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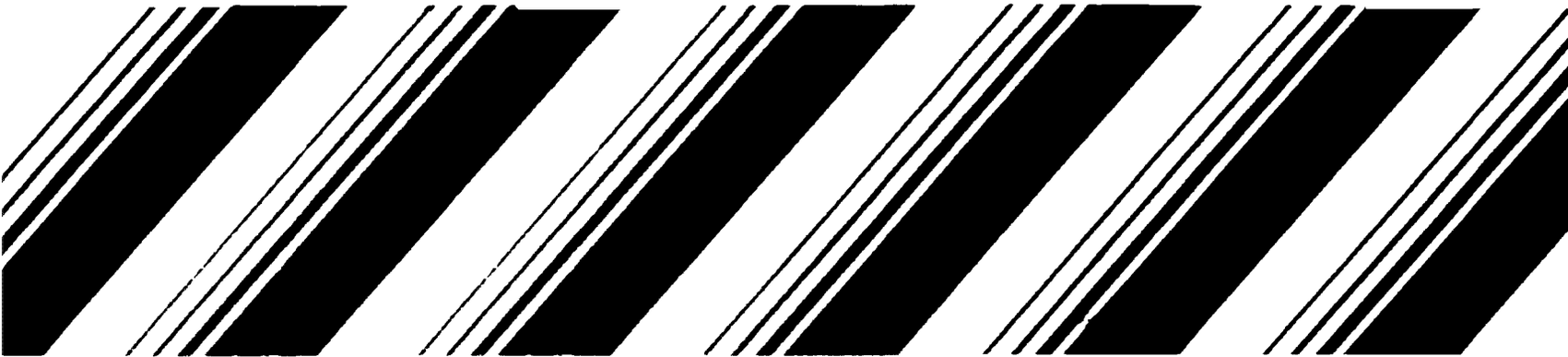
Estimated Costs of Preparation and Submission of Reproposed Premanufacture Notice Form



ESTIMATED COSTS FOR PREPARATION AND SUBMISSION OF REPROPOSED PREMANUFACTURE NOTICE FORM

Prepared for

Office of Toxic Substances
U.S. Environmental Protection Agency

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PREFACE

This document is a contractor's study prepared with the supervision and review of the Office of Toxic Substances of the U.S. Environmental Protection Agency (EPA). The purpose of the study is to estimate the cost to the chemicals industry for preparation and submission of the reproposed Premanufacture Notice (PMN) form. This reproposed form was prepared by the EPA Office of Toxic Substances as part of the implementation of Section 5 of the Toxic Substances Control Act.

This report forms the basis in substance and detail for the summary of costs presented in Section I-B.4 of the Preamble to the reproposed form (40 CFR Part 720).

This report was submitted in fulfillment of Contract No. 68-01-4717, Task 7, by Arthur D. Little, Inc. Work was completed as of September, 1979.

This report is being released and circulated at the same time as publication in the Federal Register of a notice of proposed rulemaking under Section 5 of TSCA. The study is not an official EPA publication. It will be considered along with any comments received by EPA before or during the proposed rulemaking proceedings in establishing final regulations. Prior to final promulgation of the premanufacture notice form, the accompanying study shall have standing in any EPA proceeding or court proceeding only to the extent that it represents the views of the contractor who performed the study. It cannot be cited, referenced, or represented in any respect in any such proceedings as a statement of EPA's views regarding the subject industry or the cost of preparing and submitting a PMN form.

TABLE OF CONTENTS

LIST OF TABLES

I. EXECUTIVE SUMMARY

A. INTRODUCTION

In connection with reproposal of the Premanufacture Notification (PMN) form by the Environmental Protection Agency (EPA), Arthur D. Little, Inc. has estimated the range of costs that may be incurred by U.S. chemical companies for preparation and submission of the reproposed PMN form for a new chemical.

The purpose of this report is to present estimates of the direct costs to a manufacturer for the initial preparation of a premanufacturing notice. It does not consider the costs associated with supplemental reporting requirements. Also, it is not intended to be an analysis of the economic impact of premanufacture notification. These items will be the subject of a future report.

The process for cost estimation included: (1) the identification of important variables affecting notification costs and the development of specific assumptions regarding their impact; (2) the determination of skills required to complete the PMN form; (3) the estimation of the level of effort and costs associated with completion of the PMN form; and (4) interactions with EPA staff to insure mutual understanding of the form and its instructions, and to review the cost estimates. Independently, specific time and cost estimates for preparing and submitting the PMN form were obtained from eight chemical companies.

B. FINDINGS

We estimate that completion of the reproposed PMN form will generally range from approximately $1,200 to $8,900. These estimates are for completion of the PMN form in the absence of claims for confidentiality. The range of cost estimates is associated with the wide variety of companies which comprise the U.S. chemical industry and assumes that the cost of submitting a PMN form will vary depending upon the company's approach to the PMN process.

Assumptions were developed which relate various factors to the cost of submitting a PMN form. We assumed that companies will make a good faith effort to comply with the intent of EPA-PMN requirements. In addition, we have assumed that large companies will have more information available than small companies and will consequently bear a higher cost for reporting that information. Also, we have assumed that the cost of submitting a PMN is directly proportional to the complexity of a chemical process.

Our time estimates represent a manufacturer's effort at an early stage in the PMN program. It is possible that the costs may change as experience is gained in preparing and submitting PMN forms. Depending on the validity of these and other assumptions used in this report, as they apply to specific companies, actual costs may be either greater or less than the estimates we have presented.

The results of our estimates are shown below. The wide range of hours estimated for completing Part II of the PMN form is related to significant variations in the complexity of chemical processes as well as the number of manufacturing and processing sites associated with the new chemical.

		Clerical	Technical	Managerial	Total
Part I:	General Information	2-10 hrs	7-59 hrs	2-13 hrs	11-82 hrs
Part II:	Human Exposure and Environmental Release	4-20	7-144	2-10	13-174
Part III:	List of Attachments	1-8	12-56	3-12	16-76
Part IV:	Federal Register Notice	1-2	1-8	1-2	3-12
	Total Time	8-40 hrs	27-267 hrs	8-37 hrs	43-344 hrs
	Cost per hour	$10	$25	$50	-
	Total Cost	$80-400	$675-6675	$400-1850	$1155-8925

If confidentiality of PMN information is claimed, we estimate the additional costs for asserting and substantiating these claims to range from approximately $900 to $6400. The actual cost will be more dependent upon the importance of confidentiality to a manufacturer's business than on company organization and structure or the proposed format for asserting and substantiating claims of confidentiality. Since confidentiality may not apply to all chemicals or companies, it is appropriate to consider this cost only for those companies making confidentiality claims.

Because of the large number of interacting variables that may influence company costs for completion of the PMN form and the uncertainty in determining how these interactions will operate, the results of our analysis should be treated as broad estimates rather than precise ones.

Estimates of the costs to prepare and submit a PMN form obtained from eight chemical companies, selected to include a range of company sizes and products, range from approximately $900 to $43,000 (exclusive of costs for asserting and substantiating claims for confidentiality). Six of the company's estimates cluster in the $2,000 to $4,000 range; however, there is no assurance that sampling another group of companies would result in the same clustering. The range of cost estimates provided by this sample of chemical companies reflects, to some extent, these companies' perceptions and uncertainties regarding the specific information needs for individual PMN submissions as well as their inexperience and unfamiliarity with the PMN form itself.

Estimates for asserting and substantiating claims for confidentiality obtained from two chemical companies range from $600 to $6,000; six other companies contacted were unable to provide estimates of these costs.

This sample of chemical companies is not statistically representative of either the chemical industry as a whole, or producers of new chemicals. Therefore, company estimates presented in this report should be considered only as generally indicative of possible company responses.

II. BACKGROUND

An important component of the implementation of the Toxic Substances Control Act (TSCA) is the requirement for each person who intends to manufacture or import a new chemical substance for commerical purposes to submit a notice to EPA at least 90 days before manufacture or import commences. As a result of this requirement, all chemical substances not included in the inventory published by EPA are designated as new chemical substances and will require the submission of a Premanufacture Notice (PMN) form.*

On January 10, 1979, EPA published a proposed PMN form with instructions (44 Federal Register 2242). Included with this publication of proposed rules and notification forms were estimates of the range of costs manufacturers might incur in completing the forms. These estimates were developed for EPA by Arthur D. Little, Inc. as a component of the preliminary economic impact study that was prepared in late 1978 (Impact of TSCA Proposed Premanufacture Notification Requirements, EPA Report Number EPA 230/2-12/78-005). In addition, EPA published in January 1979 an "Explanatory Appendix--Premanufacture Notice Forms."

