
1 Summary

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The Premanufacture Notice (PMN) Program is the U.S. Government's effort to identify toxic substances before they enter commerce, to impose controls when necessary, and thereby to reduce unreasonable risks to human health and the environment. The Toxic Substances Control Act (TSCA) requires that a Premanufacture Notice be submitted to the Environmental Protection Agency (EPA or the Agency) at least 90 days before a new chemical is manufactured or imported into the United States.

Using the information in the PMN and professional judgment, EPA reviews each PMN to determine if the chemical described in the notice presents or may present an unreasonable risk to human health or the environment. When EPA does not conclude that an unreasonable risk may be associated with the substance described in a PMN, manufacture of the chemical can begin at the end of the 90-day PMN review period.

In the event that EPA determines that the substance presents or will present an unreasonable risk, the Agency can regulate its manufacture.

If EPA decides that the information presented in the PMN is: 1) insufficient for the Agency to make a reasoned evaluation of the health and environmental effects that might be associated with the substance, and 2) that the substance may either (a) present an unreasonable risk or (b) be produced in quantities such that there will be substantial environmental or human exposure, the Agency can restrict or ban the manufacture of the substance pending the submission of additional appropriate data.

When exposure to the substance under the conditions of use described in the PMN is of no concern to EPA, but the Agency has concerns about potential risks under other conditions of use, the Agency can write an order requiring submission of more data before the substance can be manufactured for a "significant new use."

A PMN is to contain certain information about the new chemical to enable EPA to make deci-

sions necessary to protect human health and the environment under the provisions of TSCA. Because TSCA does not allow EPA to require that information be generated about a substance simply because the substance is new, it was expected that the amount and type of information present on PMNs would vary.

The PMN program differs significantly from a premarket testing program that was adopted by the European Economic Community (EEC) and was considered for adoption by the Organization for Economic Community and Development (OECD) (3). The PMN program requires the submission of data within the possession of the submitting company, and TSCA forbids EPA from ordering the generation of test data simply because the chemical described on the PMN is new. In practice, this means that data the company generates in its normal course of business are submitted to EPA.

The EEC program requires the submission of specified test data, whether or not the submitting company would have generated those data in its normal course of business. In other words, the EEC approach requires testing. Furthermore, as production volumes increase, EEC requires the submission of additional data. In contrast, once a new chemical has completed PMN review, it is no longer subject to regulation as a new chemical. Both the PMN and the EEC programs may add exemptions and make other alterations to their general requirements. The General Accounting Office is now preparing a report that compares the OECD system to the PMN program; the report is expected to be completed in late 1983.

This OTA background paper responds to a request for a report that describes the nature and extent of information reported on PMNs in general and on PMNs submitted for certain subgroups of chemicals, such as those that have now entered manufacture, and on EPA's use of those data in decisionmaking about new chemicals (fig. 1). It reports the examination of all PMNs received by EPA in the first 2 years of the program's opera-

Figure 1.—Letter of Request for This Background Paper

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U.S. House of Representatives
Subcommittee on Commerce,
Transportation, and Tourism
of the
Committee on Energy and Commerce
WASHINGTON, D.C. 20519
June 7, 1982

Dr. John H. Gibbons
Office of Technology Assessment
600 Pennsylvania Avenue, S.E.
Washington, D. C. 20510

Dear Dr. Gibbons:

As you are aware, there has been considerable debate in recent months regarding the effectiveness of the premanufacturing notice (PMN) provisions of the Toxic Substances Control Act (TSCA). Concerns regarding the impact of these provisions on innovation have been addressed in numerous studies including the OTA'S just completed assessment, "Technological Innovation and Health, Safety, and Environmental Regulations". However, little, if any, assessment has taken place regarding (1) the extent to which current PMN submissions either fulfill or compromise efforts to perform the preventive health and environmental protection mandate of the Act, and (2) the expected effects of EPA's proposed exemptions from the PMN process.

