4
Frequency of Submission of TSCA-Specified Data on Premanufacture Notices

4. Frequency of Submission of TSCA-Specified Data on Premanufacture Notices

The Toxic Substances Control Act (TSCA) specifies that a company that plans to manufacture or import a new chemical in the United States submit a Premanufacture Notice (PMN) to the Environmental Protection Agency (EPA). The PMN is to contain information that identifies the chemical, projects the amount of the chemical to be made for specified uses, estimates the number of workers involved in manufacture, and describes byproducts produced in the chemical's manufacture and methods for its disposal. The frequency with which TSCA-required information was submitted was examined on PMNs that:

1. had been submitted before the end of June 1981, completed review by the end of September 1981 and the manufacture of which had begun by the end of September 1982 (called here "manufactured PMNs"),
2. PMNs like those in 1 except that EPA had not been informed about commencement of manufacture through the end of September 1982 (called here "non-manufactured PMNs"),
3. all PMNs submitted in June 1982 (called here "June 1982 PMNs"), and
4. PMNs that have not completed review because EPA issued a "5(e) order" requiring submission of more information (called here "regulated PMNs").

NUMBERS OF PMNs SUBMITTED TO EPA

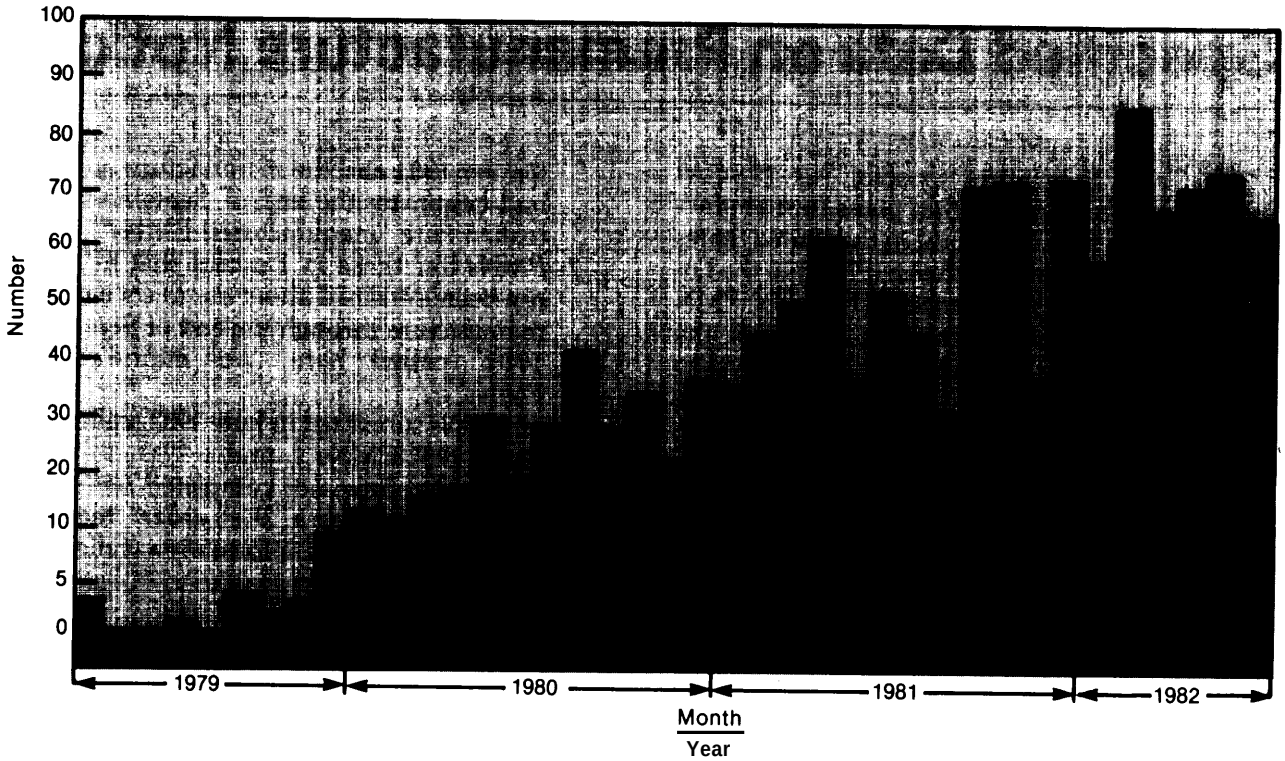
Figure 4 shows the numbers of PMNs received by EPA since the program's inception. As is readily apparent, the number of submitted PMNs was small at first, but rapidly increased. A number of factors might account for the increasing numbers of PMNs. It maybe that companies hastened the development process for new chemicals immediately before the start of the PMN program in order to list the chemicals on the Inventory of Chemical Substances without having to experience the delay and uncertainty of the PMN review process. That scheduling change could have contributed to a subsequent hiatus in the introduction of new chemicals. As a result of hurrying development of chemicals closest to production, the time necessary to complete development of chemicals at earlier stages might have been lengthened. Also, companies might have found it necessary to use the time when few PMNs were submitted to develop methods to prepare and submit the notices. Finally, any PMN-imposed additional burdens to develop and submit information might have caused a delay in submission of PMNs.

