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DRAFT ECONOMIC IMPACT ASSESSMENT FOR THE PROPOSED TOXIC SUBSTANCES CONTROL ACT (S.776)

ENVIRONMENTAL PROTECTION AGENCY

JUNE 1975

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Office of Toxic Substances
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The draft report estimates the direct costs to industry associated with the implementation of the principal provisions of the proposed Toxic Substances Control Act (S.776). The annual direct costs are estimated to be between $78.5 and 141.5 million. About two-thirds of these costs are shown to be attributable to the areas of premarket screening and regulatory actions, with about one-third attributable to the requirements concerning industrial testing and reporting.

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PREFACE

In recent months many requests have been received from Federal agencies, Congressional staffs, and other organizations for an estimate of the economic impact of the proposed Toxic Substances Control Act. Given the complex structure of the chemical industry, the uncertainties as to the nature of the regulations which would be promulgated to implement the Act, and the difficulty of predicting the chemical problems of the future, any such estimate must be very uncertain at best. Nevertheless, an attempt has been made to develop an economic assessment which will be helpful in identifying the types and severity of the impacts that are likely to be associated with the legislation.

This draft Report sets forth very preliminary estimates of the direct costs to industry that are likely to result from implementation of the principal provisions of the legislation. While S.776 has been used as the basis for the estimates, many of the observations in the draft Report should be applicable to other versions of the pending legislation as well. However, it must be emphasized that most of the cost estimates, and particularly the estimates concerning premarket screening and regulatory actions, are highly speculative. The draft Report also includes a few observations concerning indirect costs to industry, the impact of the legislation on employment concerns, the impact on inflation, and international aspects.

The Office of Toxic Substances is interested in improving the preliminary economic impact assessment presented in this draft Report and would welcome comments on the estimates.

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SUMMARY

As summarized in Table 1, the direct costs to industry associated with the implementation of the principal provisions of the proposed Toxic Substances Control Act (S. 776) are estimated to range from about $80 to $140 million annually. On the order of two-thirds of these costs are attributable to the highly speculative areas of premarket screening and regulatory actions, with almost all of the remainder associated with the somewhat more predictable, but still very uncertain, requirements concerning industrial testing and reporting.

As a perspective for the estimated costs, sales for the sector of industry that would be most directly affected by the legislation (i.e. Chemical and Allied Products less food additives, cosmetics, drugs, and pesticides) were about $72 billion in 1974, profits after taxes exceeded $5.5 billion, and R and D expenditures were about $2 billion. If all industrial sectors which could be affected by the legislation are considered, the sales volume in 1974 was probably double this level, and the profits and R and D expenditures were also much higher.

The estimated employment dislocations associated with regulatory actions might result in the loss of one thousand or more jobs annually out of the more than one million jobs in the Chemical and Allied Products sector and twelve million jobs in the Chemical Processing sector. The bulk of these displaced workers should be readily absorbed in the employment pool of the affected sectors which has been expanding at a rate of tens of thousands of new jobs each year. However, there will probably be localized situations where opportunities for job mobility are limited and the introduction of substitute products is not feasible.

In the international area, exports during 1974 of chemical products (less food additives, cosmetics, drugs, and pesticides) exceeded imports by $4.8 billion as the world demand for chemicals continued to grow and tariff protection for the U.S. market remained at a relatively high level for most chemical products. Given the strong international position of U.S. industry, the costs associated with the legislation should not seriously affect the balance of payments position. Also, there is a reasonable likelihood that some industrial countries will take steps similar to those of the United States in this area of regulation.

The impact on the Wholesale Price Index, Consumer Price Index, and the GNP Deflator of the costs to industry plus the costs of administering the proposed law should be very small.

Indirect impacts on industry would include the cumulative effect of regulations on the climate for innovation, changes in the scope and direction of research activities, and possible shifts in production and marketing patterns. Predictions in these areas are fraught with uncertainties and have not been attempted.

In addition, quantification of the foregone economic and social benefits to society resulting from limitations on chemicals for which there might not be adequate substitutes does not seem possible.

Finally, meaningful estimates cannot be made of the investment losses and the employment dislocations which would be prevented through regulatory actions against new products that are determined to be environmental problems early in their lifetime rather than after major commercial investments and the associated labor force are in place. Similarly, it is not possible to estimate the additional administrative and technical jobs which would be created by industry to comply with the legislation.

Table 1: Preliminary Estimate of Annual Direct Costs to Industry

	No. of Chemicals Affected	Costs to Industry (Millions of Dollars rounded to nearest $.5M)	
Section 4 (Testing)			
Existing Chemicals	200	4.5 - 8.5	
New Chemicals	150	3 - 6	
			7.5 - 14.5
Section 5 (Premarket Screening)			
Administrative Costs of Notification of New Chemicals	600	2 - 2.5	
Administrative Costs of Notification of New Uses	400	1.5 - 3	
Delays due to Testing Requirements	150	7.5 - 11.5	
Delays due to Industrial Uncertainty	300	2.5 - 8.0	
			13.5 - 25
Section 6 (Regulation of Hazardous Chemicals)			
Limitations on Selected Uses of Important Chemicals & Restrictions on Minor Use Chemicals	3-4	23 - 31	
Minor Actions Involving Labelling, Quality Control, and Restrictions on Very Narrow Uses	10-20	4.5 - 9	
			27.5 - 40
Section 7 (Imminent Hazard)			
Restrictions	1 every 3 years		10 - 20
Section 8 (Reports)			
Annual Reports	1500-2000	4.0 - 10	
Record Keeping	No estimate	14 - 27	
Health & Safety Studies			
Preparing Bibliography	400-600	1 - 4	
Retrieval of Studies	200-300	.5	
			19.5 - 41.5
Section 26 (Fees)			
Test Data Submissions	250		.5
Total			78.5 - 141.5

THE GENERAL FRAMEWORK FOR ESTIMATING ECONOMIC IMPACT

A preliminary estimate of the annual costs to industry which are likely to result from compliance with the anticipated types of regulations pursuant to the major provisions of the proposed Toxic Substances Control Act (S.776) is presented in this draft Report. Estimates at this time are critically dependent on the assumptions as to the nature of the implementing regulations. The assumptions used herein are based on an interpretation of the explicit legislative requirements in the context of the legislative history that has been developed during the past four years. Also, the following considerations have influenced the assumptions that have been made:

-- Frequency and character of toxic chemical incidents and recent trends in this regard.