In the comment period which followed publication of the proposed PMN form, many companies and organizations, including the Chemical Manu-

*Many chemicals were submitted after the December 1978 closing date for publishing the inventory and are not included in this initial printing (May 1979). Chemicals submitted by manufacturers after this closing date, but before June 30, 1979, will be included in the inventory and the manufacturer will not be required to complete a PMN form.

facturers Association (CMA, formerly the Manufacturing Chemists Association) submitted modified or alternative forms to EPA. In response to these comments and as a consequence of EPA policy decisions, several PMN form drafts were prepared by EPA staff in the period from March 1979 until August 1979. The revised mandatory parts of the PMN form, to which this study is addressed, represent the outcome of EPA's deliberations.

The principal purpose of this report is to estimate the direct costs to a manufacturer for the initial preparation of a premanufacturing notice using the EPA Premanufacture Notice form as reproposed.* This study is not intended to be an analysis of the economic impact of premanufacture notification. A secondary purpose of this report is to estimate the direct costs to a manufacturer for the initial preparation of a premanufacturing notice using the CMA (MCA) proposed Premanufacture Notice form of March 26, 1979. This cost estimate is contained in Appendix A.

*The importer and exporter PMN forms are also expected to be reproposed. The cost of preparing and submitting these two forms has not been estimated in this report.

III. APPROACH

The cost estimates presented in this report were developed through a series of steps which included estimating the time required to complete each section of the two forms. These time estimates provided the basis for estimating the total labor costs. The steps used in this analysis included:

- Discussion with EPA staff responsible for developing the form to insure understanding of the form and instructions.

- Development of a set of assumptions on the nature of chemical company organizations and the internal processes involved in the manufacturers' preparation of a PMN form.

- Identification of specific elements of information requested in forms.

- Design of worksheets to be used in obtaining estimates of time requirements. These worksheets were based on the previously identified information elements; each line on the worksheet corresponded to a major item of technical information or data requested in the PMN Form.

- Completion of the worksheets by six staff professionals experienced in chemical marketing, chemical and environmental engineering, chemistry, data analysis, or toxicology. Through staff discussions and an iterative process, estimates of the ranges of time (in person hours) expected to be required to complete the forms were developed for three labor categories, clerical, technical, and managerial.

- Collation of information from worksheets to develop a composite estimate of ranges of time required to complete the forms.

- Calculation of the range of total direct labor costs associated with completion of a PMN form by multiplying time estimates by assumed labor rates for the three labor categories.

- Discussions of time estimates with EPA personnel to confirm mutual agreement on the meaning of the items in the forms.

- Interviews with eight chemical companies to obtain their time and cost estimates for completing the PMN form. Companies were selected to include a range of company sizes, product lines, markets, research and development capabilities,

and patterns of new chemical introduction. Interviews were conducted at the companies' sites with persons who will be responsible for completing or coordinating work on the PMN form. Company representatives were asked to review the draft PMN form in advance of or during the interview and then to estimate the cost of completing various parts of the draft form. In connection with these estimates, company representatives were asked to describe the availability of data from within the company (e.g., libraries, laboratories, specialists) and to assess their ability to obtain data from outside the company (e.g., from customers) in making a "reasonable" effort to answer questions on the PMN form.

- Comparison of chemical company time and cost estimates with the Arthur D. Little, Inc. time and cost estimates; however, no revisions to the estimates were made on the basis of this comparison.

IV. ASSUMPTIONS AND UNCERTAINTIES IN NOTIFICATION COSTS

To estimate the costs of preparing and submitting a PMN form under Section 5 of TSCA, it was necessary to make a number of assumptions related to the way specific circumstances may affect the cost of each individual PMN submission. These case-specific assumptions, which are described in greater detail below, can be grouped into three major categories: those that relate to company organization and structure, those that are chemical specific, and those that pertain to the proposed PMN regulations. These assumptions were developed primarily as a result of our staff experience with the chemical industry, supplemented by review of public comments on the January 10, 1979 proposed PMN form, and discussions with EPA Office of Toxic Substances staff. Information from companies contacted for this study indicate that these assumptions are realistic.

Moreover, underlying this analysis is the assumption that companies submitting a PMN form will make a good-faith effort to comply with EPA requests. This response would include making a "reasonable" effort to obtain information both from within and outside the company, and including all available information with the expectation that the PMN would not be declared invalid. Finally, it is recognized that the specific cost of preparing a PMN form will depend on the collection, analysis, and organization of various data elements to respond to the structure of the form.

A. ASSUMPTIONS RELATED TO COMPANY ORGANIZATION AND STRUCTURE

Company size, operational style, existing information storage and retrieval methods, and information availability can affect the notification costs experienced by individual companies.

(1) *A larger company is assumed to have ready access to more extensive economic and technical information than a smaller company.*

The size of a company will, in general, reflect the amount of information that is available for each of the categories in the PMN form, as well as the degree of automation that is used in storing and retrieving this information. Although accessibility to data is assumed to be more facile for a larger company, the complexity of such a company's information systems may require extensive personnel commitments. This complexity, combined with the assumption that smaller companies will have less data to report for each new chemical, suggests that the cost for completing a PMN form will increase with company size.

(2) *Companies operating with a highly centralized organizational structure are assumed to have easier accessibility to data than decentralized companies.*

The effort to obtain and organize information for inclusion in PMN forms would be lower for companies with information and management controls in a central location under a limited number of key persons than for

companies that are dispersed both managerially and geographically. While there are large companies operating with a highly centralized organizational structure that will be able to take advantage of the data-gathering efficiencies, we have generally assumed for this analysis that larger companies would be less centrally controlled than smaller companies.

(3) *The presence of an active research and development department in any company is assumed to increase the amount of information available on new chemicals.*

In companies where R&D efforts play an important role in product development, one can expect a large body of data to be generated in connection with the development process. The existence of these data would require that they be reported where relevant. Thus, the presence of an active R&D unit is expected to increase notification costs. Although large companies tend to have large R&D departments, the size of the department does not influence cost as much as the extent of new product development activity relative to the size of the company. Thus, companies choosing to emphasize development of new chemicals will have more information and will bear a greater cost to report that information.

(4) *All manufacturers are assumed to have sufficient skills to complete the PMN form.*

The diversity of data requested in a PMN form could utilize many different skills, and thus implies input from a substantial number of persons in some companies. (See Chapter V for details.) Although smaller companies would not be expected to have specialists in each skill area, we have assumed that company officers would utilize their knowledge, as well as that of their staff, to complete the PMN form to the best of their ability. Moreover, it is assumed that their "best-effort" answers, which may include several "don't know" responses, will constitute valid completion of the PMN form. This assumption does not imply that all companies will complete the form, or are expected to complete the form, in equal detail.

(5) *In smaller chemical companies, it is assumed the PMN Form will be completed by senior management and technical personnel.*

Although the PMN form may be completed through the combined use of clerical, technical (or staff), and management input, smaller chemical companies may not have staff experienced or available to devote to completing the PMN form. Therefore, this task could fall largely to company management, with clerical support. In such cases, the average labor cost per person hour would be higher than in larger chemical companies which would be expected to utilize technical and support staff to prepare and present much of the data used in the PMN.

(6) *Three general labor categories and labor rates were assumed in preparing these estimates.*

In developing specific cost estimates, we used three labor categories and standard labor costs per person hour as follows: clerical--$10 per hour; technical--$25 per hour; and management (or legal)--$50 per hour. These costs include direct salaries and benefits but do not include corporate overhead. Each labor category is defined below:

- Management--This term is used to describe a salary category that could include corporate officers and corporate counsel as well as, in larger organizations, department heads, heads of research divisions, plant managers, senior design engineers, heads of marketing and sales divisions.

- Technical--This describes a salary category that could include staff professionals in various skill areas, such as chemistry, toxicology, engineering, risk analysis, and environmental science, as well as information and data handling specialists. (See Chapter V for details.)

- Clerical--This category includes clerks, secretaries, junior level professionals and technicians.

We have assumed that these categories and rates are representative of the types of people in the chemical industry who would be responsible for preparation and submission of the PMN form.

