

A G E N D A

MEETING OF THE CMA BOARD OF DIRECTORS
Monday and Tuesday, January 11 and 12, 1982
Grand Ballroom, Arizona Biltmore
Phoenix, Arizona

TAB

Monday, January 11, 1982 - 8:00 a.m.

8:00-8:01 1. Call to Order -- Chairman Creffice

COMMITTEE CHAIRMEN REPORTS

8:01-10:00 2. Communications Committee
Chairman: M. C. Carpenter, The Dow Chemical Company

10:00-10:35 3. Chemical Regulations Advisory Committee
Chairman: E. Hamilton Hurst, Nalco Chemical Company

10:35-11:10 4. Patent and Trademark Committee
Chairman: Richard G. Waterman, Dow Chemical U.S.A.

11:10-11:45 5. Occupational Safety and Health Committee
Chairman: Thomas F. Evans, Monsanto Company

ASSOCIATION ACTIVITIES

11:45-11:55 6. Member Services Report -- Victor H. Peterson

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LUNCH (North Patio)

This Board meeting will continue Tuesday,
January 12, 1982, beginning at 9:00 a.m.
in the Grand Ballroom.

Next meeting of the Board of Directors: 2:00 p.m., Tuesday, April 6, 1982, CMA
Board Conference Room, Washington, D. C.

CMA 073515

Chemical Regulations Advisory Committee

Report to CMA Board of Directors

January 11, 1982

I interpret my assignment today to be one wherein I should highlight for you the activities of your Chemical Regulations Advisory Committee (CRAC) as they pertain to the implementation of the Toxic Substances Control Act (TSCA) and to indicate our thinking and plans for the coming year.

You have in your premeeting papers, a detailed summary prepared by the CMA staff which covers all of the activities that CRAC has carried out this past year. Perhaps this summary or my remarks will create some questions from the group to which I can respond at the end of this prepared presentation.

Before I can effectively present to you the highlights of our past activities and plans for the future, it is appropriate that we spend a few minutes summarizing the present status of implementation of the law.

I. CURRENT STATUS

Just ten days ago, TSCA celebrated its fifth birthday. It hardly seems like it has been five years since the law went into effect, but that's the way it is -- "time passes quickly when you are having fun."

What has been accomplished in five years with TSCA? The answer to that question depends on the perspective of who is answering. The Regulators (EPA) would point with pride to the publication of the TSCA Inventory listing some 60,000 chemicals manufactured and/or marketed in the U.S. The Agency would extol their efforts in implementing the Premanufacture Notification (PMN) System in which over 1,100 new chemicals have been processed in the 2-1/2 years it has operated. The third point of accomplishment would be the Section 8(e) Substantial Risk Report System, wherein 420 reports have been received and reviewed.

EPA says they have accomplished a lot in just five years! The environmentalists, however, answer the question differently. From their point of view the inventory, while published, was months late. The PMN system rules, while proposed, have never been finalized. They believe the Agency is accepting PMNs from industry with insufficient data and testing on new chemicals particularly toxicological testing data. For existing chemicals, no test rules have been finalized. The Agency has regulated only a few existing chemicals -- Polychlorinated biphenyls (PCBs), disposal of dioxins and certain uses of chlorofluorocarbons and asbestos. The

regulation of PCBs was required in the law itself and even then EPA's regulations were arbitrary resulting in a lawsuit to begin new rulemaking. In short, the environmentalists believe TSCA has not been implemented. The law is five years old and the Agency is still not doing what Congress intended it to do.

From the position of those being regulated (industry), irrespective of the pace of EPA in putting rules into final form, TSCA is working, it is accomplishing the job intended by Congress. The Inventory is published, although not completely -- reportedly some 5,000-6,000 chemicals have not been listed publicly. The PMN System has not been finalized, and the system proposed by EPA should not be finalized. The current interim system is operating fairly smoothly and industry can best communicate the risks or lack of risk associated with a new chemical in the "free-style" dialogue approach now being used. The Agency has demonstrated in over 1,100 cases now that it can effectively review new chemicals for unreasonable risk using this approach.