-- Two years of intensive staff work by the Office of Toxic Substances to provide a basis for implementation of this type of regulatory authority.

-- Experience in administering reporting, testing, and regulatory provisions of other environmental laws, and particularly the laws concerning pesticides and fuel additives.

-- Recent experience in developing approaches to the anticipation of and response to chemical problems.

-- Advice of the National Academy of Sciences concerning test protocols and decision-making related to toxic chemicals.

-- Consultations with a number of chemical manufacturers concerning implementation of this type of legislation.

-- The budgetary authorization level of about $11 million annually (section 26a).[1]

The analysis centers on the costs to industry during years two through six following enactment of the legislation, using the 1975 price index. In subsequent years the costs associated with some activities should decline while others should increase. For example, the number of

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[1]While many of the factors bearing on regulatory activities directed to pesticides are considerably different from the factors that will affect similar activities directed to industrial chemicals, the annual EPA budget of about $43 million for pesticides activities gives some indication of the level of activities that might be expected under the proposed legislation. For example, many years have been required to register about 1,800 pesticidal chemicals in 35,000 formulations. More than eight years have been required to develop registration guidelines setting forth testing requirements. About two pesticidal chemicals are cancelled each year. Finally, 40 chemicals will receive intensive study during FY 1976.

existing chemicals subjected to testing requirements each year should decline as the backlog of existing chemicals is reduced. On the other hand, the number of new chemicals subjected to test requirements each year should increase as the number of promulgated standards for test protocols covering chemical classes increases.

The costs of the legislation will be distributed across a broad segment of U.S. industry. While the sector most directly affected will be the Chemical and Allied Products sector less food additives, drugs, cosmetics, and pesticides, a number of other manufacturing and processing activities also involve chemical activities and could be affected by the legislation. A very rough estimate is that the Chemical and Allied Products sector less food additives, drugs, cosmetics, and pesticides represents about one-half (by sales volume) of the total industrial activities that could be affected by the legislation. Sales for the Chemical and Allied Products sector less food additives, drugs, cosmetics, and pesticides were $72 billion in 1974 and profits after taxes were $5.5 billion. Overall sales in this sector increased by 70 percent from 1970 to 1974, and profit levels doubled. Continued growth of both sales and profits are projected for the next decade.[2]

The inflationary impact of the legislation should be very small, taking into account the annual costs to industry of $80 to 140 million, the projected EPA expenditures of $11 million annually, and the new costs to other agencies assisting in the administration of the law which will probably initially be in the millions of dollars but could conceivably reach considerably higher levels.[3]

Quantification of the foregone economic and social benefits to society resulting from limitations on chemicals for which there are no adequate substitutes does not seem possible.

The complexities of the international chemical market make it very difficult to quantify the effects of toxic substances regulation on international commerce. U.S. chemical exports in 1974 were $8.8 billion

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[2]The estimates of past performance are based on information provided by the Federal Trade Commission drawing on Quarterly Financial Report for Manufacturing, Mining, and Trade Corporations. With regard to future trends for the Chemical and Allied Products sector, Chemical Week, January 8, 1975, forecasts an 11 percent increase in profits during 1975, and Kline Guide to the Chemical Industry (Charles H. Kline and Company, Inc., Fairfield, New Jersey, 1974) estimates an annual average growth rate for sales of 6.2 percent through 1985.

[3]The Macroeconomic Aspects of Federal Pollution Control Programs, Chase Econometrics, Inc., January 1975, concludes that an average annual cost of about $20 billion for water and air pollution controls during the 1973-1982 period would result in an average annual rate of increase of 0.2 percent for the Wholesale Price Index, 0.1 percent for the GNP deflator, and 0.2 percent for the Consumer Price Index.

while imports were about $4 billion.[4] Given the growing world-wide demand for chemicals, the current tariff structure for chemical imports,[5] and the well established position of U.S. industry in international markets, the costs associated with this legislation should not have a major impact on this currently favorable balance of payments. Also, Sweden and Japan have already enacted toxic substances legislation and other countries, and particularly Canada, will probably adopt similar measures should the United States take steps in this regard.

While the principal types of costs to industry are covered in the analysis, some costs such as legal fees associated with court actions and inconveniences caused by administrative inspections are not included. Similarly, while the potential adverse impact on employment of regulatory actions is considered, no attempt has been made to estimate the new administrative and technical jobs within industry which will be required to comply with the proposed law.

A number of potential indirect effects on industry of the legislation have also not been addressed such as (a) the cumulative effect of regulations on the climate for innovation, and subsequent changes in the scope, direction, and payoff of R&D activities, and (b) possible shifts in production and marketing patterns within U.S. industry resulting from new regulatory requirements. Forecasts in these areas are highly speculative at best. The regulatory experience in very narrow industrial sectors, such as foods and drugs, may have some relevance but does not provide a good basis for reaching sound conclusions when addressing the entire chemical industry.

No attempt has been made to estimate what portion of the increased costs to industry would be passed on to the consumer, and only for sections 6 and 7 has the portion that would be absorbed through tax deductions and other financial arrangements been estimated.