Questions in this regard surfaced repeatedly during the Subcommittee's reauthorization hearings on TSCA, though few objective answers could be rendered due to the scarcity of independent assessment of these questions. Given the substantial nature of these outstanding concerns, and in light of the OTA's assessment, "Technologies for Determining Cancer Risks from the Environment", which encompasses both toxic substances risk assessment and regulatory analysis, the Subcommittee is requesting that OTA review TSCA's PMN provisions and submissions. The assessment should include the following components:

- (1) Characterization of the notices received to date regarding classes of chemicals and their uses.
- (2) Assessment of data that were submitted on (a) different classes of chemicals, (b) substances that were subsequently placed on the market as compared to those that were not, and (c) substances that would be exempted from PMNs under EPA's currently proposed changes;

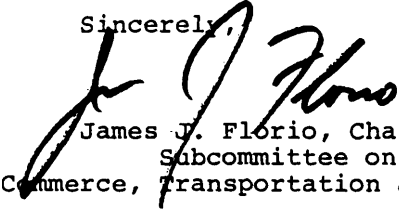
Figure 1.—Letter of Request for This Background Paper—Continued

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- (3) Analysis of the impact of the original data submissions on subsequent EPA decisions under the PMN section.

The Subcommittee anticipates that the OTA would use the recommendations of the Organization for Economic Cooperation and Development (OECD) and other appropriate organizations on premanufacturing testing policy in its assessment of the new chemical testing program under TSCA. In addition, it is expected that the OTA would observe all rules and procedures regarding the protection of confidential data used in the assessment.

Sincerely,



James J. Florio, Chairman
Subcommittee on
Commerce, Transportation and Tourism

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tion (through June 1981) and those submitted in June 1982. In addition, the data reported on PMNs that describe chemicals of certain specified classes were analyzed separately. For instance, PMNs that describe chemicals that, according to EPA records, are now being manufactured were analyzed and compared to those that described chemicals that have not yet been manufactured.

EPA is considering exempting some classes of chemicals from PMN reporting requirements. PMNs submitted for the classes of chemicals likely to be exempted—chemicals used and consumed only at the site of manufacture, chemicals to be manufactured in amounts of less than 10,000 kilograms annually, and polymers—were also analyzed separately.

To collect the information reported in this background paper, 45 items for which data might be submitted on PMNs were identified. The presence

or absence of each of the 45 items was recorded and the frequency of submission of the items for all PMNs and some subsets of PMNs was computed.

TSCA, by mandating the submission of available data, leaves to the submitting company decisions about which data are to be developed. Therefore, the reported data reflect company decisions about what data are important. The absence of data from PMNs makes EPA's task of deciding whether a new chemical may be an unreasonable risk more difficult. On the other hand, the fact that a submitting company does not have to submit data that it regards as unnecessary represents a saving to the company, and if the chemical presents no risk, then both society and the company benefit.

If EPA decides that particular data are necessary for the evaluation of a new chemical and that such

data are absent from the PMN, the Agency can make an informal request for the data, or it can write an order requiring their submission. Which-ever mechanism is used to ask for the data, the burden is on EPA to show that the data are necessary. Requiring submission of more data, especially toxicity data, would reduce the number of times that EPA makes decisions without such data. It would also place the burden for developing data on the submitting companies.

In some cases, the absence of important information—of types that neither the company nor EPA recognizes as essential—may compromise the protection that the Agency affords to human health and the environment. Requiring the submission of a list of test results would guard against that happening, but at the same time, some of the required data might be unnecessary—at least for some chemicals. In those cases, the costs of developing that information would not reduce risks to human health or the environment.

In general, the frequency with which PMNs contained the TSCA-specified and required information items about the identity of the chemical, its expected production volumes, its likely uses, the number of workers who might be exposed in their places of employment, and methods for its disposal was high. More than 90 percent of all PMNs reported those items. One TSCA-specified reporting requirement, that the PMN identify byproducts associated with the manufacture or processing of the chemical, was less frequently met. Only 67 percent of PMNs reported byproduct information. Overall, 62 percent of PMNs reported all TSCA-specified information; 86 percent reported all but byproduct information.

