Federal Regulations Applicable to the Fatty Acid Industry

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ABSTRACT

Recent legislation including the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the Solid Waste Disposal Act, the Resource Conservation and Recovery Act, and, especially, the Toxic Substances Control Act, is having a great impact on chemical manufacturers. The burgeoning maze of rules, regulations, policy statements, implementing these acts imposes serious obligations on all those engaged in fatty acid manufacture, processing, distribution, and research and development. The Manufacturing and Processing Notices, Sec. 5, and Reporting and Retention of Information, Sec. 8, requirements of TSCA, require extensive recordkeeping and reporting, and will affect industry's development of new products and significant new uses of products. The status of fatty chemicals on the inventory of existing chemicals and the SDA efforts in the listing of premanufacture notification are extremely important to all segments of the fatty acid and derivative industries.

INTRODUCTION

Certain aspects of the implementation of the Toxic Substances Control Act (TSCA) have explicit bearing on future innovation in fatty chemicals. The main thrust of TSCA is contained in Sec. 5, Manufacturing and Processing Notices, under which a manufacturer must notify the Environmental Protection Agency ninety days before manufacturing a new chemical substance for commercial purposes. This is called a premanufacture notice (PMN).

This PMN requirement will have a most profound, far-reaching impact on the chemical industry. If after July 1, 1979, one proposes to manufacture a fatty chemical or import one from anywhere outside the customs territory of the U.S. he first must consider whether it is on the Inventory of existing chemical substances. If the substance is on the Inventory, he can go ahead and manufacture/import with no restrictions – *at this time*. If the substance is not on the Inventory and any supplements thereto, after July 1, he must notify EPA ninety days prior to any such manufacture or import. Some aspects of this premanufacture notification (PMN) are discussed later.

What is the Inventory?

TSCA requires EPA to compile and keep current a list of all chemical substances manufactured or imported for commerce in the U.S. This, the Inventory, EPA considers to be "first published" July 1, 1979.

The Act stipulates that this list be first published not later than 315 days after the effective date of the Act – that was Nov. 11, 1977. Nonetheless in Dec. 1977, the Agency issued Inventory reporting rules requiring manufacturers/importers to report by May 1, 1978, all chemical substances manufactured or imported for commercial purposes in 1977. Materials manufactured for the first time between May 1, 1978, and June 30 this year could also be reported. Any such will comprise the first supplement.

Recognizing that one doesn't sit down with a yellow pad and make a list of the myriad chemicals manufactured by its members, the Soap and Detergent Association (SDA) in November 1976 formed the TSCA Subcommittee of the Legal Committee to interact with EPA in implementing TSCA and especially in developing rules for the Inventory.

Early on, EPA decreed that the Inventory would be ordered by Chemical Abstracts Services Registry number (CAS Reg. No.). In April they published the three-volume Candidate List of some 37,000 chemical substances with corresponding CAS Reg. Nos. If the substance to be reported for the Inventory was on the Candidate List one merely reported the CAS Reg. No. and the alpha-numeric eight-digit EPA code designation along with the additional production volume by manufacturing site, etc. information on Form A. It was the ex parte contacts who convinced EPA they needed this additional information and who caused the reporting rules to be revised, delaying publication of the Inventory and providing 567 days of grace before PMN requirements could go into effect. If the substance was not on the candidate list and one could obtain the CAS Reg. No., it was reported on Form B with the specific chemical name. If the CAS Reg. No. was not known or not available *or* the chemical identity was claimed confidential, the substance was reported on Form C with enough information to clearly identify the substance.

For Class 1 chemical substances, i.e., those whose composition can be represented by a definite chemical structure, reporting was relatively straightforward: (a) specific chemical name; (b) the chemical formula; and (c) the chemical structure. Even for polymers whose constituents were all Class 1 substances, it was necessary only to list the monomers by chemical name and CAS Reg. No. However, virtually all fatty chemicals are Class 2 substances whose composition could not be fully represented by a chemical structure diagram. CAS claims they do not assign CAS Registry Nos. and Index names to such substances. This is not true.