Finally, the analysis does not address the environmental benefits that would be derived from regulatory actions taken under the Act nor the expected improvement in the cost/effectiveness of the regulatory decisions that would be taken under other authorities drawing on reporting and testing information acquired under this Act. Similarly, no attempt has been made to estimate the possible cost savings to industry and the

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[4] Summary of U.S. Export and Import Merchandise Trade, Bureau of Census, Foreign Trade Division, December 1974, tables 4 and 5.

[5] The average tariff for all chemical imports in 1973 was 1.8 percent. The tariff for all chemicals less the benzenoid crudes and petroleum was 4.6 percent. The tariff for finished chemicals and benzenoid intermediates ranged up to 20 percent and higher, based on 1.7 cents per pound plus 12.5 percent of the American selling price. These figures were provided by the Chemical Divison of the U.S. International Trade Commission, based on data from Schedule 4 of the Tariff Schedule of the United States.

prevention of employment dislocations resulting from interception of problem chemicals during the premarket phase and appropriate Governmental action at that time to prevent environmental damage in contrast to the current approach of taking corrective actions only after large commercial investments and the associated labor force are in place.

TESTING FOR HEALTH AND ENVIRONMENTAL EFFECTS (Section 4)

Table 2: Estimated Costs of Testing Requirements

	Existing Chemicals	New Chemicals
A. No. of Chemicals Requiring Limited Tests	180	135
B. Average Cost per Limited Test Requirement	$10-20,000	$10-20,000
C. No. of Chemicals Requiring Major Tests	20	15
D. Average Cost per Major Test Requirement	$200-400,000	$200-400,000
E. Portion of Tests that Would Be Done by Industry in Absence of Act	1/4	1/3
Total Costs [(A X B) + (C X D)] X (1 - E)	$4.4 - 8.7M	$2.9 - 5.8M

Section 4(a) clearly implies a selective approach in determining which chemicals should require testing and in determining which tests should be required. Test requirements will undoubtedly vary among chemical classes and among chemicals of the same class depending on available data. Determining factors as to the requirements will probably include contemplated uses and likely exposure patterns, anticipated market volume, physical and chemical properties of the chemical, and existing health and environmental effects data.

Test requirements for most of the chemicals (estimated to be 90 percent) that will be selected are anticipated to be limited, involving a mix of modest tests for each chemical. While the costs will vary, the current estimate is that the average cost will be on the order of $10-20,000 per chemical. The physical and chemical properties and chemical stability of a compound can frequently be ascertained from simple and inexpensive tests costing about $500. Acute animal toxicity tests by various routes cost on the order of $1,000 each. Subacute testing, if required, is considerably more expensive, about $15,000. Whether results of certain mutagenicity tests, which probably will cost about $2,000 per compound could be a reliable indication of carcinogenicity is an area of active investigation. Relatively inexpensive environmental fate tests will also be important in some cases.

The remaining ten percent will be subjected to more extensive testing. A typical example might be to require, in addition to the limited tests described above, selected long-term chronic effects tests which could bring the total to $200,000 or more per chemical. In some cases the costs would be still higher; in other cases, somewhat lower.

The total projected costs of testing range between $7.3 million and $14.5 million, while the estimated R and D expenditures of the chemical industry in 1973 were $2.1 billion with R and D expenditures predicted to be $2.7 billion in 1975.[6] Thus, on a national basis the incremental costs to industry seem minimal, between 0.3 and 0.5 percent of the overall R and D budget. However, depending on how these costs are distributed within industry, the cost impact of specific test requirements could in some cases be quite significant for the affected firms.

A related concern is the present limitations on available qualified scientists and facilities to carry out test requirements. As testing expands, special efforts will be needed to insure that a high quality approach to testing is preserved.

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[6] 1973 Estimate from "Twenty-percent Increase in Energy Activity Paces Industry Research and Development Spending in 1973," Science Resource Studies Highlights, National Science Foundation, NSF 74-319, December 4, 1974. 1975 estimate provided by Chemical Week.

PREMARKET SCREENING OF NEW CHEMICALS AND NEW USES (Section 5)

Table 3: Estimated Costs of Premarket Screening

Administrative Costs of Notification of New Commercial Chemicals

A.	No. of New Chemicals	600	
B.	Average Administrative Cost per Chemical Notification	$3-4,000	
C.	Total Administrative Costs (A x B)		$1.8 - 2.4M

Administrative Costs of Notification of New Uses

A.	No. of Significant New Uses that Are Reported	400	
B.	Average Number of Reporting Establishments for Each New Use during First Year of Use	4	
C.	Average Administrative Cost per New Use Notification	$1-2,000	
D.	Total Administrative Costs (A x B x C)		$1.6 - 3.2M

Delays due to Testing Requirements

A.	No. of New Chemicals Delayed	150	
B.	Average Delay Time	1 Year	
C.	Average R & D Investment in Each Chemical at Time of Delay	$500K	
D.	Cost of Capital	10-15%	
E.	Total Costs (A x B x C x D)		$7.5 - 11.3M

Delays due to Industrial Uncertainties as to Governmental Actions

A.	No. of New Chemicals Delayed	200	
B.	Average Delay Time	1/4-1/2 Year	
C.	Average R & D Investment in Each Chemical at Time of Delay	$500K	
D.	Cost of Capital	10-15%	
E.	No. of Significant New Uses	400	
F.	Portion of New Uses Delayed by Industry	1/4	
G.	Average Delay Time	1/4-1/2 Year	
H.	Average R & D Investment in Each New Use at Time of Delay	$50K	
I.	Total Costs [(A x B x C) + (E x F x G x H)] x D		$2.6 - 7.9M

Administrative Costs of Notification of New Commercial Chemicals

It is assumed that firms will spend a considerable amount of time consulting with EPA concerning new chemicals, and the administrative costs to industry of these consultations are reflected in Table 3.