B. CHEMICAL SPECIFIC ASSUMPTIONS

The characteristics of the specific chemical for which a PMN is being submitted, including its identity, by-products, amount manufactured, uses, occupational and consumer exposure, toxicity, disposal routes and amounts, environmental and health effects, and sales and profit potential, can all impact the cost of completing a PMN.

(1) *It is assumed that companies producing a new chemical strictly for an industrial application will have performed fewer tests and have less available information than for the case of a new chemical being sold into a consumer application.*

Even without PMN, many manufacturers of consumer-related products demand detailed information on health and environmental effects from their suppliers. In addition, end-use patterns and transportation modes for consumer-bound products are generally more complex and difficult to analyze than are those for industrial products. Thus, it is assumed that a PMN of a new chemical destined for consumer application will, in general, require a greater expenditure of time and money than will a PMN of a chemical destined for an industrial application.

(2) *It is assumed that the time and effort needed to compile information for a PMN are proportional to the complexity of the chemical product/process.*

In general, complex products and processes have associated with them a possibility for the existence of by-products, co-products, and impurities. These situations will require more time (and greater cost) on the part of the submitter of the PMN than for a simple one step batch process. However, where several new products resulting from the same process require a PMN, the cost of a PMN submission for the related chemicals is likely to be substantially less than the cost of submission for the same number of new chemicals from independent processes.

(3) *For purposes of this analysis, it is assumed that chemicals will not be subject to TSCA, Section 4, Testing Requirements.*

For purposes of this analysis, we have assumed that chemicals will not be included in a class of chemicals subject to TSCA, Section 4 test rules and therefore additional test data will not need to be generated or reported. There is uncertainty regarding both what kind and how many new chemicals may be subject to Section 4 test rules.

(4) *As the toxicity of a chemical product increases, it is assumed the company will perceive the need to supply more detailed data with the PMN.*

Although the agency has issued no formal guidelines for testing, it is assumed that companies will perceive a need to provide additional data to support a PMN submission as the toxicity of the chemical product increases. This need may arise from a company's perception that the

Agency will view apparent toxicity as a major reason to delay the PMN process by requesting additional tests. Thus, companies will supply data during their initial submission in an effort both to avoid a future delay and to support a position that the benefits of the new chemical outweigh the risks. Furthermore, for new chemicals which are related to known toxic chemicals, considerable data may be available that the company could submit with a PMN.

(5) *Corporate strategy decisions with respect to the expenditure of time and funds to complete and submit a PMN form are assumed to be directly related to the anticipated sales and/or profit potential of the new chemical.*

In cases where the anticipated sales of a new chemical are significant, a company may decide to invest a high level of effort in PMN submission, perhaps by developing and submitting large amounts of data. Conversely, for a chemical with more limited sales potential, a low level of effort would be devoted to PMN submission. Similarly, the potential profit margin for a given chemical may also influence the magnitude of work and expenditures that would be committed to PMN preparation. Our estimates of the cost for preparation and submission of the PMN form reflect a likely range of effort by chemical companies but do not reflect situations under which extremely high (or low) levels of effort might be considered appropriate by companies.

C. REGULATORY ASSUMPTIONS

A number of specific elements of the TSCA PMN regulation, as proposed on January 10, 1979, have the potential to exert a strong influence on the total process of premanufacture notification. However, since the purpose of this report is to assess the cost of an initial PMN submission, only the costs associated with completing the form itself and with asserting and substantiating confidentiality claims are considered in this report. Other regulatory factors, including those that impact later stages of the PMN process, such as invalid notice, follow-up reporting, extension of notification period, supplemental reporting, and notice of continuing review, have not been considered in the preparation of this cost analysis but will be considered in a subsequent report. In addition, the statutory exemptions to the PMN submission such as the R&D and test-marketing exemptions, have not been considered as part of this analysis.

(1) *The process of asserting and substantiating claims for confidentiality is assumed to have a major affect on the direct costs of a PMN submission.*

Not every company will claim information provided on the PMN form as confidential. However, for those companies that do make such a claim, the issue of confidentiality may be extremely important to the company and it is reasonable to expect that considerable time and effort will be devoted to substantiating the confidentiality claims. Since the

need for confidentiality is not applicable to every PMN situation, the cost of developing and substantiating claims is not included in the base cost estimates. The issue of confidentiality is discussed separately in Chapter VI, Section D.

(2) *Manufacturers are assumed to make a "reasonable" effort to contact customers to obtain information on processing and use.*

Manufacturers are instructed to obtain reasonably ascertainable data on process and use. We have construed this to mean that manufacturers will attempt to contact customers for this information. However, a specific manufacturer's ability to obtain information from customers will be highly variable and dependent on the industry segment, the size of the company, and customer relationships. For example, customers may refuse to divulge use information for proprietary reasons or because of competition with the supplier, who may also be a processor.

D. UNCERTAINTIES IN NOTIFICATION COSTS

As for any analysis based on limited data, there are several uncertainties that should be considered in interpreting the findings of this report.

One uncertainty is the way in which EPA and chemical companies view the requirements of the PMN process. The uncertainty currently surrounding these requirements may be reduced as acceptable levels of detail evolve for PMN forms.

Moreover, even if Agency and company response patterns were better understood, the cost estimates presented in this report would only approximate actual expenditures within a wide range because of the multiple factors that influence each individual PMN submission. Therefore, the estimates define a likely range of values that may be exceeded or reduced in any specific situation.

Several other specific uncertainties that impact on the cost estimates presented in this report are highlighted below.

(1) *TSCA, Section 4, Testing Requirements.*

The applicability of TSCA, Section 4, Testing Requirements, to a new chemical may result in the performance of substantial testing even before a PMN is submitted. If a new chemical is subject to a Section 4 test rule, the company proposing to manufacture the new chemical must conduct testing as required or obtain a testing exemption from EPA.

Currently, it is uncertain what kind or how many new chemicals will be subject to Section 4 test rules.*

The costs incurred by a company for obtaining test data on a new chemical could be substantial and could be attributable to either Section 4 or Section 5 of TSCA. In addition, the costs of preparation and submission of these data could add substantially to the cost of PMN. We have not included these costs in our estimates.

(2) *Lack of specific testing guidelines under TSCA, Section 5.*

The Agency does not request specific testing under Section 5 of TSCA to support a PMN form, although the Agency is considering recommendation of testing guidelines. The current absence of guidelines may increase the uncertainty on the part of companies planning to submit forms for new chemicals. As a result, we anticipate some chemical companies may elect to expend testing resources in excess of those they might otherwise consider necessary in the absence of either PMN or testing guidelines. Conversely, in the absence of regulatory guidance on testing protocols, other chemical companies may consider submitting only a minimum amount of information in a PMN form, thus keeping initial notification costs very low. This lack of specificity regarding TSCA Section 5 testing guidelines allows companies to develop different strategies for approaching PMN, thus making cost estimates uncertain.

*This subject is more properly considered under rulemaking for Section 4 of TSCA. It is only mentioned here to demonstrate the uncertainty of its application to new chemicals.

(3) *Agency interpretation of the definition of "reasonably ascertainable" information.*

"Reasonably ascertainable" is a legal term. Application of this term to the PMN process will only be clearly understood following considerable experience. Although what is "reasonably ascertainable" to a $1 billion company may not be considered "reasonably ascertainable" for a $10 million company, further clarification is not available at this time.

V. SKILLS APPLICABLE TO PREPARING PREMANUFACTURE NOTICE FORM

In large companies with extensive technical and marketing staffs, a substantial number of individuals would be expected to participate in the preparation of a PMN, each providing the information and guidance for specific technical or business items in the form. The following skill table (Table 1) pertains to the reproposed PMN form and reflects the ability of a company of sufficient size to support a cadre of professionals in a wide spectrum of areas.

In contrast, many chemical companies (possibly the majority), including those with sales of as much as $20 million, do not have extensive and diverse personnel resources to participate in preparation of the PMN form. Therefore, it is likely that the PMN form in these companies will be completed largely by the senior technical person(s) and/or the head of the company who, in many cases, is also the primary marketing, research, and sales person(s). In such cases, one would expect the depth of information and analysis to be substantially less than in larger companies and to be reflected in less detailed reporting or possibly no reporting in certain areas of the PMN. (These and other assumptions are detailed in Chapter IV.)