Although there is some flattening out of the rate of increase, the number of PMNs continues to increase. Since the beginning of 1982, EPA has received more than 70 valid notices each month.

It is important to remember that PMNs are required only for new substances. Many chemical products are formulations or mixtures of already existing chemicals, and those are exempted from the PMN reporting requirements by TSCA (see ch. 2). The number of new formulations and mixtures introduced each year was not determined by OTA, but it is certainly many times greater than the 1,000 or so new chemicals which require PMNs. Since the components of the mixtures and formulations are listed on the Inventory, they are subject to the provisions of TSCA that apply to existing chemicals.

98-826 0 - 83 - 6

Figure 4.–Number of Valid PMNs Received Each Month: April 1979 Through June 1982



SOURCE: Drawn from data collected by the Environmental Protection Agency.

CHEMICAL NAME AND PRODUCTION VOLUMES

Whatever is accepted about the usefulness and applicability of Structural Activity Analysis (SAR) (see ch. 2), it is clear that knowledge of the chemical's structure is central to the process of estimating chemical and biological properties. TSCA specifies that new chemicals be named and that formulas and structures be provided for chemicals when available. The reporting of these items is essential to review of the PMN.

Chemicals are named according to standard rules, and names, therefore, provide information about the substance. The name is a critical element in learning about the structure of the chemical, and, in turn, knowledge of the chemical's structure underpins EPA's review of the PMN. An accurate name is also necessary for listing the chemical on the EPA's Inventory of Chemical Substances at the end of the review period.

Essentially all PMNs report the chemical name (table 3). OTA's examination found 11 PMNs, a little more than 1 percent, that did not report a name. All of the PMNs that did not include names described polymers (see table 4).

The amount of the substance to be manufactured is an important element in estimating exposures. As is shown on table 3, essentially all PMNs report estimated production volumes. If EPA implements the program it is considering to exempt low-volume substances from PMN review, the estimates of production volume will take on additional importance.

Table 3.—Completeness of PMNs for TSCA-Specified Information

	Manufactured		Non-manufactured		June 1982		Regulated	Totals	
	Number	Percent	Number	Percent	Number	Percent	Number	Number	Percent
PMNs	331	100	330	100	70	100	9	740	100
Number with:									
Chemical name	325	98	326	99	69	99	9	729	99
Chemical class	331	100	330	100	70	100	9	740	100
Production volume	329	99	328	99	69	99	9	735	99
Uses	325	98	322	98	69	99	9	725	98
Byproducts	233	70	207	63	49	70	8	497	67
Number of workers	315	95	302	92	68	97	9	694	94
Disposal	313	95	298	90	65	93	9	685	93
All TSCA-specified information	218	66	190	58	46	66	8	462	62
All TSCA-specified information except by products	293	89	274	83	62	89	9	638	86

SOURCE: Office of Technology Assessment.

Table 4.—Number of Class 1, 2, and 3 PMNs That Have Name, Structure, and Formula

		Name		Formula		Structure		Formula and structure	
Class	Total	Number	Percent	Number	Percent	Number	Percent	Number	Percent
1	293	293	100	273	93	264	90	256	87
2	73	73	100	35	48	39	53	28	38
3	374	363	97	134	36	70	19	46	12

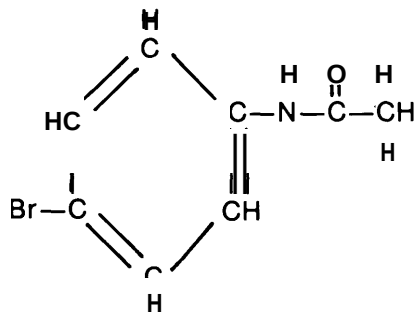
SOURCE: Office of Technology Assessment.

CHEMICAL FORMULAE AND STRUCTURES

EPA has divided all substances subject to regulation under TSCA into three classes. Essentially:

- Class 1 substances have a single component chemical and that chemical can be described by a chemical formula;
- Class 2 substances are complex combinations of chemicals, which cannot be described by a chemical formula; and
- Class 3 substances are polymers.

