

Methods Used in Study of Information Content of Premanufacture Notices

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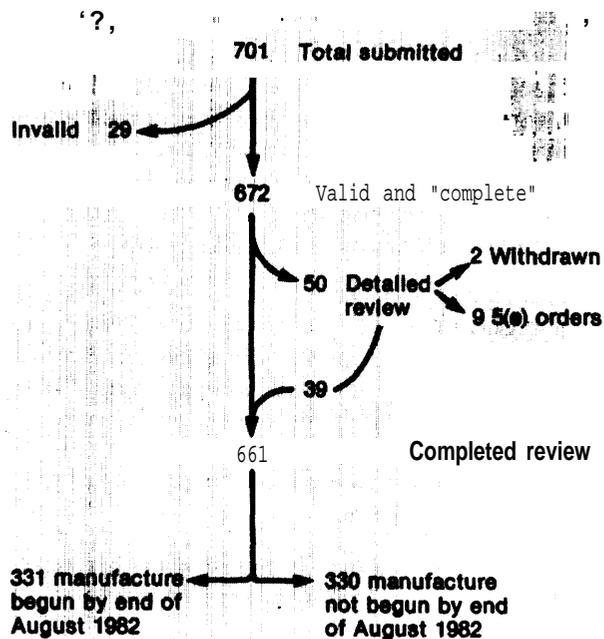
PMNS EXAMINED BY OTA

All premanufacture notices (PMNs) considered by the Environmental Protection Agency (EPA) to be valid and complete that were received by EPA from the beginning of the program (July 1, 1979) through the end of June 1981 and which either completed PMN review *or* were withdrawn because of a 5(e) notice being planned *or* written were examined. In addition, the PMNs submitted in June 1982 were examined by OTA. The total number of examined PMNs was 740; 670 of which were received in the first 2 years of the program and 70 of which were received in June 1982.

Figure 2, which is based on records obtained from EPA, describes the disposition of the 701 PMNs that entered review through June 1981. Twenty-nine of the PMNs were returned to the submitters as invalid; some of these PMNs described chemicals already on the Inventory of Chemical Substances, and no PMN was necessary for them. Others of the invalid PMNs were judged to be incomplete.

Of the 672 valid PMNs, 50 underwent detailed review, indicating that additional review was necessary to resolve some uncertainty about risk that remained after the initial screen. Nine of the fifty were associated with unreasonable risk during the detailed review, and 5(e) orders were written. In each of those nine cases, the submitters abandoned their intent to manufacture or import the new substance and withdrew the PMN rather than perform testing. In the case of two other PMNs that underwent detailed review, the manufacturers decided to withdraw the PMNs before a 5(e) order was written. The remaining 39 PMNs that underwent detailed review *were* either: 1) judged not to present an unreasonable risk or 2) judged not to present an unreasonable risk because the submitters undertook voluntary actions to reduce hazard or exposure after EPA informed the submitters of agency concern.

Figure 2.—Disposition of PMNs Submitted From July 1979 and Including All Those That Completed the 90-Day Review Period by the End of September 1981



SOURCE: Office of Technology Assessment from data collected by the Environmental Protection Agency.

Mr. Florio's letter (fig. 1) requesting this study specifically asked that OTA compare PMNs describing marketed (manufactured) chemicals to those that described chemicals that have not been manufactured. OTA used EPA-compiled records to separate the PMNs received through June 1981 into those that had been manufactured by August 1982 and those that had not.

Some EPA employees told OTA staff that there is no legal requirement that a submitter report that manufacture has begun and that separating the PMNs between those that described chemicals that

have begun manufacture and those that have not may be subject to significant error. However, EPA encourages submission of a "notice of commencement" (NOC), and industry reviewers of the first draft of this study firmly expressed their opinion that NOCs were viewed as a required notice and that they were submitted. OTA depended on EPA's classification of a chemical as being manufactured or not, which in turn depended on the Agency's having or having not received an NOC. There may be some error in those classifications. EPA was in the process of sorting out its NOC records when OTA was examining PMNs, and three different lists of manufactured chemicals were produced during that time. Some 40 chemicals listed as "manufactured" on EPA's first list were removed from subsequent lists because clerical or transcriptional errors at EPA had incorrectly classified them. OTA used the most recent available information from EPA, which should have the fewest errors in classification.