Additional physical and chemical information beyond that which is specified in TSCA was reported on 96 percent of all PMNs, and at least one item about toxicity was reported on 53 percent. OTA looked at physical-chemical and toxicity information reported on some subgroups of PMNs, and found more frequent reporting on PMNs that describe substances that are more likely to be hazards. For instance, reporting of both physical-chemical information and toxicity data was more frequent on PMNs that described substances which, according to EPA records, subse-

quently began manufacture. Toxicity information was more frequently reported on PMNs that described nonpolymeric substances. That seems especially welcome, given that a near majority of PMNs have no toxicity information, because hazard is more often associated with nonpolymeric substances than with polymers (polymers are chemicals composed of repeating subunits).

These generally positive observations must be tempered by the fact that about half of PMNs reported no toxicity information. Furthermore, only 17 percent of PMNs have any test information about the likelihood of the substance's causing cancer, birth defects or mutations—three biological effects that were singled out for special concern in TSCA.

The conclusions to be drawn from the results of the analysis presented here must be limited to generalizations about the frequency of submission of information. The results show that more data are reported for some classes of PMNs than for others.

The following chapters present the results of OTA's analysis of the technical content of PMNs and, where appropriate, related findings and conclusions. However, the *interpretation* of the results is not a matter of inherent validity or of one interpretation's being correct and others being wrong. Instead, the interpretation to be placed on the results will depend on the beliefs and outlook of the reader.

If the reader is of the opinion that no premanufacture reporting should be required or that only the information items specified in TSCA should be submitted, the results may be interpreted to show that the PMN program is resulting in too much information being submitted. If, on the other hand, the reader thinks that particular items of information other than the TSCA-specified items should be reported on every PMN, the results may be interpreted to show that too little information is being reported.

Considering the results in more detail may lead to a middle position. There is, as shown in this paper, a tendency for information to be submitted for substances likely to be more hazardous or to result in more widespread exposures. For instance,

toxicity data are submitted more frequently on PMNs that describe nonpolymers, which as a group are more likely to be hazardous, than on PMNs that describe polymers; more data are submitted on PMNs that describe consumer-use products than on other PMNs. Those observations are consistent with the idea that companies develop and report appropriate data to EPA.

The data that lead to the satisfying conclusion that more information is being reported about more worrisome groups of chemicals also show the frequency of toxicity data reporting. About 40 percent of nonpolymers scheduled for annual production in excess of 10,000 kg did not report any toxicity data. About 30 percent of PMNs describing nonpolymer, consumer use chemicals, to be made in amounts greater than 10,000 kg annually, did not report any toxicity. Taking a middle position might lead to the conclusion that the trends are encouraging, but attach reservations to conclusions about whether the information now reported is adequate for the review of all new chemicals.

Regardless of how the information about the frequency of submission of data is interpreted, immediate questions arise about whether the infor-

mation available for a particular substance was appropriate and sufficient. Answering those questions would require an examination of EPA's decisionmaking process about at least some PMNs on a case-by-case basis. That study would be different from the one reported here, and would involve a process similar, in some regards, to that used by EPA to review PMNs. A group of scientists would review the data on the PMNs, supplement that information with other information available from the scientific literature and experts, decide if EPA's decision was appropriate, and ask whether additional information on the PMN might have made a difference in the decision.

The next two chapters discuss the regulation of new chemicals (ch. 2) and the methods used by OTA in this study (ch. 3). Chapters 4 through 6 present the results of examining PMNs for the reporting of TSCA-specified data items (ch. 4), of physical-chemical data (ch. 5), and of toxicity data (ch. 6). Chapter 7 presents comparisons of toxicity data reported on certain subgroups of PMNs (e.g. site-limited chemicals compared to all others and consumer-use chemicals compared to all others). Chapter 8 discusses actions taken by EPA to regulate new chemicals, and chapter 9 is a general discussion of the the OTA findings.