT. TONIC SUBSTANCES MANAGEMENT MEMO

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CRAC ACTIVE ON MANY FRONTS

Highlights of recent reports of MCA's Chemical Regulations Advisory Committee show progress in a number of areas of concern and include:

Section 4--Testing

No significant EPA advances in testing standards or protocols have been reported, but EPA will hold public meetings this spring to review their status. The schedule is:

- March 15-16--New Orleans.
- March 27-28--New York.
- April 10-17--Chicago.
- April 19-20--San Francisco.
- May 1--Washington.

More direct contact will be made with EPA principals responsible for policies and procedures for testing and carcinogenicity policy. The policy is expected to be published sometime this month.

The effects of this activity due to the recent coordination of toxicological research by the National Cancer Institute, Food and Drug Administration, National Institute of Environmental Health Sciences and National Institute for Occupational Safety and Health could not be predicted. However, the committee believes that the evidently poor quality of research by regulatory agencies must be recognized and countered.

For additional information about subjects mentioned in this memo, contact Jim Turner at MCA. His number is (202) 328-4286.

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The Interagency Regulatory Liaison Group's report on 24 "hazardous substances" discusses further action for each substance, including additional testing.

Section 5--Premanufacturing Notification

Covington and Burling, represented by Peter Hutt, has been engaged to develop positions on the issues of invalidity and confidentiality.

Section 8--Reporting

Subsection (a). EPA's work group is believed to be preparing a sequel to its controversial first draft, but none has yet been made available.

Subsection (c). EPA's request for statistics for "significant adverse reactions" (SAR) had produced few responses, and these are at a level of 0.5-1 per 1,000 employees per year. A clearer understanding of the definition of SAR probably would increase the response level; similarity to Section 8(e)'s "substantial risk" is evident.

Subsection (d). EPA's denial of MCA's petition to revise or withdraw the final rule for this subsection was evaluated. It was agreed that the legal affairs task group develop legal support for the two essential issues (mandatory reporting of R&D substances in health and safety studies and of substances in a Section 4(e) category other than the one manufactured), and prepare a critique of EPA's denial for transmittal to assistant administrator Steven Jellinek.

Subsection (e). A proposed Question and Answer Bulletin on Notification of Substantial Risk is no longer timely. Likewise, outside counsel's paper on legislative history and definitions of key terms should be held in abeyance.

Subsection (f). Concerning labelling issues in Section 6 (c) (3), no date has been established for the intended meeting between representatives of the Occupational Safety and Health Administration and EPA's Cynthia Kelly.

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The Du Pont Company's Edward Bartkus has suggested a joint federal-industry effort as an alternative to EPA's proposed Chemical Regulations Guidelines System authorized under Section 10 of TSCA. Several private information-service contractors are reported to be actively soliciting trade association support for non-federal programs. The situation will be monitored.

Legal Affairs

MCA has submitted comments on EPA's proposed approach to implementing TSCA.

EPA's Dec. 7, 1978 public meeting on Section 8(e)--Notification of Substantial Risk--was described as "not constructive." The Committee agreed that there is no legal justification at this time for proposing changes in the policy statement for this section.

Economic Impact Study

The criteria for selecting nominees for the advisory panel were discussed, as were procedural problems apparent in balancing the need for confidentiality with that for credibility. Another issue being dealt with is the construction of cost-effective questionnaires.

Economic Impacts Study Contacts are invited to attend a project briefing meeting at either the Hyatt Regency Hotel in Houston January 24 or the Washington Hilton Hotel in Washington February 7.

Meeting attendees should come prepared to discuss potential cost impact of TSCA's Sections 4, 5, 6, 8 and 12 on their company and also be familiar with current organizational ability and limitations to identifying these costs within the accounting system.

U. S. member companies who have not as yet designated an individual as MCA/TSCA Economic Impacts Study Contact or who desire further information on the meetings planned for January 24 and February 7 should contact Henry Sauer at MCA on (202) 328-4261.

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International Issues

During early March, an MCA contingent will meet in Europe with representatives of the European chemical industry's trade associations and the supranational groups, the Council of the European Federation of Chemical Industries and the Organization for Economic Cooperation and Development to exchange views on TSCA.

The International Center for Industry and Environment will meet January 24-25 at the U. S. Chamber of Commerce headquarters in Washington. CRAC will be represented.

Educational Meetings

The American Chemical Society has scheduled a symposium on "The Impacts of TSCA" September 11-12 in Washington. George Ingle and John Behun will cochair the event.

A joint Harvard/MIT program is being developed for a tentative 1979 course on risk/benefit in toxicology. MIT plans a 10-week course for government and industry toxicologists, tentatively in mid-1979.

UCLA will sponsor a seminar February 25-March 2 on "The Evaluation of Public Programs and Regulations: Applications of Decision Analysis."

The next CRAC meeting will take place February 21 at MCA headquarters in Washington.

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