The EPA's proposed rule for PMN reporting (44 F.R. 59764) provides an example of a Class 1 substance. The name of the chemical in the example is N-(4-bromophenyl) acetamide; its formula, a listing of the atoms in the chemical, is C_8H_8ONBr; its structure is represented by a drawing that shows the arrangements and relationships of the atoms in the chemical:



Such precise representation is not possible for a complex combination of chemicals (Class 2), but knowledge of the components that go into the combination can sometimes be represented by formulae and structures.

Chemical polymers (Class 3) are chains of smaller chemicals. A linear homopolymer is a

chain of a single monomeric subunit. If the monomer is chemical A, the linear homopolymer is A-A-A-A-A-A . . . . Except for the fact that chain lengths may vary, say 50 or 100 or 500 or more As in different preparations, such a polymer can be represented accurately by structures and formulae.

Other polymers can have two or more different monomers, say B, C, and D, and their order of assembly may vary. For instance, a polymer made from a mixture of B, C, and D might be any of a great variety of polymers (. . . B-C-D . . ., or . . . D-B-B-B-C ..., etc.) that differ in composition and length. It is impossible to describe such heteropolymers by structures or formulae although each of the monomers can, of course, be so described.

Further adding to the complexity of polymers is that some branch. For instance, monomers E, F, and G might react to produce a backbone of E and F (. . . E-E-F-E-F . . .) with the G monomer being attached to all or some of the Es (. . . E-E-F-E-F ..., or . . . E-E-F-E-F . . .).

```
      G                G   G
```

Few chemical reactions go to completion, and polymer preparations frequently have "unreacted" or "free monomers" associated with them. Sometimes the monomers are known to be toxic, and in those cases, knowing the percentage of free monomers or short polymers that is present is important.

As expected, given the relative ease of producing such information for Class 1 chemicals, 93 percent of Class 1 PMNs presented chemical formulae, 90 percent presented structures, and 87 percent both (table 4). The absence of this information from PMNs that do not report it may mean that the submitting company does not have the data.

Reporting of formulae and structures was much less frequent for Classes 2 and 3. As is shown on table 4, about half of Class 2 substance PMNs included either formula or structure and **38** percent included both. Industry and EPA reviewers of the first draft of this paper pointed out that information about the chemicals that were used in the reaction to produce a Class 2 substance frequently provides important data about the composition of such substances in lieu of formulae and structures. EPA reviewers further stated that the observed low frequency of reporting of formulae and structures for Class 2 substances produces a distorted view of the information the Agency receives on PMNs for those substances. The Agency reviewers expressed general satisfaction with the information submitted for Class 2 substances. Other reviewers expressed dismay about the absence of such information. And, again, a determination of what errors might have resulted from the absences would require a study of particular PMNs and the decisions made about them.

Of the PMNs for Class **3** substances, **36** percent included a formula, 19 percent a structure, and 12 percent both. If the name of the polymer is sufficient to indicate the identity of the monomeric subunits and their relationships, no further information may be necessary.

BYPRODUCTS

The TSCA-specified item least frequently reported on PMNs is the identification of byproducts produced during the manufacture of the new substance (table 3). Industry reviewers of the first draft of this paper pointed out that some reactions produce essentially no byproducts, and that the absence of information might reflect that no byproducts were present. While that may be the case, when a submitter reported that no byproducts were formed, that was recorded by OTA, and it is represented in the counts reported on table 3.

OTA examined the possibility that PMNs that described site-limited chemicals might more frequently not report byproduct information, and that excluding those from consideration might have a significant impact on the percentage of PMNs that report byproducts. However, 60 **(52** percent) of the 115 PMNs that described site-limited chemicals reported byproduct information. Therefore, although the percentage of site-limited PMNs that reported byproduct information was less than for all PMNs considered

together, excluding them from consideration would not materially affect the percentage of reporting of byproduct information.

The importance of byproducts **varies.** If the byproduct is a common chemical with no toxicity or if it is present in very low concentrations, it is of little or no concern. At the other extreme, the "dioxin" that is now of such concern because of health effects, is a byproduct of several manufacturing processes. A byproduct that is toxic or one about which little is known presents special problems. In any case, absence of reported byproduct identity decreases EPA's ability to evaluate any risk associated with the chemical's production and its byproducts.

