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Subject TOXIC SUBSTANCES MANAGEMENT MEMO

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TOXIC SUBSTANCES MANAGEMENT MEMO.

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Toxic Substances Management Memo

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PROTECT CONFIDENTIAL INFORMATION, MCA TELLS ADMINISTRATION

Firm rules and procedures are required to provide an effective check on federal agencies' need to know with proper protection of bona fide trade secrets and confidential information. That is the thrust of remarks submitted by MCA to the administration's Toxic Substances Strategy Committee. The committee, representing 16 federal agencies, has published a work plan aimed at developing administration initiatives for government-wide toxic substances strategy and policy. It deals with the effects of present federal protection accorded trade secrets and similar information involved in controlling health and environmental problems caused by toxic substances.

Specifically, MCA addresses the following four issues:

Sharing of Trade Secrets Among Federal Agencies

Although section 9 of the Toxic Substances Control Act provides for intra- and inter-agency communications, MCA finds no justification in that act or in the Freedom of Information Act for encouraging federal agencies to share trade secrets not necessary for execution of specific tasks by the second agency.

Where agencies do share information involving trade secrets, the Association says that mere guidelines for maintaining security are not enough. Firm, standardized, audited and enforced rules and procedures must apply. An example of the certainty needed, MCA says, is that specified by the Department of Defense in "Industrial Security Manual for Safeguarding Classified Information."

For additional information about subjects mentioned in this memo, contact Jim Turner at MCA. His number is (202) 483-6126.

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Disclosure of Trade Secrets by a Federal Agency to Contractors

Congress has indicated clearly that government contractors, must be held responsible for the security of confidential information entrusted to them as agents of the federal government, MCA notes.

The Association suggests that each contract drawn by an agency should include a provision for the security of confidential information. It should specify safeguards to be taken and spell out penalties for breach of security.

Do Safety and Efficacy Data, Health and Safety Studies, Etc., Qualify as Confidential Information?

MCA believes that a glossary of terms is necessary to describe accurately the information within these broad categories which may justify confidential treatment and offers to help prepare such a glossary.

When information on health and effectiveness is requested by a third party under the Freedom of Information Act and trade secrets or confidential information may be involved, MCA suggests that summaries of such information might be provided.

While most information on health, safety and efficacy are not confidential or trade secrets, MCA notes that some portions should not be disclosed. Research protocols may reflect commercial advantage in the testing expertise employed, and many have been recognized as confidential material. The nature of the protocol may identify the targeted market, a matter of considerable commercial value. Full disclosure of all effectiveness data could be similarly revealing. Furthermore, MCA says, where preclearance consideration may control entry of a product into a regulated market, the safety and efficacy data represent a significant commercial value.

Consideration of Confidentiality During Rulemaking

Regarding maintenance of confidentiality in a rulemaking procedure, MCA points out that Norwegian Nitrogen Co. v. United States, 288 U.S. 294 (1933), still applies. That decision provides that confidentiality may be granted without denying due process to participants who do not have access. Accordingly, the Association recommends that procedures to protect confidentiality in a rulemaking proceeding should be adopted.

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MCA COMMENTS ON PROPOSED HEALTH AND SAFETY STUDY REPORTING

MCA has responded to a number of issues raised by the Environmental Protection Agency in its Proposed Rule for Health and Safety Study Reporting; Submittal of Studies of Substances Recommended for Priority Consideration. Comments are by appropriate section numbers.

730.1 Definitions (a) "Manufacture or Process"

Paragraph (4) of this definition would expand the jurisdiction of the Toxic Substances Control Act's section 8 beyond that intended by Congress into product research and development, MCA says. The same legislative intent which excludes small quantities for research and product development under TSCA section 5(h) (3) (B) also governs the limitation of section 8 through the "commercial purposes" language of section 8(f). Upstream research and specialized steps of product development are not intended to be covered by the statute, MCA says, and does not represent "interstate commerce" in any material subject to its regulation (section 2(a) (3)).

Furthermore, MCA says, TSCA's section 14 disclosure requirements for health and safety studies on marketed chemical products should not encompass research and development. The types of safety testing performed on "old" chemical substances during research or development operations would likely disclose to competing firms, through section 14(b), the consideration of alternate uses for existing compounds. While the public has a legitimate interest in new uses which may be covered by final regulations under TSCA's section 5, MCA says the public does not have a similar awareness right concerning non-marketed compounds which are undergoing research and evaluation. MCA urges, therefore, that preliminary safety work on non-commercial compounds be excluded from reporting requirements.

As a matter of policy, MCA says that EPA should use only authority given to it under TSCA for regulating distributed chemical substances. Issues of jurisdiction should not be allowed to impede careful development of a consistent and well-founded regulatory policy. Such would be the case, MCA says, if the agency were to invoke a purported section 8 authority to gain research and development data on chemicals well prior to their commercial distribution. Because of these factors, MCA urges that section 730.1(a) (4) be deleted from the proposed rules.

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730.1(b) and 730.3(a) Juridical Persons

MCA supports applying this part to juridical persons only, as expressed in section 730.3. Since manufacturers, processors and distributors of chemical substances are, in almost every instance, juridical persons, MCA believes it would be well to clarify that it is these juridical persons who will be held responsible for compliance with the rule.

730.1 Definitions. (c) "Study"

In this application, MCA notes that a study means "any report of a formal investigation which utilizes defined methodologies and yields preliminary or final results, and includes underlying data and information." Since almost every study or investigation can provide a great amount of preliminary results when analyzed at any time before final results are issued, MCA says that this paragraph could be construed to obligate a continuous stream, possibly daily, of preliminary results to EPA. Such data would have little value to the agency, MCA believes. It is "final" results which are important, and MCA recommends that the proposed rule should indicate that. MCA suggested modifying the definition to assure EPA of getting results of completed or terminated studies which will be of value to the Office of Toxic Substances.

730.1 Definitions

MCA points out that this section lacks a precise definition for "environmental effects" for which relevant health and safety studies are required for submission.

Also the proposed rule requests submission of health and safety studies on categories of some chemicals. MCA recommends that the definition (paragraph (d)) of "substance" be expanded to include identification by CAS number and corresponding name.

730.5 Listing and Submission Requirements (a) (1) Lists of Health and Safety Studies

All testing done by or for a manufacturer or processor who sponsors or endows a study should be subject to reporting requirements. But MCA believes that the scope of the investigation potentially required by this section is excessively broad and would lead to duplicative reporting. To avoid this, MCA recommends modifying the language of this section

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to insure that all data are submitted to EPA but limiting duplicative reports to original information evaluated by the generator.

730.5(a) (2) Complete Copies of Health and Safety Studies

MCA believes that this section should be restated to allow a person submitting a report to retain voluminous underlying data, while allowing EPA to request specific data needed.

730.5(b) Reports Not Required (ii) Those With No Claims of Confidentiality

There are numerous health and safety or monitoring studies which are performed, reported or made available to the government under other federal laws and regulations. Obviously, MCA says, any report that has been already submitted to a federal agency, with or without claims of confidentiality, should be exempt from this requirement.

730.7 Confidentiality Claims (d) Assertion of Claim

Section 730.7(d) (4) states that confidentiality will be deemed waived on failure to furnish a second copy of the submitted report, with the confidential information excised. This requirement is unduly punitive, MCA says. A more equitable regulation, the Association believes, would provide for notice by EPA to the submitter within a reasonable period to cure the defect in the submission before the claim of confidentiality is waived. This would preserve confidentiality in cases where an inadvertent clerical error results in a faulty submission, MCA points out.

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