For purposes of the Inventory CAS selected preferred names for many such substances and listed them in the Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB) section of the Candidate List with newly assigned Reg. Nos. After struggling with the listing in the UVCB section and more particularly with the omissions in attempting to list our fatty chemicals according to the Inventory reporting rules, the TSCA Subcommittee task group proposed to TPA systematically derived, chemically descriptive EPA Substance Names for these Class 2 fatty chemicals. The names consist of two or three parts: (a) an alkyl descriptor which describes the long chain alkyl group; (b) the functionality descriptor which identifies the functional group(s); and (c) the salt descriptor identifying the cation, if any. For example: C_{14}-C_{18} alkyl amine.

The procedure evolved into a grid comprised of 27 alkyl, 115 functionality and 14 salt descriptors. To report the above example for the Inventory it was necessary only to report the name C_{14}-C_{18} alkyl amine and corresponding SDA number 17-029-00 and not the source as hydrogenated tallow amine, etc.

On April 5, SDA distributed this as an alternate procedure for identifying fatty chemicals for the Inventory to its member companies. This was just three weeks before the end of the reporting period. Most companies had already compiled their Inventory using terms like tallow amine, soya fatty acids and bis (hydrog. tallow) dimethyl ammonium chloride. Consequently, this very important quat is not reported by the more generic SDA number. The less significant unsaturated tallow product was reported as SDA

01-047-00 and is listed in the Inventory as bis (C_{8-18} and C_{18} unsat. alkyl) dimethyl ammon. cl.

EPA went on to publish this procedure as Sec. 1 of Addendum III to the Candidate List. Its availability was announced in the Federal Register on April 17. We were assured that the reporting period would be extended to permit companies to use the alternative procedure.

The result of the Agency's inexcusable delay and high-handedness in refusing to extend the reporting period was that only three companies used the procedure and 108 compounds were reported by SDA number. At least that is all that is listed in Vol. III, User's Guide to the Inventory, under SDA. However, EPA/CAS evidently used the alkyl descriptors in a great many substance definitions – see Part 1, Appendix A, to Vol. I. Also under CAS Reg. No. 68002-59-5 Quat. Amm. Cmpds. Di (C_{14}-C_{18} alkyl) dimethyl ammon. cl. The SDA procedure is published as Part 2, Appendix A of the Inventory.

I urge a greatly expanded use of this systematically derived, chemically descriptive nomenclature as the preferred nomenclature in the revised Inventory to be published next year.

So much for the Inventory. It is just the prelude. EPA says the list was first published "June 1, 1978." If this date holds, it means the PMN requirements of TSCA become effective July 1. If you plan to introduce a new chemical substance into commerce after July 1, you must first notify EPA at least ninety days before its manufacture for commercial purposes may commence. A *new* chemical substance is one that is not included on the Inventory of chemical substances and any supplements thereto. A master list is maintained by EPA.

Following a preposterously prodigous effort last year, EPA published on January 10 the proposed PMN Requirements and Review Procedures for comment. This is the document that scores 35 below zero on a scale of 0 to 100 for clarity and readability. Their intent was to publish final rules considering all comments prior to July 1. There were over 180 comments on the proposed rules. The MCA comments alone encompassed over 400 pages with about 30 pages of simplified forms.

Without going into detail, it will have to suffice to state that the proposed PMN requirements greatly exceed the statutory authority granted the Agency by the Act, and attempts to circumvent the intent of Congress by rule making. Congress after extended debate rejected the concept of registration or Agency prior approval of new chemical substances such as are required under FIFRA and FFDA. The proposed requirements would do just that. Congress concluded it would suffice that EPA and the public be notified at least ninety days before manufacture of a new chemical substance for a commercial purpose could commence. If the manufacture, distribution, processing, use or disposal of the substance would impose an unreasonable risk to health or the environment, the Act grants EPA authority to take appropriate regulatory action to mitigate such risk, even to prohibiting its manufacture.

