Air Products and Chemicals, Inc.

cc: W. M. Smith, L. Tepper, R. H. Schenck, J. C. Novak, A. J. Diglio, R. Collins, W. Ent, G. Handley, E. Handwerk, J. Starr, R. Fleming

DATE: Sept. 8, 1977

TO: TSCA COMPLIANCE COMMITTEE

FROM: C. E. BLADES

6-352

TSCA BULLETIN NO. 17

Four forms (Form A, Form B, Form C, Form D) are proposed by EPA for reporting chemical substances according to reproposed rules (Aug. 2, 1977).

Form A - For substances on the Candidate List (Strawman).

Form B - For substances not found on Candidate List but which have an assigned CAS Registry No.

Form C - For Confidentials or for substances with no assigned CAS Registry No.

Form D - Voluntary reporting of product trademarks to certify all ingredients have been reported elsewhere in the inventory.

Details available from TSCA Chairman (C. E. Blades).

C. E. Blades

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Reporting

EPA PROPOSES TRADEMARK LIST TO CERTIFY INVENTORY INCLUSION

Reporting of commercial products by trademark names with a certification that all constituents have been included in the inventory list of chemical substances required under the Toxic Substances Control Act was proposed by the Environmental Protection Agency August 24.

The proposal was presented at a public meeting in Washington held to hear comments on EPA's reproposed inventory reporting regulations (Current Report, July 29, pp. 695, 710). Cynthia Kelly, chairman of the inventory work group in the Office of Toxic Substances, presented drafts of four reporting forms (see Full Text section of this issue) for public comment. Forms A and B are revisions of forms included in the originally proposed regulations (March 18, p. 3). Forms C and D are new.

Proposed Form A would be used to report chemicals included on the EPA candidate list (April 22, p. 161). Reporting would be done by Chemical Abstracts Service Registry Number and the EPA code designation printed in the candidate list, which is used to verify the accuracy of the CAS number. Proposed Form B would be used for substances not included on the candidate list but which do have a CAS number. Proposed Form C would be used for substances for which there is a request that the identity be kept confidential and/or for which no CAS number is known. Proposed Form D would be for voluntary reporting of product trademarks to certify that all ingredients have been reported for inventory in compliance with TSCA.

Kelly noted that not all substances included in the candidate list will be on the inventory list. Items that will be automatically included are spelled out in the reproposed regulations. Apart from these, it is the responsibility of manufacturers to make sure that their products are included.

Principal Issues

The main issues discussed at the meeting concerned the depth and detail to which reporting should be done, definitions of and responsibilities of small manufacturers, and various confidentiality issues — what can be claimed as confidential and how confidentiality can be maintained and assured. The divergence of views among regulators, those who would be regulated, and public-interest groups was marked.

Representatives of chemical companies argued that requirements for reporting of production site and volume contained in the reproposed regulations went beyond the congressional intent for inventory reporting authorized by Section 8 (b) of TSCA. They said reporting of use, volume, exposures, and health effects is separately authorized under Section 8 (a) of TSCA and that by mixing the two, EPA is going beyond its authority and collecting useless data on chemicals that do not pose a threat to health or the environment.

Jackie Warren, Environmental Defense Fund, said there was nothing illegal about EPA's combining authority under Sections 8 (a) and 8 (b) and that the clear intent of Congress was for EPA to have information on which to base regulatory decisions and that this should certainly include site and volume data. Warren said that EDF would have preferred the inclusion of use data as well.

On the matter of confidentiality, Louis Slesin, Natural Resources Defense Council, was hissed and jeered when he said that the Act won't work if data are kept secret. He said NRDC would object to secrecy in the strongest possible terms.

Chemical company representatives testified that site-specific data is highly variable, ephemeral, fluctuates with supplies and markets, and must be kept confidential for the viability of business operations.

OSHA Testimony

The lead witness was Grover Wrenn, deputy director of the health standards program, Occupational Safety and Health Administration. Wrenn said OSHA had been working closely with EPA in the development of the regulations, and he commended EPA for the reproposed regulations. He said that volume and plant-site data were urgently needed to allow rapid response in emergencies. He said such data could also be used to schedule health inspections of high-risk chemicals.