As is shown on figure 2, half of the PMNs that were received by EPA through June 1981 were classified as being manufactured by August 1982. Therefore an examination of all the PMNs received by that date provides a comparison between 331 chemicals that were reported to have begun manufacture after EPA's receiving a PMN and 330 that had not.

The PMNs received through June 1981 that described the nine substances that did not proceed

to manufacture because of EPA writing 5(e) orders were also inspected. In those nine cases, EPA decided that it had insufficient information to make a decision about unreasonable risk to human health or the environment and required that the submitters generate more data before manufacture could begin. In each of those cases, the submitters decided not to produce additional data, review was suspended as incomplete, and the substance did not begin manufacture.

In addition to the PMNs received through June 1981, the PMNs received in June 1982 were examined. Comparison of the PMNs received during the two time periods was expected to reveal any differences in PMN content between the 1979 to mid-1981 period and June 1982.

A shorthand nomenclature has been adopted to distinguish between and among the groups of PMNs examined by OTA. Those PMNs that were received through June 1981 and that described chemicals that had begun manufacture before the end of August 1982 are called "manufactured PMNs." Those that were received through June 1981 and that had not begun manufacture by August 1981 are called "nonmanufactured PMNs." All PMNs received in June 1982 are called "June 1982 PMNs." The nine PMNs for which EPA wrote 5(e) orders during the period 1979 through September 1981 are called "regulated PMNs."

INSPECTION OF PMN FILES

PMNs are submitted either on an EPA-provided form (44 F.R. 59764 and see app. B), on a form developed by the Chemical Manufacturers Association (CMA) (see app. B), or in other formats including letters. Upon receipt, each PMN is photocopied and distributed to the appropriate review groups in EPA. One copy is maintained in the document control room until the 90-day (or, in exceptional circumstances, longer) review period is completed, and a copy is then deposited in an inactive document control room.

In most cases, each inactive PMN is stored in a file folder along with additional information

produced and obtained during EPA's review. During OTA's examination of PMNs, 11 file folders were empty. Because the original PMN documents were being photographed at a location away from EPA during the summer of 1982 when OTA was carrying out its examination, no copy of those 11 PMNs was available to OTA. Unless those 11 PMNs are included in the 29 "invalid" PMNs shown on figure 2, those PMNs are not included in any tabulation of PMNs reported here.

An annoying filing habit hampered OTA's inspection of some PMNs (and would hamper any other inquiry as well). Frequently, manufacturers

submit several PMNs at the same time. Sometimes the PMNs submitted together are closely related; for instance, two forms of an organic chemical differing only in that one is a sodium salt and that the other is a potassium salt. Other times, the PMNs submitted together have nothing in common except that they are the products and intermediates in a series of reactions. For instance, Chemical A + Chemical B → Chemical C. Putting such PMNs together in a single file results in the PMN forms being intermixed, and although separable by attention to numbers on the form, information retrieval is slowed.

OTA staff examined each PMN file for the presence or absence of information (45 items) and recorded findings on the form illustrated in figure 3. To a major extent, OTA's investigation depended on recording whether or not an item of information was present. Three reasons could account for OTA's reporting that no information had been submitted for an item:

1. The submitter had not presented the information.
2. The submitter had presented the information, but the information was not present in the file inspected by OTA.
3. OTA incorrectly recorded that no information was present.

There was no way to judge the frequency with which a piece of information was lost from a file (reason 2), but it was essentially impossible for a single item or a few items of information that were reported on a PMN to be lost. PMNs are

stapled. Therefore, if any information reported on the PMN was found about a substance, probably all the PMN-reported information was found. However, some EPA staff mentioned to OTA that records of telephone conversations with submitters were sometimes lost from the files. Therefore, some information that was reported to EPA might have been lost from the files and not recorded by OTA. In fact, the concern expressed about lost telephone records was so great that even though the OTA data collection form provided for the tabulation of data requested by EPA subsequent to the PMN submission, those data were not analyzed separately. Instead, the presence of a datum was recorded whether it was submitted on the PMN or secured by a phone call during the review process.