Administrative Costs of Notification of New Uses

It is assumed that firms will expend a smaller, but still significant, administrative effort in the premarket notification process for each significant new use. It is further assumed that on the average four

manufacturers will be actively considering each new use during the first few months and hence involved in the premarket notification process. After this initial period, a new use presumably will be picked up in the annual reporting requirement for all concerned firms.

Delays due to Testing Requirements

It is difficult to generalize the delays that are likely to result from premarket testing requirements, or the costs of the delays. It is assumed that a limited test requirement will delay commercialization of a chemical by nine months, and a major test requirement three years. Since 90 percent of the affected chemicals will be subjected to limited test requirements, the average delay time is estimated to be one year.

Testing usually is undertaken relatively early in the R & D cycle. Nevertheless, substantial capital may have already been invested by the time that testing is undertaken, both to develop the specific chemical of interest and to rule out other candidate chemicals. The expenditures in this regard will vary widely from product to product but should only infrequently exceed the $500,000 average investment assumed in this analysis.

Delays due to Industrial Uncertainty as to Governmental Actions

In addition to its concerns over the new chemicals requiring testing, industry may be hesitant to proceed with commercialization of some of the other new chemicals until ascertaining how EPA will react to the premarket notification.

REGULATORY ACTIONS (Sections 6 and 7)

Table 4: Estimated Costs of Regulatory Actions

Limitations with Significant Impact (Section 6)

A.	No. of New Chemicals Banned	2	
B.	R & D Investment for Each Chemical at Time of Ban	$3M	
C.	Percentage of R & D Investment Recoverable	20%	
D.	Cost of Banning New Chemicals [A x B x (1 - C)]		$4.8M
E.	No. of Minor Use, Existing Chemicals Banned	1	
F.	No. of Manufacturers Involved with Each Minor-Use Chemical	4	
G.	Investment of Each Manufacturer	$5M	
H.	Percentage of Investment Amortized at Time of Ban	50%	
I.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, and Equipment	25%	
J.	Percentage of Remaining Investment Recoverable through Tax and Other Financial Arrangements	25%	
K.	Costs to Manufacturers of Banning Existing Chemicals E x F x G x [(1 - H) - (1 - H)(1 - I - J)]	$5M	
L.	Costs to Suppliers (.5 x K)	$2.5M	
M.	Costs to Processors (.5 x K)	$2.5M	
N.	Total Costs of Banning Minor Use, Existing Chemicals (K + L + M)		$10M
O.	No. of Actions Limiting Uses of More Significant Existing Chemicals	1	
P.	No. of Manufacturers Involved in Each Action	8	
Q.	Investment of Each Manufacturer in Each Chemical	$20M	
R.	Percentage of Overall Investment Affected by Each Action	20%	
S.	Percentage of Investment Amortized at Time of Action	50%	
T.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, and Equipment	25%	
U.	Percentage of Remaining Investment Recoverable through Tax and Other Financial Arrangements	25%	
V.	Costs to Manufacturers of Limiting Uses O x P x Q x R x [(1 - S) - (1 - S)(1 - T - U)]	$8M	
W.	Costs to Suppliers (.5 x V)	$4M	
X.	Costs to Processors (.5 x V)	$4M	
Y.	Total Costs of Limiting Uses (V + W + X)		$16M
Z.	Costs of Limitations on 4 Chemicals (D + M + Y)		$30.8M
AA.	Range of Costs for 3 to 4 Chemicals	$23.1 - 30.8M	

Limitations with Lesser Impact (Section 6)

A.	No. of New Chemicals Banned	2
B.	R & D Investment for Each Chemical at Time of Ban	$500K
C.	Percentage of R & D Investment Recoverable	20%
D.	Cost of Banning New Chemicals [A x B x (1-C)]	$800K
E.	No. of Actions Limiting Uses of Minor Chemicals	2
F.	No. of Manufacturers Involved in Each Action	4
G.	Investment of Each Manufacturer	$2M
H.	Percentage of Overall Investment Affected by Each Action	20%

I.	Percentage of Investment Amortized at Time of Action	50%	
J.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, and Equipment	25%	
K.	Percentage of Remaining Investment Recoverable through Tax and Other Financial Arrangements	25%	
L.	Costs to Manufacturers of Limiting Uses [E x F x G x H x [(1 - I)(1 - J - K)]	$800K	
M.	Costs to Suppliers (.5 x L)	$400K	
N.	Costs to Processors (.5 x L)	$400K	
O.	Total Costs of Limiting Uses (L + M + N)		$1.6M
P.	No. of Labelling Actions	5	
Q.	No. of Manufacturers Affected by Each Action	10	
R.	Cost for Each Manufacturer	$20K	
S.	Costs of Labelling Actions (M x N x O)		$1M
T.	No. of Quality Control Actions	1	
U.	No. of Manufacturers Affected by Each Action	10	
V.	Costs for Each Manufacturer	$100K	
W.	Costs of Quality Control Actions (T x U x V)		$1M
X.	Costs of 10 Regulatory Actions (D + O + S + W)		$4.4M
Y.	Range of Costs for 10 to 20 Actions		$4.4-8.8M

Imminent Hazard (Section 7)

A.	No. of Existing Chemicals Banned	1 every 3 years	
B.	No. of Manufacturers Affected by Each Action	6	
C.	Investment of Each Manufacturer	$10-20M	
D.	Percentage of Investment Amortized at Time of Ban	50%	
E.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, and Equipment	25%	
F.	Percentage of Remaining Investment Recoverable through Tax and other Financial Arrangements	25%	
G.	Costs to Manufacturers of Each Ban B x C x [(1 - D) - (1 - D)(1 - E - F)]	$15-30M	
H.	Costs to Suppliers (.5 x G)	$7.5-15M	
I.	Costs to Processors (.5 x G)	$7.5-15M	
J.	Costs of Each Action (G + H + I)	$30-60M	
K.	Costs per Year (1/3 x J)		$10-20M

The costs of regulatory actions will vary widely depending on the chemical and the nature of the limitation. Conceivably, a single regulatory action could have serious economic implications. However, broad sweeping actions under this legislation are highly unlikely given the requirements of Sections 6(c) and recent experience in dealing with chemical problems. Regulatory actions are more likely to fall into the following categories: restrictions on selected uses of certain existing chemicals; requirements concerning labelling and quality control to limit contaminants; and prohibitions on extremely hazardous new chemicals and existing minor use chemicals that cannot otherwise be contained.