The development of test protocols has been a slow process and it has delayed EPA's issuance of test rules. In the meantime, numerous industry-initiated test programs have commenced on products needing additional testing, whether brought into the health and safety spotlight by EPA or the companies' own initiative. Cooperative testing programs permitted under TSCA are taking place -- even though the rules are not in place to require such programs. From industry's point of view, TSCA is working -- new chemicals are subjected to PMN review and testing of existing chemicals is taking place.

The first five years of TSCA have seen numerous rules proposed by the Agency. CRAC and CMA members have reviewed these and in almost all cases, found the proposals to be either overly burdensome, beyond the intent of Congress, or unworkable or unmanageable for either the Agency or the industry. To date, we have seen none of these types of rules finalized. Under the current Administration, many of the proposed rules are being reworked, almost from scratch, we are told. Just how the new philosophy of EPA will be translated onto paper in the form of rules is difficult to predict, but we are hopeful.

II. MAJOR CRAC EFFORTS IN 1980-81

I mentioned earlier that there have been numerous activities wherein CRAC has interacted with the Agency, Congress or with the environmentalists. I do not intend to take you through a long list of activities. I will highlight three areas of major strategical importance to us. In April 1981, CRAC testified before the House Subcommittee on Commerce, Transportation and Tourism at a TSCA reauthorization hearing. At that time, we outlined our concern with the EPA

implementation progress to date, continued to support the spirit of TSCA as passed by Congress, and recommended that TSCA not be amended at that time. It was interesting to note that neither the Agency nor the environmentalists, when specifically asked by Congressman Florio, requested amendments to TSCA. This seemed to be disappointing to the Committee as they (Mr. Florio) expressed concern over the lack of EPA accomplishments under TSCA. In fact, the House Subcommittee on Commerce, Transportation and Tourism continues to express interest in assessing the quantity of testing being done on new chemicals and the need for additional testing and information. This will be a continuing issue that we will face and will need to handle.

Secondly, and this ties into the point I just mentioned, the Organization for Economic Cooperation and Development (OECD) has developed as a "Decision," ready for signature by the 24 member countries, a program which would call for a "minimum premarket data" package to be developed on all new chemicals. CRAC and the International Affairs Group (IAG), through the Department of State (DOS) were successful in convincing DOS that American industry did not support such a policy despite the former EPA Administration's assertion that such a policy was acceptable for the U.S. Our TSCA law does not require the generation of test data for PMNs. Had the DOS signed such a treaty on behalf of the U.S., it would have started us down the path of amending our laws so that U.S. could live up to its treaty commitment. The "minimum pre-marketing data package" would cost an estimated \$50,000 to \$100,000 for each new chemical.

This issue is still not settled internationally and final resolution may not take place for several months. However, the call for additional testing on new chemical substances on three fronts -- the international impetus fostered by OECD, the interest of Congressman Florio's Committee, and the claim by the environmentalists that industry is not doing sufficient testing on new chemicals warrant our continued attention. CRAC has maintained that testing should be done as appropriate for new chemical substances based on its expected properties and use of those chemicals. This testing should not be done on a cookbook or by-the-numbers approach, but should be done on the basis of need, as judged by qualified personnel. It is the primary responsibility of the company manufacturing the chemical to make this appropriate judgment.

We were successful in changing the U.S. position at the "last hour." We have submitted revised language for consideration by OECD, which recognizes the differences in existing domestic laws and regulations of all member countries. This has not been widely accepted by other OECD members, particularly European countries pushing for MPD on all new chemicals. We are holding to our guns here and plan to do so even

if it means no international agreement. Acceptance of the MPD package would represent a drastic change in the thrust of TSCA. Our suggested rewording of the agreement does, in our opinion, protect our interests and enables each country to operate according to its laws.

Our third major area of activity has been to petition and pursue with EPA the granting of exemption to PMN process as permitted by Section 5(h)(4) of the Act. Our study of the PMNs submitted to the Agency disclosed that a high percentage of new chemicals were of such a nature that no unreasonable risk would be encountered in manufacturing, processing or use. The PMN system required that these chemicals be subjected to the PMN process, which delayed manufacturing and market introduction unnecessarily and at a cost which was not justified.

