

*The Information Content of Premanufacture
Notices*

April 1983

NTIS order #PB83-241059

**The Information Content of
Premanufacture Notices**

Background Paper

Library of Congress Catalog Card Number *83-600522*

For sale by the Superintendent of Documents,
U.S. Government Printing Office, Washington, D.C. 20402

Preface

Some chemicals have been associated with deleterious effects on human health and the environment. Responding to concerns that newly developed chemicals might pose risks to health or the environment, Congress included provisions in the Toxic Substances Control Act that require manufacturers and importers of new chemicals to notify the Environmental Protection Agency (EPA) before new chemicals are introduced into commerce. The implementation of those provisions began in July 1979, and the EPA has now received more than 1,500 Premanufacture Notices that describe new chemicals.

The Office of Technology Assessment (OTA) prepared this background paper, "Information Content of Premanufacture Notices," in response to a request from the Subcommittee on Commerce, Transportation, and Tourism of the House Committee on Energy and Commerce. OTA examined 740 Premanufacture Notices, and this study reports the results of analyzing those notices for the presence or absence of the information specified by the Toxic Substances Control Act and for other items of physical-chemical and toxicity information that are useful for estimating potential health and environmental effects. In addition, this study reports the regulatory and voluntary compliance actions that EPA has taken as a result of reviewing Premanufacture Notices.

The general finding of this study is that the amount of information contained in Premanufacture Notices varied widely. Every notice contained most or all of the information items specified in the law, and many also reported nonspecified and useful information about the characteristics and toxicity of the chemical. At the same time, about half of the notices did not contain any toxicity data. This absence is not surprising given that the law does not require companies submitting Premanufacture Notices to carry out toxicity studies, but only to notify EPA of toxicity data that they have available.

Certainly, the absence of toxicity data complicates EPA's efforts to decide whether a new chemical may present an unreasonable risk to health or the environment. But the importance of toxicity data for making decisions about particular chemicals varies. Those data are less important for chemicals that closely resemble others for which there is much information and experience. They are critical for unusual chemicals or chemicals for which there is limited information. An additional study would be necessary to evaluate the EPA's decisionmaking process and whether or not it was compromised by absent data. The last chapter of this report outlines such a study.

OTA background papers are prepared by OTA staff and contractors, and drafts of the papers are sent for review to interested organizations and individuals. This paper was written by Michael Gough and Stedman Stevens; John Bell designed computer formats and programs. The 30 individual and organizational reviewers of the first draft are listed in appendix C.

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