TABLE 1

INFORMATION AND PROFESSIONAL SKILLS APPLICABLE TO PREMANUFACTURE NOTICE FORM

TYPES OF INFORMATION	PROFESSIONAL SKILLS										
	MANAGERIAL	LEGAL	SALES & MARKETING	CHEMISTRY	TOXICOLOGY	ENGINEERING	OCCUPATIONAL HYGIENE	ENVIRONMENTAL SCIENCES	STATISTICS	RISK ANALYSIS	TRANS-PORTATION SYSTEMS
Confidentiality	X	X		X	X	X					
Manufacturer Identification	X										
Chemical Identity				X							
Impurities				X	X	X					
Production Volume	X		X								
Category of Use	X		X								
Contact with Drinking Water	X		X					X			
Manufacturing History	X										
Hazard Warnings		X	X	X	X	X	X	X			X
Transport											X
Risk Assessment	X	X		X	X	X	X	X		X	X
Process Information				X		X		X		X	X
By-products, Co-products, etc.				X		X		X			
Pollution Control						X		X			
Gross Mass Balance				X		X		X	X		
Occupational Exposure				X	X	X	X				
Environmental Release & Disposal				X		X		X			
Detection Methods				X							
Consumer Exposure			X	X	X	X			X	X	
Federal Register Notice		X		X	X		X	X			
Attachments	X	X	X	X	X	X	X	X	X	X	X

Source: Arthur D. Little, Inc., estimates.

VI. ARTHUR D. LITTLE, INC. ESTIMATES OF COSTS FOR PREPARATION AND SUBMISSION OF PREMANUFACTURE NOTICE FORM

A. PROCESS AND ASSUMPTIONS

Our staff developed cost estimates for preparing and submitting the PMN form by estimating the time needed to complete individual items on the form. The cost estimates were developed using PMN form drafts of June 28 and July 23, 1979; however, they have been revised to be consistent with our understanding of the PMN form as it will be reproposed. These estimates are based on a projection of steps that will ordinarily be followed in the preparation of a PMN form (Table 2). These projected steps are general and are independent of the specific requirements of any individual form. Although a step for asserting and substantiating claims for confidentiality is included in Table 2, this step is not included in the base estimates presented in Section B of this chapter, but rather is discussed separately in Section D.

Estimates of the cost for preparing the notice form are based on our estimate of the likely responses of a prudent firm--one that will submit the form with the expectation that it will be acceptable in terms of both the sufficiency and nature of the data supplied. The costs and increased market risks resulting from delayed review prior to manufacture will be an incentive for many companies to try to satisfy EPA expectations with the initial notification.

TABLE 2

PROJECTED STEPS TO COMPLETE PMN FORM

ANALYSIS OF DATA REQUIREMENTS

- Administrative
- Legal
- Technical

COLLECTION AND ORGANIZATION OF INFORMATION

- Data retrieval (computer, local manual, distant post or telex)
- Analysis and verification
- Organization of information to comply with EPA format

COMPLETION AND SUBMISSION OF FORM

- Clerical work
- Legal and Management review
- Submission of completed PMN form

DEVELOPMENT AND SUBSTANTIATION OF CLAIMS FOR CONFIDENTIALITY

- Strategy Development
- Development of Substantiation
- Form Preparation
- Management Review

Company organization and structure, specific chemical-related data and regulatory factors can also influence the costs of preparing and submitting a PMN form, as has been discussed in Chapter IV, and have been considered in a general way in preparing these cost estimates.

In addition, several other assumptions have a bearing on this analysis of the premanufacture notification costs.

(1) *The time estimates given in this report are assumed to represent a manufacturer's effort in an early stage of the learning curve. The costs of PMN submission at later stages of the learning curve have not been included in this analysis.*

At the outset, the time required for companies to complete the PMN form will reflect their unfamiliarity with the form itself and with the responses from the Agency to the submitted forms. It is expected that the administrative costs will decrease as companies become familiar with the Premanufacture Notice form and with the responses from the Agency to the submitted forms. For example, with experience, companies may find it to their advantage to arrange their data collection and recovery protocols to fit with Agency requirements. However, these and other learning curve effects have not been included in this analysis; the estimates presented represent a manufacturer's effort in an early stage of the learning process.

(2) *It is assumed that data requested in the PMN form has not previously been requested by other Federal or state agencies.*

No allowance was made in this analysis for the possibility that data developed for other Federal agencies or for the satisfaction of state or local requirements would also be appropriate for use in completion of the Premanufacture Notice form. Although similar data may be required by other agencies, it is expected that the different needs of these organizations, in comparison to the requirements of EPA, may necessitate a unique effort to complete a satisfactory Premanufacture Notice form and result in little cost savings.

(3) *It is assumed that the availability of the various types of data requested on the PMN form will vary among companies, and that some PMN forms will be submitted with significantly lower levels of detail than others.*

The range of cost estimates provided in this report acknowledges the varying levels of knowledge, expertise and sophistication found in the chemical industry. The range also relates to the "reasonably ascertainable" issue which was discussed in Chapter IV of this report.

B. RESULTS

Time estimates to complete the Premanufacture Notification form, assuming no claims for confidentiality are made, are shown in Table 3. Estimates were prepared in accordance with the methodology described in Chapter III, Approach. Following the derivation of these time estimates, they were reviewed with representatives of EPA to ensure that there was mutual agreement as to the Agency's intent in the formulation of the questions and data requirements.

The time estimates lead to a range of costs from $1155 to $8925 to complete the form (Table 4). The ranges detailed in Table 3 and Table 4 are likely values for different types of companies and are not intended to represent extreme (maximum or minimum) points. Clerical time is not detailed in Table 3, but was estimated separately and ranges from 8 to 40 hours for all parts of the PMN form.

Table 3

TIME ESTIMATES TO
COMPLETE PREMANUFACTURE NOTICE FORM[1]
(Assuming no claims for confidentiality by filing company)

	Technical (hours)	Managerial (hours)
PART I. General Information		
SECTION A. Manufacturer Identification		
1. Person Filing Notice 2. Technical Contact 3. Parent Company 4. Intended Manufacture Year 5. Prenotice Communication Number	--	1-8[2]
SECTION B. Chemical Identity		
1. Class I Chemical Substance[3] a. CAS Registry No. b. Specific Chemical Name c. Molecular Formula d. Synonyms e. Trademarks f. Structural Diagram	1-4	--
2. Class II Chemical Substance[3] a. CAS Registry No. b. Specific Chemical Name c. Synonyms d. Trademarks e. List of Precursor(s)	1-4	--

Table 3 (Cont.)

	Technical (hours)	Managerial (hours)
PART I. General Information (continued)		
SECTION B. (continued)		
3. Polymers[3] a. Monomers and CAS Registry No. Range of Composition, Maximum Residual b. Minimum Molecular Weight	1-5	--
4. Impurities (Identify, quantify)	1-8	--
SECTION C. Generic Names	0-4	0-1
SECTION D. Production and Marketing Data		1-2
1. Production Volume a. First Year b. Second Year c. Third Year	1-4	
2. Category of Use a. List Categories of Use(s) b. Other Use(s) c. Contact with Drinking Water	1-8	
3. Previous Manufacture 4. Hazard Warnings	1	
5. Customers	0-8	

Table 3 (Cont.)

	Technical (hours)	Managerial (hours)
PART I. General Information (continued)		
SECTION E. Transport		
1. Shipping Name/Hazard Class 2. Mode of Transport	1	--
SECTION F. Risk Assessment	0-16	0-2
SECTION G. Detection Methods		
1. In workplace air 2. In effluent streams 3. In materials requiring disposal 4. In end products	1-4	--
PART II. Human Exposure and Environmental Release		
SECTION A. Industrial Sites Controlled by Submitter		
1. Process Information 1.1 Identity of Site 1.2 Type of Site 1.3 Hours of Operation 1.4 Amount Manufactured	1-4	
2. Block Diagram a. Major chemical reactions b. Mass of all feed materials, by-product materials and products c. Release points	1-24	

Table 3 (Cont.)

	Technical (hours)	Managerial (hours)
PART II. Human Exposure and Environmental Release (continued)		
SECTION A. (continued)		2-6
3. Occupational Exposure		
3.1 Identity of Site 3.2 Occupational Exposure at Site	2-16	
3.3 Direct Exposure 3.4 Physical State 3.5 Other Substances[4]	2-16	
4. Environmental Release and Disposal 4.1 Identity of Site 4.2 Quantity, Duration, Media 4.3 Composition 4.4 Pollution Control Equipment	1-12	
SECTION B. Industrial Sites Controlled by Others		0-2 0-2
1. Process Information - Identity of Site	0-2	
2. Process Description	0-14	
3. Occupational Exposure 3.1 Identity of Site 3.2 Occupational Exposure at Site 3.3 Direct Exposure 3.4 Physical State	0-20	

Table 3 (Cont.)