If there is insufficient information to assess the risks associated with the manufacture, processing, etc. *and* such manufacture may present an unreasonable risk *or* the substance will be produced in substantial quantities and may enter the environment or result in significant human exposure, EPA may issue an order regulating the substance until sufficient information is developed.

The proposed reporting form for manufacturers is sixty pages long, compared to three pages for the revised Investigational New Drug application. A.D. Little under contract to EPA estimates it would cost $9,000-$40,000 just to complete the form, not including any costs to develop the mandatory information requirements. EPA magnanimously indicated that this form could be used during the interim when PMN is required – July 1, 1979, until the final rules and forms are promulgated. You can take this suggestion for what it is worth. But EPA now says they will accept a PMN in any form that complies with Sec. 5(d). These requirements are not diminishing.

Sec. 5(d) lists the information that a PMN *shall* include: (a) common name, chemical identity, molecular structure; (b) categories of use; (c) reasonable estimate of total amount to be manufactured for each use; (d) description of byproducts; (e) all existing data on health and environmental effects reasonably ascertainable; (f) estimate of number of individuals and duration of exposure; (g) manner of disposal.

If it becomes your lot to submit a PMN before the final forms are approved – maybe next year, if there is no litigation; with court challenges, who knows when – I urge you to obtain adequate technical and legal counsel.

A more recent proposal from EPA is the March 16 PMN Testing Policy and Technical Discussion document. The Legislative History of TSCA shows that Congress extensively debated and rejected mandatory premanufacture testing for all new chemicals. Other sections of TSCA clearly show that Congress provided for testing guidance prior to PMN review only if the PMN submitter expressly requests it. Nevertheless the discussion document and accompanying support document state EPA's ". . .long term goal is to publish a series of recommended tests and methods along with relatively detailed guidance concerning the need for testing for effects in given situations."

When the Agency says it will consider comments on the discussion document, publish proposed PMN testing guidelines and publish *final* testing guidelines it is clear that they consider this as an advance notice of proposed rule making rather than the "voluntary guidelines" they purport it to be. Comment on this discussion document closes June 14, 1979.

Warren Muir, Deputy Assistant Administrator for Testing and Evaluation, is now saying: "Many industries have tried to develop explicit rules for determining when and which tests should be performed on new substances, but they found it couldn't be done in a workable fashion."

The Agency must respond to specific petitions for guidance under subsection 4(g) and could make model protocols available through the Office of Industry Assistance, but they cannot legitimately propose and publish final PMN testing guidelines as though they are rules or regulations.

On May 9, EPA published Proposed Health Effects Test Standards for TSCA Test Rules and GLP Standards for Health Effects, for comment by August 7, 1979. The Agency is proposing these test standards "to assure that data developed under Sec. 4 test rules can be used by EPA to determine whether the tested chemicals present an unreasonable risk of oncogenic or other chronic effects. . ."

They estimate that the cost per chemical is approximately: oncogenic effects – $400,000; other chronic effects $500,000; combined – $800,000. The prechronic range finding studies for these are estimated to cost: oncogenic effects – $50,000; other chronic effects – $100,000; combined. – $130,000. Public meetings on these test standards proposals will be held in Chicago and Washington, DC, late this summer.

In response to a suit by the NRDC, the Agency has promised to issue the first Sec. 4 test rule by Dec. 31 and others at quarterly intervals thereafter. This will mean that the selected chemicals will have to be tested for the specific effect(s) listed in the order. Costs will be borne by the manufacturers and possibly the processors of the substance.

TSCA is a fact of life and the testing, PMN, regulation of hazardous substances and imminent hazards and reporting and recordkeeping requirements will be with us from now on. Everyone concerned with the chemical industry should assume responsiblity to see that the Act is administered in a reasonable and prudent manner as Congress intended.