OTA staff could have misreported the absence of information (reason 3 for OTA reporting that an item of information was not reported). Such errors are bound to occur, especially in an effort that includes collecting 45 pieces of information about 740 PMNs (a total of 33,300 pieces of information). To estimate the frequency of such errors, the information collected by OTA about whether each PMN described a Class 1, Class 2, or Class 3 substance was rechecked. Each of the 740 PMNs was reexamined to determine how frequently the class of the chemical reported on the notice was correctly recorded by OTA. That examination showed that 23 errors were made in 740 entries, or an error rate of 3 percent. (The data presented in this background paper report the corrected counts about chemical classes.)

INFORMATION COLLECTED FROM PMNs

The OTA data collection form (see fig. 3) was designed to facilitate recording of the presence or absence of information required by TSCA (see lower right hand corner of form) and the presence or absence of some data items identified by the Organization for Economic Cooperation and Development (OECD) as useful in reviewing the properties of new chemicals. Those data items, called the Minimum Pre-marketing Data (MPD) set, were accepted by the European Economic Community (EEC) as a common standard for the

premarket review of many new chemicals and were considered for adoption as a mandatory reporting system by OECD. However, in a December 1982 meeting, OECD decided that reporting of the MPD data is only one way to provide information about the toxic effects of new chemicals. The United States, the only OECD member that did so, objected to the MPD requirement because it represented "inflexible, across-the-board, one-time notice requirements for all new chemicals," and EPA, which represented the

Figure 3.—Form Used by OTA in Collection of Data From PMNs

PMN

File #_ _____ CMA _____ OTHER _____
 EPA _____ Date NOC Filed_ /_ _ Time Difference Days

Parent Subsidiary- Manufacturer Feedstock Source Sole Customer
 Further Processor- Other-

Production Volume---Exemption _____ Non-exemption _____

Import _____ country _____ Non-import _____

Polymer_ Low Volume Site-limited _____ Intermediate Other _____

Final Disposition:

Specify any additional information requested YES OR NO

OECD

<p><u>CHEMICAL ID</u> Chemical Name Formula CAS# - Finger-print Spectra Degree of Purity -</p> <p><u>PRODUCTION</u> Estimated Production/year Intended Uses Ind. Corn Cons SL Inter Disposal Methods Mode of Transportation</p> <p><u>RECOMMENDED PRECAUTION AND EMERGENCY MEASURES</u></p> <p><u>ANALYTICAL METHODS</u></p> <p><u>PHYSICAL DATA</u> Melting Point Boiling Point Density - Vapor Pressure Water Volubility Partition Coefficient Hydrolysis Spectra- Adsorption-Desorption Dissociation Constant Particle Size</p>	<p><u>ACUTE TOXICITY</u> Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Skin Irritation Skin Sensitization Eye Irritation -</p> <p><u>REPEATED DOSE TOXICITY DATA</u> 14-28 Days</p> <p><u>MUTAGENICITY DATA</u></p> <p><u>ECOTOXICITY DATA</u> Fish LC₅₀ -at least 96 hr exposure Daphnia -reproduction 14 days Alga -growth inhibition 4 days</p> <p><u>DEGRADATION/ACCUMULATION DATA</u> Bio-degradation: Bio-accumulation:</p> <p><u>EPA, TSCA section 5 requirements:</u> Chemical Name and Structure Intended Uses Estimated Production Volume Byproducts #of Workers to be Exposed Disposal Method Toxicity</p>
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/=data present
 XX=data absent

SOURCE:Office of Technology Assessment.

United States at the OECD meeting, prefers the more flexible PMN reporting requirements that have been developed under the Toxic Substances Control Act (TSCA) (3). In some cases, other items of information, neither specified by TSCA nor identified by OECD, were submitted on a PMN and those were noted by OTA on its forms.

The OTA form provided space to record the type of form used for the PMN submission and whether or not the substance had entered manufacture (NOC = “notice of commencement” of manufacture). In addition, OTA recorded whether or not the substance might be exempted from the usual PMN review under EPA’s proposed low-volume, polymer, or site-limited intermediate exemption programs. These classifications on OTA’s part were necessarily rough. If the PMN identified the substance as being made in amounts of less than 10,000 kg annually, or as a polymer, or as a site-limited intermediate, that information was

recorded. Some of these chemicals might not fit into an exemption category because of reasons not reported on the PMN or recorded by OTA, and in some cases the submitter might prefer to submit a regular PMN rather than an exemption notice even if the exemption program were in effect. Nevertheless, the submitter-supplied information about production volumes, site-limited and polymer attributes allows some analysis of the information content of PMNs that describe members of classes being considered for exemption from PMN reporting requirements by EPA.