	Technical (hours)	Managerial (hours)
PART II. Human Exposure and Environmental Release (continued)		
SECTION B. (continued)		
4. Environmental Release and Disposal 4.1 Identity of Site 4.2 Quantity, Duration and Media 4.3 By-product material requiring disposal	0-8	
SECTION C. Consumer and Commercial User Exposure		
1. Table - Route, Frequency and Number Exposed	0-16	
2. Exposure Levels	0-4	0-2
3. Product Aspect Affecting Consumer Exposure	0-4	
4. By-products of Use	0-4	
PART III. List of Attachments		
a. Physical and chemical properties data	4-16	1-4
b. Health and environmental effects data	8-40	2-8
c. Notice attachments[5]		
d. Confidentiality attachments[6]		
e. Voluntary attachments[7]		

Table 3 (Cont.)

	Technical (hours)	Managerial (hours)
PART IV. Federal Register Notice		
A. Chemical Identity B. Manufacturer Identification C. Use Data D. Test Data	1-8	1-2

NOTES:

[1]Clerical time estimated for the PMN form to be between 8 and 40 hours.

[2]Includes time for final technical, management and legal review of the entire completed form.

[3]Only one of these subsections (1, 2 or 3) will be completed for any individual chemical. Thus, only the time and cost estimates of only one item are included in the totals.

[4]Includes by-products, co-products, feedstocks, and intermediates.

[5]Time estimates for attachments have been included in the estimates above.

[6]See Chapter VI, Section D for development of cost estimates for asserting and substantiating claims.

[7]No time was estimated for voluntary attachments.

SOURCE: Arthur D. Little, Inc. estimates.

Table 4

SUMMARY OF TIME AND COST ESTIMATES FOR
PREPARATION AND SUBMISSION OF PREMANUFACTURE NOTICE FORM[1]

		Clerical	Technical	Managerial	Total
Part I:	General Information	2-10 hrs	7-59 hrs	2-13 hrs	11-82 hrs
Part II:	Human Exposure and Environmental Release	4-20	7-144	2-10	13-174
Part III:	List of Attachments	1-8	12-56	3-12	16-76
Part IV:	Federal Register Notice	1-2	1-8	1-2	3-12
	Total Time	8-40 hrs	27-267 hrs	8-37 hrs	43-344 hrs
	Cost per hour	$10	$25	$50	---
	Total Cost	$80-400	$675-6675	$400-1850	$1155-8925

[1]Assumes no claim for confidentiality made by filing company.

SOURCE: Arthur D. Little, Inc., estimates.

C. DISCUSSION OF COST ESTIMATES

This discussion is intended to provide an understanding of the specific estimates presented above.

The sections in Part I of the form cover items of general information required by TSCA. The time range estimated for completion of Section A includes the attention given to final management and legal review of the completed form and represents, at the low end (one hour), a modest review of a simple form containing minimal information. At the upper end, eight hours would allow for a detailed review by one or more senior management personnel (e.g., president, director of research, corporate counsel, etc.).

The time estimates for chemical identity (Section B) would be expected to cover a range of activities including transcription of existing data for chemicals for which notice is planned, and input from literature specialists and chemists to search and validate chemical structure data bases. The time estimates for acquiring and transcribing data on impurities, which might be required in the case of a complex mixture of substances, would involve similar activities. The derivation of generic names (Section C) would be required only if confidentiality were claimed, thus a low estimate of no time is indicated for this item.

In Section D, a maximum of 12 hours may be expended to assess production volumes and items concerned with information on use. Under some cir-

cumstances, such as making a chemical for speculative sale, manufacturers would have available neither production nor use data, and a lower estimate of one hour for each category appears to be suitable.

For chemicals destined as intermediates within the same chemical complex, no transportation would be required, thus requiring no time for Section E. In contrast, a chemical shipped to many customers by different modes of transport would require multiple pieces of information, or about one day's effort in completing this section.

If a risk assessment evaluation (Section F) is available, it must be included. Thus, for companies that have not prepared a risk assessment, this section would require no time. For those that have prepared a risk assessment, a range of costs would depend on the complexity of the risk assessment document and on the effort necessary to prepare a submission suitable to EPA from an internal company document(s). An upper time estimate of 16 hours is reasonable for consideration of a new chemical for which a company has prepared a detailed internal risk assessment. In general, one would expect such detailed assessments in the larger companies that have adequate professional staff to prepare these documents.

Section G requests information on detection methods. Because it is likely that a company has considered this aspect of the manufacturing operation an upper bound of four hours would seem sufficient to summarize this information even for complex chemicals or processes.

Part II of the form requests information on human exposure and environmental release. The time estimates for the components of Section A which deal with information on industrial sites controlled by the submitter represent a rather wide range. Reporting process information will be influenced by a number of factors, including the number of steps in the process, the complexity of the process, a number of locations of manufacture, and final disposition of product and by-products. As each of these items increases in magnitude and/or complexity, the costs would be expected to increase. Further, the capabilities of a company in process engineering and design (as may be reflected by company size and mode of operation) would also influence the time and costs to complete this section of the PMN form.

Similarly, these factors will also influence the time expended in dealing with the other components of Part II (occupational exposure and environmental release and disposal). In general, simple processes with few starting materials resulting in few or no by-products will require a minimum time for reporting the information.

Section B of Part II requests information on industrial sites controlled by others. As in Section A, the details of the process will play a large role in determining the amount of time necessary to complete this part of the PMN form. At a minimum, no time would be involved if the chemical in question is utilized only within the company of the submitter, or if the manufacturer had no information nor could obtain any on the processing and use of the chemical in customer operations.

An intermediate in a synthesis sequence or a material incorporated directly into an industrial or consumer use product by the manufacturer would be examples of substances not requiring consideration in Section B. In contrast, a chemical substance that is widely sold or distributed could result in substantial costs to the manufacturer if a large effort is expended to obtain information from customers or if the manufacturer possesses detailed information on customer processing, use, or disposal of the new chemical. It is assumed that companies will make a reasonable effort to get this information from customers, if they do not already have it, in order to respond to the PMN request for data on this subject. The Agency has not developed final guidelines with respect to the depth and thoroughness of information that will be considered "reasonably ascertainable" under this section to fulfill expectations for a valid PMN notice. Moreover, the acquisition of data from customers will depend in large measure on the relations between suppliers and customers and on industry practice in certain product areas. areas.

Similarly, in Section C, which deals with consumer and commercial user exposure, chemicals for which no consumer or commercial sales are envisioned would not require completion of this section. One difficulty in acquiring information for Sections B and C of Part II may be the reluctance of customers to reveal use or processing data in order to maintain a proprietary position. Thus, varying amounts of information are likely depending in large part on the working relationships between manufacturers and customers.

The time estimates to provide the attachments for physical and chemical properties and health and safety data as requested in Part III are necessarily of a wide range. This range reflects the amount of information that may be available in different companies, as well as the detail in which these data will be submitted. For example, a complex organic chemical is likely to be produced in a complex chemical process in conjunction with by-products, co-products, and intermediates, many of which may not be on EPA's chemical inventory. This would necessitate submittal of any test data which exists for these related chemicals. In addition, if the chemical is sold into consumer markets, the manufacturer is likely to have test data in several areas (possibly including acute toxicity, consumer exposure, worker exposure, and safety and handling), which must be supplied to EPA in a PMN form. Conversely, for a simple inorganic compound, proposed for industrial use, a company is likely to have more limited test data to submit in the PMN.

The data for Part IV, Federal Register Notice, would generally be available from other parts of the PMN notice. However, since this item is communicated to the public immediately, companies will be likely to complete and review this section with considerable care. Thus, a maximum of eight hours technical time and two hours managerial time should be sufficient to complete this part.

D. CONFIDENTIALITY

Background

The costs of asserting and substantiating claims of confidentiality are discussed in this section independent of the costs of preparing and submitting a PMN form. These costs should be viewed as incremental to the costs for PMN submission.

The costs associated with asserting and substantiating claims of confidentiality are likely to vary widely from company to company within the chemical industry, depending on a number of factors, including the importance of confidentiality to a company's overall competitive strategy. Although some companies will not claim any of the information submitted on a PMN as confidential, many companies are expected to have strong needs to protect their products, processes, and customers. Thus, depending on each company's need for confidentiality on a specific product, the amount of time and effort devoted to making and substantiating these claims will vary.

