

Actions Taken by the Environmental Protection Agency as a Result of Reviewing Premanufacture Notices

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The heart of any questioning about the Premanufacture Notice (PMN) program is whether it has protected human health and the environment from unreasonable risks. A partial answer to that question will become available in the years to come as information is accumulated about the health and environmental effects of substances that passed through PMN review and then entered commerce. In the meantime, a less satisfactory answer to questions about the accomplishments of the PMN program can be obtained by examining actions that the Environmental Protection Agency (EPA) has taken to reduce exposures to chemicals that may present unreasonable risks.

From among the PMNs examined by OTA, nine described chemicals that did not begin manufacture because of formal EPA actions. Six of those described phthalates, which at the time of review were especially suspect because of a then-recently completed National Cancer Institute test that showed some phthalates to be carcinogenic (9). Two of the remaining three were benzidine dyes, which have long been associated with human carcinogenicity. The fact that the benzidine dyes were submitted shows that some chemicals strongly associated with human toxicity are considered for manufacture.

EPA's insisting on more tests for those nine chemicals prevented their being manufactured. In those cases, when EPA issued a 5(e) order, the submitter decided not to submit the requested information and withdrew the PMN. The reasoning behind the submitters' decisions is not known and may differ depending on the chemical and the submitter. However, when EPA determined that the new chemical might present an unreasonable risk, the submitting company may have agreed that the chemical was more likely than not to har-

bor some hazard, and that further testing might confirm the hazard.

If a submitting company decided to execute the EPA-requested tests, the tests might confirm that the chemical is hazardous. In that case, the submitter cannot manufacture the chemical and is out the money spent on developing test data. If the test data are equivocal and neither confirm the hazard nor dispel it, the submitter is also out the cost of the test. He also faces another decision about whether or not to produce more data at more cost in the expectation that more data will resolve EPA's concern about the chemical. The third possible outcome is that the EPA-requested test data show that the chemical is not hazardous and that production of the chemical can commence. In that case, for the cost of the test, the submitter gains access to the market for those chemicals.

Industry reviewers of the first draft of this background paper expressed their conviction that the cost of the required tests alone, with no consideration of the possible outcomes, was sufficient to convince the submitting companies to withdraw the PMNs. Instead of spending the money on the tests, it might be better spent on developing other chemicals.

Such activities are to be expected as a result of TSCA and implementation of its provisions to regulate new chemicals. The law provides that chemicals that are suspected of being toxic are to be identified before manufacture and prevented from being manufactured unless sufficient data are produced to show that the toxicity does not present an unreasonable risk.

Three additional 5(e) orders have been written (two in 1982; one in 1983). The two in 1982 were "consent 5(e)'s," which represented an agreement

between the submitter and EPA that manufacture of the substances would be restricted and that the company would not challenge the order in court.

In addition to the 5(e) orders, EPA had achieved 54 “voluntary regulatory” actions through the first three quarters of 1982. In those cases, EPA requested that a submitter develop additional information or impose voluntary controls. Table 23 is from an EPA memo dated July 30, 1982 (6). It shows results that EPA has obtained through its “informal regulatory actions” from the beginning of the program through June 1982.

The memo (6) briefly describes each of the informal actions. Examples of each type of action are discussed here:

- *Voluntary Testing (12 cases).* -In one case, EPA was concerned about the mutagenicity of the chemical. The submitter performed a bacterial mutagenicity test (see table 11 and accompanying text for discussion, also (9)) and the results were positive. The company complied with a request to affix warning labels to containers of the chemical to alert workers to a possible health hazard.
- *Voluntary Controls (26 cases).* -Most of the actions involved developing an appropriate warning label. For example, a PMN described a chemical for use by home hobbyists. EPA notified the submitter of its concerns about possible dermal absorption. The submitter labeled the chemical bottles with directions that rubber gloves be worn. In addition to such voluntary labeling actions, some companies have agreed to reduce exposures during manufacture and, in one case,

not to manufacture a particular group of chemicals.

- *Major Pending Negotiations Under Suspended Review Notice (13 cases).*—In these cases, EPA has negotiated with the submitter to produce additional toxicity information. The review period was suspended because the execution and analysis of tests would extend beyond the 90-day review period. Upon completion of the tests and their submission to EPA, the review “clock” can be restarted from where it was stopped.
- *Withdrawal of PMN in Face of Likely 5(e) Order (2 cases).*— In one case, EPA decided to write a 5(e) order because of large production volume and substantial potential exposure and release. The company, when notified of EPA’s intention to write a 5(e) order to require testing, withdrew the PMN.
- *Withdrawal of PMN in Face of Likely 5(f) Order (1 case).*—A 5(f) order can be written when EPA decides that a substance presents or will present an unreasonable risk to health or the environment. When the submitting company learned that EPA was preparing to regulate the substance under section 5(f), it withdrew the PMN “stating that it did not wish to be the target of EPA’s first TSCA section 5(f) order” (6).

These voluntary regulatory efforts have generated additional information, controlled exposures, and caused the withdrawal of PMNs that described chemicals that caused EPA concern. During the time the 54 voluntary actions occurred, EPA received a total of 1,499 PMNs. In other words, voluntary regulatory actions accompanied about 3.6 percent of those PMN reviews.

Table 23.-EPA Summary of Informal Regulatory Actions in Fiscal Years 1979, 1980, 1981, and First Three Quarters of Fiscal Year 1982

	Fiscal year 1979	Fiscal year 1980	Fiscal year 1981	Fiscal year 1982	Total
Informal action—voluntary testing	0	1	8	3	12
Informal action—voluntary controls	0	1	12	13	26
Major pending negotiations under suspended review period	0	0	0	13	13
PMNs withdrawn in face of likely 5(e) order	0	1	1	0	2
PMNs withdrawn in face of likely 5(f) order	0	0	0	1	1
Total	0	3	21	30	54

SOURCE: Environmental Protection Agency (1982).

In summary, EPA has taken action on 66 PMNs (12 formal 5(e) orders and 54 voluntary compliance). Whether that is an appropriate number depends on the opinion of the observer. If the observer considers most chemicals to be without hazard, taking action on about 4.4 percent of all PMNs may seem too high or just about right. On the other hand, that percentage of actions may seem too low to an observer who considers that a larger fraction of chemicals are hazardous. Thus, the implication of the percentage is a matter of interpretation.

This paper focuses on the frequency with which PMNs report various kinds of data to EPA. It points to groups of PMNs for which EPA received more or less information, but it has not delved into how EPA used the submitted information and other information in making decisions not to take any action, in which case manufacture went ahead unimpeded, or to take action to restrict manufacture or limit exposure. The last chapter of this paper (ch. 9) outlines a possible method to investigate EPA's decisionmaking process and its use of the information submitted on PMNs.