

REPORT ON TOXIC SUBSTANCES CONTROL ACT

The Toxic Substances Control Act (TSCA), administered by the Office of Toxic Substances at EPA, regulates the production and distribution of industrial chemicals more directly than any other law. Among its key features, it requires EPA review of every new chemical before commercial manufacture, it allows EPA to control the manufacture, distribution, use or disposal of any chemical -- including banning the manufacture outright -- in order to eliminate "unreasonable" risks, and it empowers EPA to require manufacturers and processors to conduct toxicological testing of a chemical where the available toxicology data are not sufficient to determine the health or environmental risks the chemical may pose.

Although TSCA was enacted in 1976, it is only in recent years that EPA has begun to implement the major authorities of the law. For example, the premanufacture notification (PMN) program for review of new chemicals did not begin until 1979, and final regulations governing the program were not promulgated until 1983. Similarly, it is only in the last two or three years that EPA has imposed testing requirements on existing chemicals or designated a few high-risk chemicals for priority regulatory attention. The slow development of the TSCA program has fueled criticism both of EPA and of the law itself. At this juncture, the chemical industry believes that the great strides EPA has made in the past few years show that the law itself is adequate, and that EPA has learned how to administer it. Nevertheless, the political pressures for reform are powerful, and some changes to TSCA seem to be inevitable. The pressures for amendments to TSCA are particularly acute in the following areas:

TSCA Section 4 -- Testing of Existing Chemicals

Some testing is being done by industry under agreements negotiated with EPA before the Agency promulgated federal rules to compel the tests. EPA has yet to promulgate a final test rule under this section, however. In response to these circumstances, two proposals for amendment have appeared.

- o H.R. 4304 would make amendments to provide express statutory authority for the negotiated testing agreements, would make such agreements enforceable just as if they were rules, and would require more opportunity for public participation in the negotiations. CMA fears that these procedural changes would make negotiated testing agreements less attractive to industry and EPA both, and would therefore impede the performance of the tests.
- o The Senate staff drafts contain a proposal for mandatory and comprehensive toxicological testing on all chemicals produced at greater than 100 million pounds per year, with limited exemptions for testing that would not be feasible or useful. The details of this proposal are objectionable in many respects but CMA may have to accede to the concept of mandatory testing for commercial chemicals to which there is widespread exposure.

TSCA Section 5 -- Review and Regulation of New Chemicals

There are two basic phases to TSCA's controls on new chemicals -- pre-manufacture review of new chemicals and limitations on the manufacture or use of new chemicals to limit potential risks identified during the review. Proposals for amendments to each of the phases have been put forward in both houses of Congress.

o PMN Review. Both the House bill and the Senate staff drafts contain as their central feature amendments that would require prospective manufacturers to submit to EPA substantially more toxicological test data than they now routinely do. The House bill would have EPA prescribe by rule a "tiered" system of tests that each manufacturer would have to perform, with the level of testing determined by the results of the first tier of tests. The Senate staff draft would incorporate the "minimum premarket data" (MPD) set of tests developed by the Organization for Economic Cooperation and Development as the basic testing requirement for new chemicals. CMA accepts the need to enhance the amount of information EPA receives with the PMNs, but opposes both of these proposals to prescribe testing requirements for all chemicals. As a response to the proposals, we have discussed with Congressional staff and EPA an alternative approach that would call upon the developer of the new chemical to prepare a detailed "assessment" of the possible risks associated with it.

o New Chemical Follow-up. This issue is closely connected to the question of new chemical testing, since arguments against generalized testing requirements tend to lean toward recognition of EPA's need for more extensive or flexible powers to track and to regulate new chemicals that may present little risk in their original use, but could present much greater risks if exposure to them becomes more widespread. Section 5 of TSCA gives EPA two follow-up tools. One permits EPA to require, by rule, that manufacturers submit for PMN review designated significant new uses of a chemical. The other authorizes EPA to restrict manufacture, use or distribution of a new chemical until more toxicity information is provided. The House bill and the Senate drafts contain provisions to facilitate EPA's use of these authorities by relaxing the types of factual findings EPA must make before using them.

Another concept for follow-up, which first appeared in H.R. 4304, is receiving serious consideration. This concept is an "interim list", which would be a special inventory for substances that were approved for manufacture only under the circumstances described in the PMN. New manufacturers would be required to submit PMNs of their own for these substances, and the original manufacturers would be required to provide PMN notice of proposed new uses. Only when sufficient information become available to assess the toxicological risk of the chemical could EPA place it on the regular inventory for unrestricted commercial development.

Other Issues Being Addressed

While testing of chemicals and follow-up of new chemicals dominate the TSCA agenda, there are other suggestions for amendments as well.

- o Section 8 -- Reporting. The Senate staff drafts would extend the possible reach of reporting rules to distributors, users, and disposers.
- o Section 9 -- Relationship to Other Laws. The House bill would largely do away with requirements for EPA to coordinate with other agencies and to defer TSCA regulation where other laws would afford adequate control.
- o Section 14 -- Confidential Business Information. Both House and Senate would require justification for every claim of confidentiality at the time it is made. The Senate drafts would also require periodic renewal of claims and would give state governments access to CBI submitted to EPA.
- o Section 16 -- Penalties. The House bill would make any knowing or willful violation of TSCA a felony (first offenses are now misdemeanors).

TSCA was due for reauthorization in 1984, but with the 98th Congress nearing adjournment it is virtually certain to be carried over into 1985. At the moment, this is the legislative status. In the House, Congressman Florio (D-NJ) and Eckart (D-OH) introduced a TSCA amendments bill in November, 1983 (H.R. 4304), but neither Florio's subcommittee nor the full Committee on Energy and Commerce has acted upon it. In the Senate, Environment and Public Works Committee staff responsible to Senator Durenberger (R-MN), chairman of the pertinent subcommittee, have been circulating drafts of proposed amendments, to which CMA has responded by discussing concerns and constructive alternatives, such as a new chemical assessment statement in lieu of the inflexible new chemical testing requirement drafted by Senate staff. Senator Durenberger is seeking to have a bill by the end of September, but none has yet been introduced. During what remains of the 98th Congress, key legislators in both chambers of Congress will be heavily engaged on other legislation, such as Superfund, and will have little time to advance TSCA amendments beyond their current status. This should allow CMA and its sister trade associations to formulate more detailed positions on the major issues and continue discussions and advocacy with the key members of Congress and their staffs between now and the opening of the 99th Congress in late January, 1985, with the objective of shaping the bills that will become the basis for debate and legislation. Meanwhile, we will maintain our communications with EPA to assist in sound policy decisions on TSCA amendments as part of the legislative strategy.

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