The “final disposition” indicated whether or not a 5(e) order was written for the substance. If there was a record of EPA-requested additional information, that was also noted in the form.

Data were transferred from the OTA form to a computer for analysis. The accuracy of the transfer of data was checked visually and corrections made before the analysis began.

SECURITY PRECAUTIONS TO PROTECT CONFIDENTIAL BUSINESS INFORMATION

EPA has to protect the confidential business information (CBI) that is included in PMNs. OTA staff who were to have access to PMNs signed a *security* agreement with EPA pledging not to divulge any CBI from the PMNs. In addition, OTA staff read the relevant parts of the EPA security guide dealing with protecting CBI. OTA made the suggestion that the first draft of this report would be first circulated to the appropriate security officials at EPA so that EPA could bring to OTA’s attention any CBI that was included in the background paper. This agreement was modified somewhat. EPA security officials inspected all tabular data in the first draft for CBI. After

they agreed that no CBI was in the tables, the draft was sent out for review. Furthermore, OTA staff agreed not to remove any PMN file or its contents from the workroom that was provided for OTA at EPA.

OTA’s legal counsel informed OTA staff that none of these conditions was necessary for OTA to obtain and examine CBI. However, in the interest of being cooperative and because the restrictions that OTA agreed to did not greatly hobble OTA’s work, OTA staff entered into the agreements mentioned above.

EPA COOPERATION

EPA staff *were* courteous and helpful to OTA staff throughout this project. Helpfulness was extended by EPA staff in day-to-day cooperation

and interviews. Many, but probably not all, of the EPA staff who aided this study are listed in appendix C.

ANALYSIS OF THE DATA

A computer program written by John Bell was used to analyze the collected data. The OTA-

collected data and the program for analysis will be made available on request to OTA.

ORGANIZATION OF THE PRESENTATION OF THE ANALYSIS

TSCA contains both specific and general reporting requirements. The items specifically required are listed in TSCA section 5 (d)(1)(a)(A). In brief, the submitter is required to name and describe the chemical, make projections of the expected uses and production volumes, estimate the number of workers who may be exposed to the substance, describe byproducts of the chemical's manufacture, and present methods for disposal of the chemical. The general reporting requirements (TSCA sec. 5 (d)(1)(a)(B) and (C)) state that the notice shall include "any test data in the possession or control of the person giving such notice" that bears on the effects of the manufacture, use, and disposal of the substance and a description of any data about health and environmental effects of the substance "insofar as known to the person making the notice or insofar as reasonably ascertainable."

EPA has defined the terms "possession or control" and "known to or reasonably ascertainable" in the proposed PMN reporting rules (44 F.R. 2265):

"Known to or reasonably ascertainable" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden or cost.

"Possession or control" means in possession or control of the submitter, or of any subsidiary, parent company, or any company which the parent company owns or controls if the subsidiary,

parent company, or other company is associated with the submitter in the research, development, test marketing, or commercial marketing of the substance Information is included within this definition if it is: (1) in the submitter's own files, (2) in commercially available data bases to which the submitter has purchased access, or (3) maintained in the files in the course of employment by employees or other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the substance.

The general reporting requirements apply to two kinds of information, those that describe the new substance and those that describe results of tests of the substance's possible toxic effects. The OTA data collection form (fig. 3) was used to collect data for this study.

OTA examined each PMN to determine how completely:

1. the TSCA-specified data items were reported,
2. what additional physical-chemical information, and
3. what toxicity information was reported.

Results of OTA's inspection of PMNs are presented in four parts. Chapters 4, 5, and 6 describe the amounts of the three types of information submitted. Chapter 7 discusses the amount of information present in subgroups of PMNs, including those subgroups that are likely to be exempted from PMN reporting requirements and those that are of interest because of consumer use.