A company's strategy for preparing and substantiating claims of confidentiality will be influenced by a number of other factors. For example, both the provisions of the Freedom of Information Act and the Agency's own general rules* governing the treatment of confidential information are likely to influence a company's process for asserting and substantiating confidentiality claims for business information provided

*40 CFR, Part 2

to EPA. Moreover, the nature of TSCA itself, in that it deals with specific chemicals and chemical processes, is such that companies will be required to submit business information which may be considered confidential. The submission of confidential business information would necessitate an assertion of a confidentiality claim even in the absence of a standardized PMN form. In many cases such a claim may have to be substantiated. It is recognized that some level of effort and cost for asserting and substantiating confidentiality would be expended in most instances in which confidential business information is submitted under the PMN program.

Other factors influencing the cost of PMN submission were discussed in Chapter IV, and include such characteristics as company size, the company's level of R&D or new chemical development activity, the degree of corporate centralization, and others. These factors can also be expected to influence the cost of claiming confidentiality, although the overall role of confidentiality in a company's strategy appears to have the foremost influence on the costs for asserting and substantiating claims for confidentiality.

In addition to the company specific factors discussed above, the format of the requirements for asserting and substantiating claims for confidentiality can influence the total cost. For example, a company's freedom to determine the scope, depth, and timing of information presented would, all else being equal, affect the total cost of claiming confidentiality.

Because of the complex interrelationships among these factors, no attempt has been made to separate the costs directly attributable to the reproposed PMN form from those costs inherent in the submission of any confidential business information.

Reproposed Confidentiality Provisions

The requirements for claiming confidentiality for elements of the reproposed PMN form differ from the requirements associated with the January 10, 1979 proposal. Under the reproposed program, a company is asked to provide substantiation for all confidentiality claims at the time the initial PMN form is submitted to EPA. Additionally, the reproposed PMN form provides specific questions for substantiation of confidentiality, thus reducing the uncertainty associated with preparation of a PMN confidentiality substantiation. The key elements of the current proposed requirements are outlined below:

- Every item on the PMN form may be claimed confidential; however, all claims must be substantiated at the time of submission.

- Six general categories of claims are recognized by EPA:
  - (A) Manufacturer's Identity,
  - (B) Chemical Identity,
  - (C) Production Volume,
  - (D) Use Data,
  - (E) Process Information, and
  - (F) Other.

- Detailed substantiations are required for the Chemical Identity and "other" categories.

- Less detailed substantiations are required for the remaining four categories.

- Claims may be made by placing letter(s) in boxes on the PMN form which correspond to the item(s) claimed. The letters correspond to the six general categories outlined above.

- In addition, a "sanitized" copy of the attachments to the PMN form must be submitted with all confidential information deleted.

- Any items of information may be "linked" to any of the first five general categories, and in such cases require an explanation of the "linkage," assuming the main category claims are substantiated.

- For certain categories of claims, generic information must be provided:
  - If chemical identity is claimed confidential, then a generic name must be included.
  - If physical/chemical properties are claimed confidential, then generic physical/chemical information must be included.

- If use is claimed confidential, a generic use must be included.
- If manufacturer's identity is claimed confidential, a generic manufacturer's description must be included.

EPA's revised approach was designed to minimize the burden to substantiate claims of confidentiality for information which may be of significant commercial value but which the Agency feels may not be as useful as other data in assessing the potential risk of new chemicals. However, the greatest substantiation is requested for data which the Agency considers necessary to conduct an independent assessment of the potential risk of the new chemical. This revised approach also was designed to discourage companies from claiming all information on the PMN form as confidential.

The format changes were initiated by EPA to meet three objectives: to provide the public with sufficient data to review premanufacture notices; to provide the Agency with sufficient information to allow it to respond promptly to Freedom of Information Act requests when received; and to minimize the need for the company to repeatedly provide additional information to substantiate a claim of confidentiality.

Arthur D. Little, Inc. Estimates for the Cost to Assert and Substantiate Confidentiality Claims

Although the exact level of effort required to develop and substantiate claims for confidentiality may be influenced by a number of factors, related to both company/chemical characteristics as well as the format of regulatory requirements, it is possible to identify a general process

that is likely to be followed by most companies in approaching the issue of confidentiality. The nature and sequence of these steps are largely independent of the specific requirements posed by EPA for claiming confidentiality. Instead, they relate primarily to the overall approach a company might take in responding to any set of confidentiality requirements. Recognizing that this list is general in nature and that the details of the process will vary by company. it seems likely that most companies will utilize some variation of the following generic process for claiming confidentiality:

(1) Strategy Development--Determine which element(s) of information on the PMN form to claim as confidential, including categories of claims and linkages.

(2) Substantiation Development--Substantiate confidentiality claims by developing responses to questions or requirements in each EPA category claimed confidential. Determine appropriate linkages. Obtain corporate management certification of claims, as required.

(3) Form Preparation--Prepare "sanitized" attachments, excluding all confidential information. Make appropriate annotations on the complete PMN form to indicate confidentiality assertion(s).

(4) Review--Review both the completed PMN form and the "sanitized" attachments with appropriate in-house staff,

and in some cases outside legal counsel, to insure the document's proper completion.

The level of effort required for the first step in this general process is likely to vary according to the number of potential decision makers involved. In small companies, a decision regarding which information to claim confidential could probably be made by the top one or two company officers with approximately two hours of total effort. Some larger companies are likely to enlist the advice of a wide range of interested departments, such as engineering, marketing, sales, R&D, environmental affairs, and legal. Such an effort may require about 24 hours. Thus, the time required to develop an appropriate strategy for confidentiality could range from approximately 2 to 24 hours.

The second step in the process, developing substantiations, may require the most significant time investment of the four major steps. The primary factors influencing the amount of time required for this step appear to be the importance of confidentiality in a company's strategy and the format of EPA requirements for claiming confidentiality. Under the currently proposed confidentiality requirements, a company desiring to maintain only one category of the information supplied on the PMN form confidential might be expected to spend up to approximately 12 hours both responding to the questions supplied by EPA for that one category and briefly reviewing those answers with a legal staff members. The Manufacturer's Identity category may require less time, depending on the number of linkages. At the other extreme, a company that desires to

maintain essentially every element on the form confidential might invest the equivalent of roughly 12 hours on each of the five categories developed by EPA, for a subtotal of 60 hours, and an additional 40 hours in such tasks as developing and answering questions for the "other" category, making appropriate linkages, and obtaining inputs from the legal staff. Thus, in such a situation, the total time invested in the second step of the confidentiality process might approximate 100 hours.*

The third step in the process--formating the responses and preparing the form--would require largely clerical input. The time is estimated to range from two hours, in a simple case, to 16 hours, in a case in which most or all items are claimed confidential.

The time required for the fourth step--review--can be expected to vary according to both the number of decision makers involved in the process and the amount of information claimed confidential. In some situations

*In the absence of EPA's current requirements to claiming confidentiality, individual companies would have more freedom to determine the scope and depth of their substantiations. Under the guidelines for claiming confidentiality that accompanied the proposed January 10, 1979 PMN form, substantiation was not required at the time of submission for all items claimed confidential. Thus, a company faced a wide range of options from providing no substantiations for some items to providing extremely detailed exhaustive substantiations for every item claimed confidential. It is, therefore, reasonable to assume that greater company-by-company variations in effort expended on the second step in the confidentiality process--developing substantiations--would occur in the absence of EPA's current confidentiality provisions. Under these conditions, the range of time required could conceivably be much broader than the range estimated above.

in which only one item is claimed confidential and only a few people are involved in the review process, a total of approximately two hours may be invested. In other more complex situations, as much as 20 hours may be required.

Our estimates for the level of effort required for claiming confidentiality is summarized below:

Step		Level of Effort
(1)	Strategy Development	2-24 hours
(2)	Substantiation Development	12-100 hours
(3)	Format Preparation	2-16 hours
(4)	Review	2-20 hours
	Totals	18-160 hours

This range of hours reflects the likely values for the entire confidentiality process for different types of companies that choose to make a confidentialtiy assertion, and is not intended to represent extreme (maximum or minimum) points. For example, a simple claim of Manufacturer's Identity without any linkages may involve substantially less than 18 total hours.