Wrenn urged that emergency reporting be required regardless of the size of the manufacturer and said that OSHA urges reconsideration of small-manufacturer exemptions contained in the proposed regulations because data from small manufacturers would provide "useful information."

Wrenn also said that OSHA strongly supported a proposal that claims of confidentiality accompany data, rather than being submitted separately later.

Small Manufacturers

Robert Polack, general counsel of Reilly Tar and Chemical Corporation appeared on behalf of the Synthetic Organic Chemical Manufacturers Association. He said that SOCMA's membership objected strongly to the "costly and largely unnecessary burden" that would be caused by the proposed regulations.

The regulations define, for purposes of inventory reporting, a small manufacturer as one "who (a) has only a single manufacturing site, and either (b) has total annual sales of less than $100,000, based on the manufacturer's latest complete fiscal year or (c) has no more than 2,000 pounds annual production (i.e., amount manufactured and imported) of each manufactured chemical substance."

Polack said, "The proposed $100,000 total sales limitation is not only ridiculously low in light of the burdensome nature of the reporting requirements, but also so low that it will exclude virtually all small manufacturing companies. It should be noted that the statement in the preamble [to the proposed regulations] that as many as 20 percent of the manufacturers in SIC 28 have sales of less than $100,000 is simply incorrect."

The proposed regulations would require inventory reporting only by industries in Standard Industrial Classifications 28 (chemical and allied products) and 2911 (petroleum refining). Polack said that SIC 28 includes processors as well as manufacturers. He said that SOCMA was unaware of any of its members who are manufacturers who could meet the proposed sales limit.

Polack said that the 2,000-pound limit on production volume is "even more absurd," and said that SOCMA was

CHEM. REG. REPORTER - 8/26/77

unaware of any company al. whose products are produced in quantities of 2,000 pounds or less.

Presenting SOCMA's recommendations, Polack said, "We urge that a firm be considered a small manufacturer if it meets any of the following three criteria. 1. Sales of less than $30 million in its last fiscal year, or 2. Less than 300 employees, or 3. Less than $15 million in assets."

David Gleeson, manager of sales and marketing for Hardwicke Chemical Company, Elgin, S.C., also said he knew of no company that could qualify as a small manufacturer either through the $100,000 total sales limitation or the 2,000-pound production limit. He said that his company qualified as a small business within the Federal Government as defined by the Small Business Administration. The current size of the company is 65-75 employees with annual sales between $9 and $11 million, Gleeson said, and he added that even in its first year of operation when it had eight employees, it could not have qualified under the criteria proposed in the regulations.

Gleeson said that in his company all personnel have line duties and that no one is assigned full-time to administrative affairs or regulatory compliance. He said that his company is currently spending $4,685 per employee annually to meet regulatory requirements, which is more than the company spends on the employee benefit package that includes group medical and life insurance, retirement plans, social security, and other employee benefits.

Gleeson estimated that to comply with the reproposed inventory regulations his company will have to spend an additional $75,000-$100,000.

Confidentiality

Gleeson also said, "I would also point out that disclosure of our captive intermediates is a threat to our existence. Several of our processes are proprietary and confidential due to the nature of our technology. Disclosure of these intermediates could reveal to a potential competitor both raw materials used and the nature of the technology. Loss of our confidential technology could well mean the end of our company.

"We feel it is imperative our confidential data be protected and seriously quesuon EPA's ability to provide that protection. Further, can EPA guarantee that other federal agencies, i.e., the Food and Drug Administration, OSHA, and the Consumer Product Safety Commission will be bound by the same claims of confidentiality as EPA is under TSCA? We recommend: that any chemical identity be entitled to confidential treatment; that the inventory be published with nonconfidential chemicals or code numbers for confidential entities; that any company, organization, or person inquiring of a product on the inventory list certify their intent to manufacture said product and; that requests for confidential data be denied."

Intermediates

The reproposed regulations define an intermediate as "any chemical substance (a) which is deliberately present in a chemical reaction sequence used to manufacture or process another chemical substance, (b) whose presence is known or reasonably ascertainable, and (c) which could be isolated and identified under conditions which are practically encountered in the environment."