The available evidence from studies done on the innovation of new chemicals also indicated there was a significant drop in the number of new chemicals being introduced because of the cost of the PMN system. It is estimated there has been approximately an 80% reduction in new chemical introductions since TSCA came into effect. This is in part due to the combination of cost burdens of the PMN system and companies' reluctance to engage in new ventures due to regulatory and cost uncertainty. We believe our petition for exemption would significantly ease the adverse impact of TSCA PMN notifications on innovations.

Our petition to EPA calls for exemption from all or part of the PMN system site-limited intermediates, small volume chemicals (less than 25,000 lbs/yr), polymers and those chemicals for which the Agency determines no unreasonable risk exists prior to the 90 days of the PMN review period. The Agency has expressed interest in our concepts and we are currently discussing with the EPA staff the additional details they need to develop in a rulemaking for such exemptions. We are hopeful we can have all of these exemptions available to the industry by the end of the summer of 1982.

III. CRAC OBJECTIVES, 1981-1982

I indicated earlier, that I would talk about our plans for 1981-1982. At our two-day CRAC planning meeting, which we held last October, we recognized several items that warrant our attention in CRAC, and for that matter, in CMA as a whole.

1. Many points within the government and society exist where pressure will develop, and is now developing, which can influence the course of TSCA implementation. While we have spent the great bulk of our time interfacing with EPA, we see other branches of government, such as, Congress, Office of Management and Budget, Government Accounting Office, and Office of Technology

Assessment and regulatory reform activities as playing a timely role as TSCA moves toward full implementation. We will broaden our approaches to include identification of these pressure points and to take appropriate action. The continuing interest of Congressman Florio's Subcommittee on the adequacy of PMN data is a good example of how groups other than EPA will need our attention. Where other CMA committees, such as the Government Relations Committee, can help us, we will employ their services or coordinate our activities with them.

2. Since industry supported TSCA, as it was ultimately drafted and passed, we believe that the statement "TSCA is a workable law when implemented in a reasonable and timely fashion" appropriately expresses the industry's and CMA's continued support for the principles and spirit of the law. It is our belief that despite the lack of regulatory action taken by EPA (final rule-making, etc.) that the law is having its intended effect on the behavior of the industry. We have, in an informal way, surveyed part of our membership and developed a long list of actions that have occurred as a result of the passage of TSCA and the public opinion climate, which produced TSCA as a law. We plan to further develop this type of information, to publicize and use it to help quiet the claim that TSCA is "not working." If Congress perceives that TSCA is not working, it might ultimately begin efforts to amend TSCA adversely. The effectiveness of TSCA may be reviewed and scrutinized during the next congressional year in oversight hearings. Our approach is to work to assure there is no perceived need on the part of Congress to adversely amend this law.

Should amendments be sought by others, we are prepared to advance those changes which we believe would improve TSCA from industry's viewpoint.

3. We are developing conceptually, a plan for how TSCA can be effectively implemented while complying with the statutory limits of the law. This plan is based on CRAC's review of EPA proposals and constructive comments we have submitted. These are summarized in the book -- "The First Four Years of TSCA" which has been highly effective and well received by the new EPA Administration. We plan to work with the Agency to encourage a full implementation of the Act. We believe there exists now with the present Agency management a "window" through which we can get implementation achieved in a "reasonable manner". We want to capitalize on this opportunity, since subsequent administration might not be as favorable. Rules that can be finalized now will be more difficult to change later on.

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4. Finally, we will continue to pursue to a successful completion, our petition for PMN exclusion and resolution of the MPD issue. We will continue to respond to all EPA-initiated activities to assure they comply with the thrust of TSCA and represent reasonable implementation.

IV. CONCLUSION

This has been a very quick summary of where we are -- our accomplishments and our plans. TSCA is working and is, as expected, affecting our business, both in dollars and cents, as well as in the way we do our business. To date, TSCA implementation to EPA has been slow. The past EPA Administration was quite aggressive in proposing rules that pushed to the outer limits and beyond, the thrust and intent of TSCA as envisioned by Congress. We in CRAC sense a change in direction, at least at the top positions of EPA under the Reagan Administration. We should see considerable progress in implementing TSCA within the next two years. CRAC will be working to assure that this implementation is in reasonable step with the legislative intent that our industry supported in 1977. I believe CRAC has been and will continue to be an effective tool for the industry, representing our industry's interest well at EPA and helping to demonstrate industry's commitment to good corporate citizenship.