The above range of hours would correspond to an estimated cost range of $900 (for 18 hours of effort at $50 per hour) to $6400 (for 160 hours of effort at $40 per hour). The differences in the hourly rates reflect a higher management content in the 18 hour estimate and a higher proportion of technical and staff participation in the 160 hour effort. At the low end of the range, the 18 hours could represent either a detailed treatment of a single category or a very general treatment of several categories.

Chemical Industry Estimates of Confidentiality Costs

As a check on our estimates, eight chemical companies were contacted and asked to estimate the time required to complete the revised confidentiality form. Although most companies contacted were willing to comment on the general importance of confidentiality in their company strategy, few felt prepared to estimate the time that would be required for this process. Those cost-related comments which were received are summarized below.

- A large company (with sales over $500 million) indicated that all of their new chemicals would require some degree of confidentiality protection. The costs associated with claiming confidentiality would range from $600 for the minimum number of claims to $6000 for numerous claims.

- A small private company indicated that most products would not require any confidentiality claims, but those that did would require extensive protection. This company estimated that the process of asserting and substantiating claims for confidentiality would require approximately $1650 in managerial and clerical time, with an additional $300 to $350 for an outside lawyer to examine each form, bringing the total to approximately $2000.

VII. SELECTED CHEMICAL COMPANY ESTIMATES OF COSTS FOR PREPARATION AND SUBMISSION OF PREMANUFACTURE NOTICE FORM

A. PROCESS

In an effort to verify estimates prepared by Arthur D. Little, Inc., we contacted eight chemical companies and asked them to estimate the time and cost for completing the PMN form, using the June 28 and July 23, 1979, drafts. These costs estimates have not been revised to reflect changes in these drafts, but any revisions would be expected to be small. In addition to incorporating the attachments as integral parts of the PMN form, explicit differences between the reproposed form and the June 28 form used by most of the chemical companies to estimate their costs, are summarized in Table 5.

The companies selected had a range of sizes, markets and product lines. Our staff met separately with representatives of these companies and reviewed the PMN form with them, discussing the approach that the company would take to submitting a PMN, the key persons responsible for the PMN, as well as the time and cost for completing the form.

Specifically, companies were asked to make their own estimates of time to complete each of the major sections of the PMN form, and then to estimate the average cost per hour for persons involved in the process. Several questions were also directed at ascertaining current testing practices, data availability within the company, and customer relationships that might facilitate obtaining information on processing or use of new chemicals.

TABLE 5

CHANGES IN PMN FORMS FROM JUNE 28, 1979

Part I.A. - Manufacturer Identification	Addition of Question 5 on Prenotice Communication
Part I.B. - Chemical Identity	None
Part I.C. - Generic Names	None
Part I.D. - Production and Marketing Data	Addition of two use categories (industrial, commercial) Addition of customer information
Part I.E. - Transport	None
Part I.F. - Risk Assessment	New Section (if available)
Part I.G. - Detection Methods	Moved from Part II.A.4
Part II.A. - Industrial Site Controlled by the Submitter	Modification of Question 1 on process information and block diagram.
	Removal of Question 3.B on environmental release and disposal of by-product. Moved questions on release, pollution control equipment and disposal operations from process description to environmental release and disposal section.
Part II.B. - Industrial Sites Controlled by Others	None
Part II.C. - Consumer Exposure	Addition of Question 4 on by-products
Part III - Attachments	Attachments A-D and Tables 1 and 2 now incorporated in the body of PMN form.
Part IV - Federal Register Notice	Was Part III, Section A; addition of Item 2 on Manufacturer Identification

B. ESTIMATES

The estimates that were obtained from staff members of the companies visited are summarized in Table 6. In addition to the time and cost estimates, the sizes of the companies in terms of annual sales volume and work forces, as well as their primary product areas are given.

TABLE 6

COMPANY ESTIMATES FOR TIME/COST TO COMPLETE PMN FORMS

COMPANY	CHEMICAL SALES ($ Millions)	EMPLOYEES	INDUSTRY SEGMENTS	TIME TO COMPLETE FORM (HOURS) Part I	Part II	Part III	TOTAL TIME (Hours)	COST RANGE $
A	1,250	13,900	Plastics, Polymers Industrial Chemicals	127-142	154-1,013[4]	84-90	365-1,245	12,800-42,800
B	500	6,900	Inorganic/Organic Chemicals	24-31	182-278	15	221-324	3,000-3,900
C	65	575	Hydraulic & Metal Cutting Fluids	6-1007[4]	64	7	77-1,078	1,900-21,900
D	10	65	Pigments & Vehicles	4-16	20-40	16-32	40-88	2,000-4,400
E	10	65	Surfactants	8-16	8-16	4-8(+40)[1]	60-80	3,000-4,000
F	7.5	50	Fragrances & Aromatic Chemicals	3	10	3(+4)[2]	16-32	900-2,000
G	5	22	Plastic Resins	3	9	1(+4)[2](+11)[3]	24-40	1,200-2,100
H	1.5	12	Silicon Compounds	16-41	51-68	1-2	68-111	1,800-3,100

[1]Additional time required to develop and substantiate claims for confidentiality and prepare "sanitized" copy of PMN form.

[2]Clerical time.

[3]For review and contact with EPA.

[4]Includes analytical work which may be necessary to adequately complete PMN form.

SOURCE: Company estimates as reported to Arthur D. Little, Inc.

C. DISCUSSION

For the most part, company estimates substantiated the estimates prepared by Arthur D. Little, Inc. except that the range of costs as estimated by the companies was wider. We believe these estimates reflect the importance of the technical factors described earlier and that companies have taken these factors into account when making their estimates. In particular, the low end of the company-derived cost estimates reflects an individual company's ability (or willingness) to submit only minimum amounts of data and to indicate that they do not know and cannot reasonably obtain additional information. The higher cost estimates reflect a company's concern over the PMN process and willingness to provide detailed information, even though such data may not be explicitly required, in the hope of insuring successful completion of the review process. As discussed previously, we believe these cost estimates reflect some degree of unfamiliarity and uncertainty regarding the PMN requirements and EPA's response to PMN submissions.

As shown in Table 5, Company A has estimated their lower-bound cost estimate of completing a PMN form significantly above the other seven companies' estimates. This is a result of Company A's higher cost estimate for technical time ($35/hr) and also of their high estimate of time required for reporting on industrial sites controlled by others. Many of their products are processed at hundreds of locations soon after introduction into the market; the company plans to obtain and report information on many of these sites.

In all cases, except Company E, the cost estimates do not include the time and cost for asserting and substantiating claims of confidentiality. This aspect of the PMN has been discussed previously in Chapter VI.

Although the companies selected for the interviews represent a wide range of activity within the chemical industry, they are by no means a statistical sample of the industry. Thus, it is impossible to draw any conclusions from these data that would relate to the industry as a whole. Even though the cost data appear to cluster in the $2000-$4000 range, there is no assurance that sampling another group of companies would result in the same clustering. Moreover, the complexity and number of interacting variables that influence each individual company must be recognized in any analysis of this type and the results should be treated with appropriate caution.

APPENDIX A

COST ESTIMATES FOR CHEMICAL MANUFACTURERS' ASSOCIATION (CMA) PREMANUFACTURE NOTIFICATION FORM OF MARCH 26, 1979

EPA asked Arthur D. Little, Inc. to provide cost estimates for the PMN form alternative provided by the Chemical Manufacturers' Association (CMA, formerly the Manufacturing Chemists Association). This form is a response from the CMA to the invitation of the Agency in January 10, 1979, proposal to comment on the PMN form. The CMA form is divided into mandatory and optional sections, similar to the proposed EPA form. Thus, the cost estimates for preparing the CMA form should be compared to cost estimates for the January 10, 1979 EPA form as well as the reproposed EPA form.

The matrix detailing the skills relevant to completing the CMA form are shown in Table A-1. This skill matrix is similar to the one for the reproposed PMN form presented in Chapter V. The time and cost estimates to complete the sections of the CMA form are summarized in Table A-2 and a detailed breakdown of the time estimates is shown in Table A-3. Clerical time has been estimated separately for each part, and is not detailed in Table A-3. For sections of the CMA form considered as mandatory (parts I and II), the total costs are estimated to be in the range of $955 to $5500.

The preparation of the optional Parts III and IV could add $7,400 and $4,100, respectively, to the cost of completing the form.