Judging from the frequency of toxic substance problems that have arisen during the past decade, and taking into account the sharper vigilance that will result from the legislation, it is estimated that

there will be on the order of three to four actions each year limiting the uses of important chemicals or sharply restricting minor-use chemicals. In addition there might be 10 to 20 minor regulatory actions involving labelling, quality control requirements, or very narrow restrictive uses. Finally, on rare occasions the use of the imminent hazard provision might be appropriate.

The foregoing estimates suggest that on the order of 22 manufacturing facilities, each representing an investment of from $2 to 20 million, might be closed each year as the result of regulatory actions. The number of employees at each facility will vary widely depending on the product, the process, and the location and design of the facility. Most of the affected facilities will probably be components of larger industrial complexes with the number of employees ranging from 10 to 30 and in some cases as high as 40 or 50. The remaining affected facilities will be at individual locations with the labor force per facility somewhat higher to allow for maintenance, security, and related tasks. A reasonable estimate is that perhaps 500 employees might be employed at the 22 directly affected facilities. This compares with a total employment of more than one million for this sector of industry.[7]

Estimates are much more speculative concerning the impact of regulatory actions on the suppliers of raw materials for the affected manufacturers and on the Chemical Process sector, which employs more than 12 million persons, as a result of the "ripple effect." At the one extreme a supplier or a processor could be totally dependent on the continued commercial viability of a single chemical manufacturing activity, and regulatory actions affecting this activity could be crucial to his business However, given the multiple interests of most suppliers and processors, the flexibility of our market forces and the experience of suppliers and processors in adapting to changes in marketing opportunities, and the high innovative capacity of US industry, such a situation will probably be unusual.

Since economic factors must be given appropriate weight in reaching regulatory decisions under Section 6, the likelihood that bans would be promulgated on chemicals for which there are no substitutes does not seem high. Also, it is assumed that in many cases the effective dates of restrictions on chemicals will be set to minimize economic impact by allowing time for adjustments. In most cases, the supplier should be

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[7] 1970 employment figures show 1.045 million employees in the Chemical and Allied Products sector and 12.659 million employees in the Chemical Process sector (Chemical and Allied Products, plus Food and Kindred Products, Paper and Allied Products, Petroleum and Coal Products, Rubber Products, Stone-Clay-Glass Products, and Primary Metal Industries, Ferrous and Nonferrous): from American Chemical Society, Chemistry in the Economy, Washington, DC 1973, page 490. Information provided by the Bureau of Labor Statistics indicates a recent annual employment growth rate of about 1.7 percent for the Chemical and Allied Products sector and about 0.6 percent for the Chemical Process sector.

able to sell his existing stocks and the processor should be able to adapt his activities to different raw materials. Thus, it is estimated that the principal impact of regulatory actions on the suppliers and processors would be the adjustment costs of adapting to the new market conditions resulting from regulatory actions, costs that might equal the overall costs to the more directly affected manufacturers. In some cases this cost estimate may be high; in other cases, such as in the case of an imminent hazard, the estimate may be low. In Table 4, these additional costs have been somewhat arbitrarily divided equally between suppliers and distributors. By analogy with the cost estimates, the employment dislocations due to the "ripple effect" should affect hundreds, perhaps 500 or more, rather than thousands, of employees in the Chemical Process sector.

The bulk of the workers displaced by regulatory actions should be absorbed in the employment pool of the affected industrial sectors which has been expanding at a rate of tens of thousands of new jobs each year. However, there will probably be localized situations where opportunities for job mobility are limited and the introduction of substitute products is not feasible.

REPORTING REQUIREMENTS (Section 8)

Table 5: Estimated Costs of Reporting

Annual Reports			
A.	Average No. of Chemicals To Be Reported	1,500-2,000	
B.	Average No. of Reporting Establishments per Chemical	25	
C.	Total No. of Reports (A x B)	37,500-50,000	
D.	Average Cost per Report	$100-200	
E.	Total Annual Cost of Annual Reports (C x D)		$3.8-10M
Record Keeping			
A.	No. of Firms Requiring Major Systems	20-30	
B.	Average Cost of Installing and Operating a Major System for Five Years	$350-450K	
C.	No. of Firms Requiring Medium Systems	1,000	
D.	Average Cost of Installing and Operating a Medium System for Five Years	$35-55K	
E.	No. of Firms Requiring Minor Systems	10,000	
F.	Average Cost of Installing and Operating a Minor System for Five Years	$10-20K	
G.	Portion of Costs which Would be Incurred without Act	1/2	
H.	Five-Year Incremental Costs of Record Keeping [(A x B) + (C x D) + (E x F)] x (1 - G)	$71-134M	
I.	Annual Costs of Record Keeping (H x 1/5)		$14.2-26.8M
Health and Safety Studies			
A.	No. of Chemicals To Be Searched for Inclusion in Bibliography	400-600	
B.	Average No. of Firms Searching Each Chemical	25	
C.	Average Cost per Search	$100-250	
D.	No. of Studies To Be Submitted	200-300	
E.	Average Cost in Preparing Each Study for Submission	$2,000	
F.	Total Annual Costs [(A x B x C) + (D x E)]		$1.4-4.4M

Annual Reports

The concept of "inventory reporting" set forth in section 8(a) of the Conference Committee Working Print of November 25, 1974, has been dropped. Thus, the intent of section 8(a) of S.776 appears to be a selective approach to requiring reports on chemicals of interest. During the five-year period under consideration, annual reports are envisaged on about five times the number of chemicals which would be covered by actions under sections 4, 6, and 7.