USES

Uses for new chemicals are divided into three categories—consumer, commercial, and industrial-on the basis of information supplied by submitters on the PMNs. About three-fourths of all PMNs specified that the substance was intended for one or more of those classes of use. In addition, OTA counted those PMNs that described site-limited or intermediate chemicals as industrial-use chemicals. Adding that number of PMNs to the number that specified either consumer, commercial, industrial, or some combination of uses and to the 27 that described a general use substance, such as a component of a paint, brings the total of PMNs that reported uses to 725 (98 percent). (See table 3).

Exposure assessment depends on estimates of the numbers of people who may be exposed to **a** substance, on estimates of the amount of the substance that exposed persons may encounter, on estimated routes of exposure, and on estimates of incidence and duration of exposure episodes. Consumer-use products are most important in terms of numbers of people who may be potentially exposed to a substance. More people use them, and any restrictions placed on uses are more likely to be ignored or misinterpreted as the number of users increases. On the other hand, the highest potential intensity of exposure is likely for products used in industry for the fabrication of other products. Commercial-use products probably fall between consumer- and industrial-use products both in terms of number of people potentially exposed and in potential intensity of exposure. Table 5 shows that the most frequently reported uses were industrial, followed in order by commercial and consumer, and last, by general. Somewhat over **40** percent of all PMNs indicated that the chemical was expected to be used in more than one class of use (table 5).

Table 5.—Number of PMNs Describing Chemicals Intended for Industrial, Commercial, and Consumer Uses

Classes of use	Number of PMNs reporting use
Industrial	552
Commercial	247
Consumer	105
Industrial, commercial	111
Industrial, consumer	65
Commercial, consumer	66
Industrial, commercial, consumer	57
General	27

SOURCE: Off Ice of Technology Assessment.

NUMBER OF WORKERS EXPOSED AND DISPOSAL

Over **90** percent of all PMNs reported the numbers of workers who might be exposed and methods for disposal (table 3). Notes in the PMN files indicated that EPA had often called submitters to make inquiries about the numbers of workers estimated to be involved in the proposed manufacture of the substances described on the PMNs.

SUMMARY OF FINDINGS ABOUT REPORTING OF TSCA-SPECIFIED INFORMATION

Overall, 62 percent of the 740 PMNs reported all TSCA-required information. That low percentage of completeness is very much influenced by the low frequency of reporting byproduct information. When that item is ignored, 86 percent of PMNs reported all TSCA-specified information (table 3). It must be remembered, however, that byproduct reporting is TSCA-specified, and its frequent absence is remarkable. Production volume, chemical class, chemical name, and proposed uses were reported on almost every PMN. The number of workers potentially exposed to the substance and disposal methods were reported on over **90** percent of all PMNs.

The frequency with which TSCA-specified data was submitted did not differ by more than a few percent among the manufactured, nonmanufactured, and June 1982 PMNs. From OTA's examination, there is no discernible correlation between the likelihood of being manufactured and the completeness of submission of TSCA-specified information. Also there is no obvious change in completeness between the PMNs submitted through June 1981 and those submitted in June 1982.

TSCA specifies that the formula (atomic composition) and structure (arrangement of atoms) of a new chemical be reported when available. In practice, reporting formula and structure should be easiest for Class 1 substances. Class 2 substances, by definition, cannot be described by formula and structure although such information can be presented for components or reactants that were used to produce the complex composition substances of this class. Class 3 substances (polymers) also present problems for submitters; they may be of varying sizes and compositions. As expected, reporting of formula and structure was most frequent for Class 1 chemicals, 93 and **90** percent respectively. The same two items were reported on **48** and **53** percent of Class 2 PMNs; 36 and 19 percent Class of 3 PMNs (table 4).

The absence of formula and structure information on Class 2 chemicals would appear to create a weakness in PMN review, which often depends on knowledge of the structure of the substance. However, both industry reviewers and EPA reviewers of the first draft of this background paper are convinced that adequate information for review of Class 2 substances is present despite the absence of any formula or structure information from about half of the PMNs reporting those substances.

The absence of exact formulae and structures for polymers probably causes fewer problems. Polymers, because of their large size, tend to be inactive biologically. Concern may be attached to the monomers that are used to build the polymers, and ideally the formula and structure of the monomers should be included. Of course, concern about monomers decreases with decreasing concentrations of free monomers and short polymers in the polymer preparation. A more detailed analysis than that undertaken here would be necessary to determine if formulae and structures were submitted appropriately for polymers with significant monomer contamination.

OTA's finding that not all PMNs contain all items of TSCA-specified information does not square with EPA's classifying them as complete. In particular, information about byproducts was missing from more than **30** percent of the PMNs. It maybe that such information had been obtained by EPA during the PMN review process and subsequently lost from the files. If that is not the case, the absence of those data would necessarily complicate EPA's review.