Polack, in his testimony for SOCMA said, "Several members of SOCMA, including Reilly Tar and Chemical Corporation, estimated that complying with the original inventory reporting requirements would cost between $175-$200 per chemical. We estimate that obtaining and providing production data for each of those chemicals will raise the cost twofold, to approximately $300-$400 per chemical. When you c der that even a small manufacturer may produce 50 products, each one of which may include several 'isolatable' intermediates in its production, the potential cost of this reporting program will be considerable, far in excess of its value to those receiving the reports.

"One of the principal reasons for the high cost of compliance is that the proposed regulations require chemical manufacturers to report not only what products they make, but also each 'isolatable intermediate' which occurs in the reaction sequence leading up to the final product. In many cases, information on the identity of these intermediates is not readily available. What information is available will have to be compiled and checked by somebody with a background in chemistry equivalent to a doctor's degree."

Polack and other industry witnesses recommended that the definition should apply to substances that actually are isolated and produced for use or distribution in commerce, rather than to substances that could be isolated.

MCA Testimony

Curtis W. Smith, representing the Manufacturing Chemists Association, said MCA would have further written comments for EPA and summarized MCA's recommendations as follows:

- ► Regulation of new uses would be premature;
- ► Clarification of the relationship between inventory reporting and pre-manufacturing notice is required;
- ► Production reporting should be in ranges by powers of 10, i.e., 1,000 pounds to 10,000 pounds, 10,000 pounds to 100,000 pounds, etc.
- ► Post-inventory reporting procedures should allow for inclusion in the inventory where good cause for failure to report can be demonstrated;
- ● Persons outside SIC groups 28 and 2911 should also have responsibility for assuring that their products appear on the inventory;
- ► All changes since the original proposal of the regulations in March should be subject to comment;
- ► MCA assumes that intermediates of pesticides and FDA-regulated materials are exempt from TSCA and requests clarification of this point if it is needed:
- ● Clarification of the distinction between manufacturers of mixtures and chemical processors is required:
- ● If computer-tape reporting is permitted, EPA should publish the format;
- ► MCA supports the definition of small manufacturer presented in SOCMA testimony;
- ► Expansion of the inventory to include site and volume data will create substantial problems with respect to the protection of confidential information. MCA recommends that EPA develop strict computer-security procedure to prevent the divulgence of unauthorized information.

What Next?

Written comments may be submitted on the reproposed regulations until September 16, 1977. They should be sent to Vicki Briggs, EPA Office of Toxic Substances (WH-557), 401 M St., S.W., Washington, D.C. 20460, in triplicate with the identifying number OTS-0810002.

In November the final regulations should be published, and reporting forms will be mailed to SIC Groups 28 and 2911.

The reporting period will end 90 days after the final regulations are published, so that reports should be in in February 1978.

In the summer of 1978 the inventory will be published and a 120-day period will start during which processors may report chemical substances not on the inventory.

Premanufacturing notification begins 30 days after publication of the inventory, presumably in the fall of 1978.

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Substantial risk definitions and guidelines appear to be in process of development. The attached extract from Chemical Regulation Reporter (Aug. 19, 1977) gives some idea of EPA thinking. The overlap between "Substantial Risk" and "Significant Adverse Reactions" records is also surfacing.

C. E. Blades

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The study, which followed 3,070 workers exposed to beryllium some time between January 1, 1942, and December 31, 1967, will be cited by NIOSH in testimony at a public hearing on a proposed Occupational Safety and Health Administration beryllium standard. NIOSH is scheduled to testify August 19.

A total of 884 deaths occurred among exposed workers at the beryllium extraction, processing, and fabrication plant, compared with the 829.41 expected. The excess of respiratory disease deaths, the study reported, included both bronchogenic malignancies (46 observed compared with 33.33 expected) and nonneoplastic diseases, excluding influenza and pneumonia (32 observed against 19.02 expected).

There also was a significant excess of deaths from heart disease (399 observed rather than 335.15 expected).

An excess of bronchogenic cancer occurred among beryllium exposed workers only 15 years after first exposure (37 observed, opposed to 24.01 expected). The report added that the excess was "most marked" 25 years after first exposure (20 observed compared with 10.88 expected), and occurred irrespective of the duration of employment.