It is assumed that the number of chemicals subjected to annual reporting requirements will increase from an initial level of 1000 discrete chemicals, including many in the same chemical classes, to a plateau level of about 3000 chemicals during the sixth year, with the average between 1500 and 2000. If there are 25 reporting establishments

for each chemical, then an average of 35-50,000 reports can be expected annually. Also, many reporting establishments will submit reports on more than one chemical; thus, perhaps 5000 establishments will be involved in the submission of the reports.

A relatively simple two-page Government form, together with appropriate instructions, for each chemical to be reported is envisaged. Most, if not all, of the affected firms currently report related information to the Tariff Commission. Thus, most of the required data should be near at hand, with the estimated costs being $100-200 per report.[8] In some cases, initial costs may be higher as some firms reorient internal data collection procedures. The costs may be lower from the outset for other firms as shown in Dow's estimate. Also, reporting establishments preparing a large number of reports at the same time should be able to cut costs per report. In any event costs per report should decline as industry becomes familiar with the requirements and as "no change" reports begin entering the system.

Record Keeping

Some of the larger companies with extensive medical and safety programs may be required to expand current data analysis and retrieval capabilities on a large scale. Many other companies may require more modest investments. For the bulk of the small companies, a more systematic use of file cabinets is envisaged.

The estimates are probably high since most responsible firms presumably maintain extensive files in the areas of interest. Nevertheless, there will be some expense in insuring that the files are centralized and in an "inspectable" form.

Health and Safety Studies

Since the mandatory reporting requirements of S.776 appear infeasible, it is assumed that they will be modified to give the Administrator discretionary authority in this area. Based on this assumption, the number of chemicals of interest is keyed to the number of chemicals which would be subjected to regulations under sections 4, 6, and 7.

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[8]The estimated cost is higher than the $40 estimated by Dow Chemical, USA, in its letter of April 1, 1975, to Senator Tunney to take into account special problems of small business and of overhead costs involved in data compilation.

FEES FOR PROCESSING TEST DATA (Section 26)

It is assumed that the fee would be waived for 100 of the 350 submissions of test data in hardship cases, with particular attention to small business. An average fee of $2,000 would be required for the other 250 submissions.

APPENDIX A: Sections 4, 5, 6, 7, 8 and 26 of S.776

Standards for Test Protocols

Section 4:

(a) GENERAL -- If the Administrator determines that --

(1) a chemical substance may present an unreasonable risk to health or the environment;

(2) there is insufficient data upon which to conclude that such a risk does in fact exist or not exist; and

(3) testing of such substance would assist in making such a determination,

then he shall, by rule, prescribe standards for a test protocol for such substance. Whenever such standards are proscribed, the Administrator shall require, in accordance with subsection (b)(3) of this section, that one or more persons formulate a test protocol for such substance, in accordance with such standards, and perform the tests required by such protocol.

(b) STANDARDS --

(1) In prescribing the standards for test protocols, the Administrator shall require that information pertaining to all relevant factors with respect to the applicable chemical substance be developed. Such factors include --

(A) the effects of such substance on human health, and the magnitude of human exposure; and

(B) the effects of such substance on the environment, and the magnitude of environmental exposure.

(2) Standards for test protocols shall require that such protocols be formulated in accordance with those standards and may require that tests be performed, in accordance with those protocols, for carcinogenicity, mutagenicity, teratogenicity, acute toxicity, subacute toxicity, chronic toxicity, cumulative properties, synergistic properties, clinical effects, epidemiological effects, ecological effects, and any other effects of such substance which might cause unreasonable risk to human health or the environment.

(3) A rule prescribing standards for a test protocol for a chemical substance shall require that any test contained in a test protocol for such substance which is formulated in

accordance with such standards shall be performed by any person or governmental entity which is a manufacturer, processor, or importer of such chemical substance.

(c) PERFORMANCE OF TESTS --

(1) The Administrator may by rule permit two or more persons, who are required to test under a test protocol formulated in accordance with standards prescribed by him, to designate one such person or a qualified and independent third party to perform such testing pursuant to a cost-sharing arrangement. If the persons required to test are not able to agree upon a designee within a reasonable time, or if the agreed-upon designee is not acceptable to the Administrator, the Administrator may order one or more of such persons, or may designate a qualified and independent third party, to perform the required testing. If the Administrator issues such an order, he shall direct the persons who are thus exempted from the obligation to perform tests to provide fair and equitable contribution for the full cost of such testing, and of the cost, if any, of formulating any test protocol, in an amount determined under rules of the Administrator.

(2) Whenever the Administrator exempts a person from the obligation to perform tests, he shall, if such exemption takes effect during the reimbursement period for such data, order such exempt person to provide reimbursement in the same manner as if an exemption had been granted under section 5(f) of this Act (unless the parties agree on the amount and method of reimbursement).

(3) In any case in which a person provides contribution or reimbursement in accordance with paragraph (1) or (2) of this subsection or of section 5(g) of this Act, section 15 of this Act shall not be construed to prevent such person from having access to any data submitted as a result of the testing as to which such contribution or reimbursement was provided.

(d) REPORTING -- A person required to perform any test required by an applicable test protocol shall submit the test data developed pursuant to such test protocol and such protocol to the Administrator promptly upon completion of such test. The Administrator may provide for the submission of preliminary and other reports during the course of such testing.