TABLE A-1

INFORMATION AND PROFESSIONAL SKILLS APPLICABLE TO PREPARATION OF MANUFACTURING CHEMISTS ASSOCIATION PREMANUFACTURE NOTICE FORM

(Parts I and II)

	PROFESSIONAL SKILLS										
TYPES OF INFORMATION	MANAGERIAL	LEGAL	SALES & MARKETING	CHEMISTRY	TOXICOLOGY	ENGINEERING	OCCUPATIONAL HYGIENE	ENVIRONMENTAL SCIENCES	STATISTICS	RISK ANALYSIS	TRANS-PORTATION SYSTEMS
Submitter Identification	X	X									
Chemical Identity				X							
Impurities				X		X					
Confidentiality	X	X		X							
Production Volume			X			X			X		
Categories of Use	X		X								
Federal Register Notice		X		X	X		X	X			
Attachments	X	X	X	X	X	X	X	X	X	X	X
Physical/Chemical Properties				X		X					
Health/Environmental Effects					X		X	X		X	
Occupational Exposure					X		X			X	
Environmental Release & Disposal				X		X		X		X	
By-products				X							

TABLE A-1 (Continued)

INFORMATION AND PROFESSSIONAL SKILLS APPLICABLE TO PREPARATION OF MANUFACTURING CHEMISTS ASSOCIATION PREMANUFACTURE NOTICE FORM

(Parts III and IV [optional])

	PROFESSIONAL SKILLS										
TYPES OF INFORMATION	MANAGERIAL	LEGAL	SALES & MARKETING	CHEMISTRY	TOXICOLOGY	ENGINEERING	OCCUPATIONAL HYGIENE	ENVIRONMENTAL SCIENCES	STATISTICS	RISK ANALYSIS	TRANS-PORTATION SYSTEMS
Risk to Man/Environment				X	X		X	X	X	X	
Data on Related Chemicals					X		X	X		X	
Structure-Activity Relation-ships				X						X	
Industrial Hygiene Considera-tions	X	X					X				
Occupational Exposure	X	X		X	X	X	X		X		
Workplace Safeguards				X		X	X			X	
Environmental Release Safe-guards	X	X		X		X		X	X	X	
Industrial Process Restriction Data	X		X							X	
Process Chemistry				X		X					
Manufacturing History	X		X								
Restrictions		X			X		X	X			X
Production Volume	X	X	X			X					
Transport		X		X	X	X				X	X
Benefits			X		X	X		X		X	
By-products, Co-products, etc.				X	X	X	X				
Pollution Control				X		X		X			
Consumer Exposure			X	X	X	X			X		

Source: Arthur D. Little, Inc., estimates.

TABLE A-2

Time and Cost Estimates for Preparation and Submission of CMA Form

		CLERICAL	TECHNICAL	MANAGERIAL	TOTAL
Mandatory	Part I (hrs.)	2-10	6-44	3-13	11-67
	Part II (hrs.)	6-30	15-108	4-14	25-152
Total Time (hrs.)		8-40	21-152	7-27	36-219
Total Cost		$80-400	$525-3800	$350-1350	$995-5550
Optional Part III	Time (hrs.)	0-40	0-204	0-38	0-282
	Cost	$ 0-400	$ 0-5100	$ 0-1900	$ 0-7400
Optional Part IV	Time (hrs.)	0-20	0-128	0-14	0-162
	Cost	$ 0-200	$ 0-3200	$ 0-700	$ 0-4100

[1]Hourly labor rate estimates: $10-clerical, $25-technical, $50-managerial.

[2]Clerical time estimate developed separately for each part.

Source: Arthur D. Little, Inc., estimates.

TABLE A-3

Time Estimates to Prepare CMA Premanufacture Notice Form

APPENDIX A

	TECHNICAL (hours)	MANAGERIAL (hours)
PART I. General Information		
SECTION A. Submitter Identification		
1. Person Filing Notice 2. Technical Contact		1-8*
SECTION B. Chemical Identity		
1. Class I Chemical Substance**		
a. CAS Registry No. b. Specific Chemical Name c. Molecular Formula d. Synonyms e. Trademarks	1-4	
2. Class II Chemical Substance**		
a. CAS Registry No. b. Specific Chemical Name c. Synonyms d. Trademarks e. List of Precursor(s)	1-4	
3. Polymers**	1-4	
4. Impurities	1-8	
5. Confidentiality (generic name)	0-4	0-1

* Includes final technical management and legal review of completed form.

** Only one of these subsections will be completed for any individual chemical. Thus, the time and cost estimates of only one item are included in the totals.

TABLE A-3 (cont.)

	TECHNICAL (hours)	MANAGERIAL (hours)
PART I. General Information (continued)		
SECTION C. Production and Categories of Use		1-2
1. Total Production Volume		
a. First Calendar Year b. Second Calendar Year c. Third Calendar Year	1-4	
2. Production per Category of Use	1-8	
SECTION D. Federal Register Notice		
1. Generic Class 2. Use Data 3. Test Data	1-8	1-2
SECTION E. List of Attachments	1-8	
PART II. Risk Assessment Data		
SECTION A. Chemical, Environment, Human, Ecological Data		
1. Physical/Chemical Properties	4-16	1-4
2. Health/Environmental Effects	8-40	2-8
SECTION B. Occupational Exposure, Disposal, By-products		
1. Industrial Sites Controlled by the Submitter		1-2
a. Occupational Exposure	2-16	
b. Disposal	1-8	
c. By-products	0-8	

TABLE A-3 (cont.)

	TECHNICAL (hours)	MANAGERIAL (hours)
PART II. Risk Assessment Data (continued)		
2. Industrial Sites Not Controlled by Submitter		
a. Workplace Exposure	0-16	
b. Disposal	0-4	

TABLE A-3 (cont.)

PART III. Optional Risk Analysis Information	TECHNICAL (hours)	MANAGERIAL (hours)
SECTION A. Risk Analysis		
1. Potential Risk to Man/Environment 2. Mitigating Data 3. Implications	0-16	0-2
SECTION B. Related Chemicals		
1. Release/Human Exposure Data 2. Structure-Activity Relationships	0-20	0-4
SECTION C. General Industrial Hygiene Program	0-40	0-8
1. Industrial Hygiene Considerations 2. Control of Accidential Worker Exposure 3. Worker Health Considerations 4. Other		
SECTION D. Specific Safeguards	0-40	0-8
SECTION E. Industrial Process Restrictions Data	0-16	0-4
1. Exclusive Industrial Use Categories 2. Distribution from Manufacture Site 3. Distribution Data 4. Restricted Use/Exclusive Control Factors		
SECTION F. Process Chemistry	0-16	0-2
SECTION G. Additional Production and Use	0-8	0-1
1. Previous Manufacture 2. Restrictions 3. Firm Orders/Percent Production Volume 4. Business Arrangements-Manufacturing/Import		

TABLE A-3 (cont.)

	TECHNICAL (hours)	MANAGERIAL (hours)
PART III. Optional Risk Analysis Information (continued)		
SECTION H. Transport	0-8	0-1
1. DOT Hazard Class		
2. Mode of Transport		
3. For Each Mode:		
a. Minimum Risk Handling Procedures		
b. Maximum Single Transportation Unit		
c. Safeguards		
SECTION I. Non-Risk Factors: Economic and Non-Economic Benefits	0-40	0-8
1. Economic Changes		
2. Environmental and Health Benefits		
3. Other Benefits		

TABLE A-3 (cont.)

	TECHNICAL (hours)	MANAGERIAL (hours)
PART IV. Optional Additional Information on Worker Exposure and Environmental Release		
SECTION A. Worker Exposure	0-16	0-2
1. Estimated Exposure During First 3 Years		
2. Derivation of Exposure Estimates		
3. Minimum Detectable Level in Air		
4. Maximum Number of Workers Exposed		
5. List Other Substances		
SECTION B. Environmental Release	0-40	0-4
1. Annual Environmental Release		
2. Receiving Waterbody or POTW		
3. Percent Emission/Effluent Reduction		
4. Derivation of Environmental Release Estimates		
5. Degradation Products		
6. Minimum Detectable Level		
7. List By-products, Co-products, Feedstocks and Intermediates		
SECTION C. Exposure From Processing and Use at Sites Not Controlled by the Submitter		
1. Worker Exposure	0-16	0-2
2. Environmental Release	0-40	0-4
SECTION D. Consumer Exposure	0-16	0-2
1. Anticipated Products, Use and Population Exposed		
2. Maximum Consumer Exposure		
3. Derivation of Estimate		
4. Product Aspects Affecting Consumer Exposure		

Source: Arthur D. Little, Inc. estimates.

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