Litigation

OUTSIDE LAWYERS FOR VELSICOL REQUIRED TO TESTIFY IN GRAND JURY INVESTIGATION

Outside lawyers for Velsicol Chemical Corporation are required to testify and produce documents in a grand jury investigation of whether Velsicol, its officers, former employees, or outside counsel withheld from the Environmental Protection Agency information which tended to show that pesticides manufactured by Velsicol induced tumors or cancer in laboratory animals.

The U.S. Court of Appeals for the Seventh Circuit ruled July 29 that the attorney-client privilege had been waived and that the work-product rule, which safeguards the confidentiality of internal memoranda, did not bar production of documents. (*Velsicol Chemical Corporation v. Parsons*, Nos. 77-1433, 77-1434).

At issue was whether three attorneys for the law firm of Sellers, Connor and Cuneo could be required to testify before the grand jury and produce documents. The Sellers law firm represented Velsicol in administrative proceedings before EPA, and it is the conduct of Velsicol and its officers in the EPA proceedings that is the focus of the grand jury investigation. The investigation of Velsicol was commenced in September 1975 by the U.S. Attorney for the Northern District of California.

The Seventh Circuit ruled that previous testimony by Velsicol's senior house counsel before the grand jury concerning remarks with attorneys of the Sellers firm had waived the attorney-client privilege. The court also ruled that the work-product rule did not bar compulsory production of documents prepared by the Sellers firm, because the focus of the grand jury inquiry is to determine if preparation of the documents was "attended by misconduct."

Recordkeeping

EPA GUIDANCE ON REPORTING SUBSTANTIAL RISK TO BE ISSUED SOON

Guidance to chemical manufacturers, processors, and distributors on reporting information on substances posing a "substantial risk" to health or the environment is to be issued soon by the Environmental Protection Agency, according to Edward Brooks of the EPA Office of Toxic Substances.

Brooks, who is branch chief for coordination and procedures in OTS, told Chemical Regulation Reporter August 16 that the guidelines, as required by Section 8 (e) of the Toxic Substances Control Act, have been submitted to the Administrator for his approval.

Although the EPA formal guidelines have yet to appear, Section 8 (e) requires that effective January 1, 1977 manufacturers, processors, and distributors notify EPA of any information showing that a chemical presents a "substantial risk" of injury to health or the environment unless that persons knows "that the Administrator has been adequately informed of such information."

A few companies have provided information without formal guidance from EPA, according to an EPA official, including a report from E.I. du Pont de Nemours & Co., Inc. on findings that acrylonitrile may be a human carcinogen (Current Report, May 27, p. 368).

Brooks said his responsibilities also include development of regulations under Sections 8 (c) and 8 (d) of the Act which require manufacturers, processors, and distributors of chemical substances to keep records of significant adverse reactions to health or the environment ascribed to a chemical and to submit health and safety studies as EPA may specify.

One issue that must be resolved in writing those regulations is whether they should be developed separately or conjointly, Brooks said, although they probably will be issued in final form as two separate rules.

EPA has said previously that all guidelines and proposed regulations under Section 8 (c) though (e) would be issued by October 1977 (March 18, p. 6).

Hazardous Materials

MTB ANNOUNCES ACTIONS ON REQUESTS FOR EXEMPTIONS FROM TRANSPORTATION RULES

Notice of action on applications for exemptions from hazardous materials transportations regulations was published by the Department of Transportation's Materials Transportation Bureau August 18 (42 FR 41690).

Modes of transportation involved are (1) motor vehicles, (2) rail freight, (3) cargo vessel, (4) cargo-only aircraft, (5) passenger-carrying aircraft.

Renewals, emergency exemptions granted, and denials are listed in the table, which is published in the Full Text section of this issue.

General Policy

TOXICS MANDATE SET FOR ESWQIAC REVIVAL COSTLE TELLS SENATE PUBLIC WORKS MEMBERS

The Environmental Protection Agency intends to revive the now-dormant Effluent Standards and Water Quality Information Advisory Committee to assist in developing best available technology guidelines for toxic pollutants.

But, EPA Administrator Douglas M. Costle told members of the Senate Environment and Public Works Committee the committee should not be re-activated under the Federal Water Pollution Control Act.

In answer to a question from Committee Chairman Jennings Randolph (D-WVa), Costle said he is "persuaded that

CHEM. REG. REPORTER - 8/19/77