(e) NOTICE -- Upon the receipt of test protocol and test data developed pursuant to it under this section, and subject to section 15 of this Act, the Administrator shall promptly publish a notice of such receipt in the Federal Register. Each such notice shall (1) identify the chemical substance for which test data have

been received, (2) list the uses or intended uses of such substance, and other information specified by the Administrator by rule, and (3) describe the nature of the test performed and the data which were developed. Such data shall be made available by the Administrator for examination by any person, except as otherwise provided in section 15 of this Act.

(f) PROCEDURE -- Rules issued under this section (and amendment thereto or repeals thereof) shall be promulgated pursuant to section 553 of title 5, United States Code. In promulgating, amending, or repealing any standard or other rule under this section, (1) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, and (2) a transcript shall be made of any oral presentation.

Premarket Screening of Chemical Substances

Section 5:

(a) GENERAL -- Commencing 180 days after the date of enactment of this Act, a manufacturer or importer of a new chemical substance (other than a mixture or a chemical substance covered by subsection (b) of this section) shall notify the Administrator of the planned manufacture or importation of such substance at least 90 days in advance thereof. When providing such notice, such manufacturer or importer shall submit to the Administrator the information referred to in section 8 of this Act insofar as it pertains to such substance. If in the judgment of the Administrator, such a substance does not present an unreasonable environmental or human health risk, he may reduce the number of days after submission of such information during which manufacture or importation may not occur. The Administrator shall give priority attention to a chemical substance with respect to which information is received indicating that serious economic or other hardships are likely to result if there is any unnecessary postponement of manufacture or importation.

(b) SUBMISSION OF DATA --

(1) After the effective date of test standards issued under section 4 of this Act, any manufacturer or importer of a new chemical substance which is covered by such standards, and who first manufactures or imports such substance after such date, shall submit to the Administrator (in lieu of the information required in subsection (a) of this section), at least 90 days prior to such manufacture or importation, the test data developed in accordance with such standards, and the applicable information referred to in section 8 of this Act which pertains to the intended use or distribution of such substance.

(2) The Administrator shall promptly publish (subject to section 15 of this Act) in the Federal Register the identity of each such chemical substance, the use or distribution intended, and a statement of the availability of any test data or other information submitted.

(c) RULE -- If warranted by data available to him, or by the absence of data, the Administrator may propose a rule under section 6 of this Act with respect to a new chemical substance. If such rule is proposed prior to the expiration of the 90-day period referred to in subsection (a) or (b) of this section, or during the extension provided for in subsection (d) of this section, such proposed rule shall apply (pending the outcome of administrative proceedings on such proposal) to any subsequent manufacture or distribution in commerce of such new chemical substance as if such proposed rule were final.

(d) EXTENSION -- The Administrator may extend, for an additional period beyond the 90-day period from the submission of required information under this section, the date after which a new chemical substance may be manufactured or imported for any particular use or distribution. Such additional period may not exceed 90 days and shall not be granted except for good cause shown. Notice of any such extension, and the reasons therefor, shall be published in the Federal Register. Such an extension shall constitute a final action for purposes of judicial review.

(e) CLEARANCE -- Unless the Administrator proposes a rule with respect to a new chemical substance, under section 6 of this Act, within 90 days after the submission of information or data under subsection (a) or (b) (or in the case of information submitted under subsection (a) within such shorter period as the Administrator may consider appropriate) or within such period as extended under subsection (e), manufacture or importation of such new chemical substance may commence. Nothing herein shall be construed to prohibit the Administrator from promulgating a rule pursuant to section 6 of this Act with respect to any chemical substance after manufacture or importation has commenced, or from taking action against any substance which is found to be an imminent hazard pursuant to section 7 of this Act.

(f) EXEMPTION --

(1) The Administrator may exempt any person from the obligation to submit test data under this section, if he determines that the submission of test data by such person would be duplicative of data previously received. Such an exempt person shall not manufacture or import such new chemical substance prior to the date of termination of the premarket screening period for

which test data were submitted under this section. Any chemical substance, or any manufacturer or importer thereof referred to under the preceding sentence, shall be subject to all the other provisions of this Act.

(2) If the Administrator, under paragraph (1), exempts any person from submitting data under this section because of the existence of previously submitted test data, and if such exemption takes effect during the reimbursement period for such data (defined in paragraph (3)), then, unless the parties can agree on the amount and method of reimbursement, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount and subject to conditions determined under rules of the Administrator) --

(A) to any person who previously submitted test data on which the exemption was based, for a portion of the costs incurred by him in complying with the requirement under this section to submit such data, and

(B) to any other person who has been required under this paragraph to contribute with respect to such data.

An order under this paragraph shall be considered final agency action, for purposes of judicial review.

(3) For purposes of paragraph (2), the reimbursement period for any previously submitted test data is a period --

(A) beginning on the earliest date (after submission of such data) on which a person who previously submitted test data on which the exemption was based was no longer prohibited from proceeding with the manufacture and distribution in commerce of a chemical substance to which such data applied, and

(B) ending two years after such date (or, if later, at the expiration of a period after such date equal in length to the period which the Administrator determines was necessary to develop the previously submitted test data).

(g) SIGNIFICANT NEW USE --

(1) A chemical substance may not be manufactured or imported for a use which is identified by the Administrator in a rule as a significant new distribution in commerce of such substance, unless, at least 90 days prior to such manufacture or importation, the person intending to manufacture or import such substance for such use submits a notice of his intention to do so to the Administrator. Any such substance shall be subject to all other provisions of this section.

(2) Any manufacturer or importer who proposes to distribute in commerce a chemical substance for which notice may be required under this subsection, shall attempt to ascertain from the person to whom he distributes such substance (hereafter in this paragraph referred to as "distributee") whether such distributee proposes to distribute such substance for a use which would be a significant new use. If the distributee refuses or is unable to inform such manufacturer or importer whether the proposed use would be a significant new distribution in commerce, the manufacturer or importer shall so inform the Administrator and shall inform the distributee that such substance may be subject to this section. Such distributee shall thereafter be treated, for purposes of this section (including this paragraph), as the manufacturer of such substance.

Hazardous Chemical Substances

Section 6:

(a) GENERAL -- If the Administrator determines that a rule with respect to a chemical substance is necessary to protect against an unreasonable risk to human health or the environment, he may prescribe such a rule under this section. Such a rule may consist of one or more of any of the following types of requirements:

(1) Requirements (A) prohibiting the manufacture, processing or distribution in commerce of such chemical substance or (B) limiting the amount of such chemical substance which may be manufactured or distributed in commerce.

(2) Requirements (A) prohibiting the manufacture or distribution in commerce of such chemical substance for a particular use or (B) limiting the amount of such substance which, or regulating the condition under which such substances, may be manufactured or distributed in commerce for such uses.

(3) Requirements mandating that such chemical substance, or an article containing such substance, be marked with or accompanied by clear and adequate warnings and instructions with respect to its use or disposal, in such form and bearing such content as the administrator determines to be appropriate.

(4) Requirements (A) that persons subject to requirements prescribed under paragraphs (1), (2), or (3), make and retain records and monitor or conduct tests necessary to assure their compliance with such requirements; (B) that manufacturers and processors of a chemical substances make and retain records of the processes used to manufacture or process such substance; and (C) that manufacturers and processors monitor or conduct tests necessary to determine whether chemical substances manufactured or processed by them are adulterated (within the meaning of subsection (e) (2)), and retain records of such tests. Any records or data required under this paragraph

shall not be considered research data or process technology for purposes of section 13(b) of this Act.

The Administrator shall select the least stringent requirement practicable consistent with the protection of human health and the environment against unreasonable risks.

(b) APPLICABILITY --

(1) The applicability of any rule issued under this section may be limited to specified geographic areas.

(2) The authority of the Administrator, under subsection (a) (2) of this section, to prescribe a rule prohibiting the manufacture, processing, or distribution in commerce of a chemical substance for a particular use includes the authority to prohibit the distribution in commerce of a chemical substance for a particular use in a concentration in excess of a level specified in such rule.

(3) Rules limiting the amount of a chemical substance which may be manufactured, processed or distributed in commerce or limiting the quantity of such substance which may be manufactured, processed or distributed for a particular use, shall provide for assigning production, processing and distribution quotas to the extent necessary, with respect to the chemical substance whose manufacture, processing or distribution is limited thereby. The permissible quota for each person who applies to manufacture or process such substance or to engage in its distribution in commerce shall be determined in accordance with criteria which the Administrator shall prescribe by rule. Such criteria shall take into account all relevant factors, including (A) effects on competition, (B) the market shares, productive capacity, and product and raw material inventories of the precursors of the chemical substance of persons applying for quotas, (C) emergency conditions, such as fires or strikes, and (D) effects on technological innovation.

(c) FACTORS -- In promulgating rules under subsection (a) of this section, the Administrator shall consider all relevant factors, including --

(1) the effects of the substance on health and the magnitude and duration of human exposure to it;

(2) the effects of the substance on the environment and the magnitude and duration of environmental exposure to it; and

(3) the benefits of the substance for a given use or uses and the availability of less hazardous substances for the same uses.

(d) EFFECTIVE DATE -- The Administrator shall specify the effective date of any rule proposed under subsection (a) of this section. Such date shall be as soon as feasible.

(e) QUALITY CONTROL --

(1) If the Administrator has good cause to believe that a particular manufacturer, importer, or processor is manufacturing, importing, or processing a chemical substance in a manner which permits or causes the adulteration of such chemical substance.

(A) he may require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance and he shall take such other actions as authorized by this Act; and

(B) if he thereafter determines by rule that such quality control procedures are inadequate to prevent the adulteration of such substance, the Administrator may order the manufacturer, importer, or processor to revise such quality control procedures to the extent which the Administrator finds necessary to remedy such inadequacy.

(2) For purposes of this subsection, a chemical substance is adulterated if it or any precursor substance used or produced in its manufacture or processing bears or contains any other chemical substance or contaminant which itself or, in combination with the chemical substance, poses or is likely to pose an unreasonable risk to human health or the environment.

(f) PROCEDURE -- Rules issued under subsection (a) of this section (and amendments thereto or repeals thereof) shall be promulgated pursuant to section 553 of title 5 of the United States Code; except that in promulgating any such rule, amendment, or repeal (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (B) a transcript shall be made of any oral presentation; and (C) the Administrator shall provide for cross-examination to such extent and in such manner as in his discretion he determines is necessary and appropriate in view of the nature of the issue involved, the number of the participants and the nature of the interests of such participants.

Imminent Hazard

Section 7:

An imminent hazard shall be considered to exist when the evidence is sufficient to show that the manufacture, processing, or distribution in commerce of a chemical substance or product containing such substance will result in any unreasonable threat to human health or the environment, prior to the completion of an administrative hearing or other formal proceeding held pursuant to this Act. If the Administrator has reason

to believe that an imminent hazard exists he may petition an appropriate district court of the United States, or he may request the United States attorney for such district to do so, to restrict the manufacture, processing, or distribution in commerce of the chemical substance or product responsible for the hazard, or to take such other action as is appropriate. The Administrator shall simultaneously, if he has not done so, propose any regulation which may be warranted under section 6 of this Act.

Reports

Section 8:

(a) GENERAL --

(1) The Administrator may, by rule, require any manufacturer, importer, or processor of any chemical substance to maintain such records, and to submit such reports to him annually, and at such more frequent time as he may reasonably require. Reports which the Administrator by rule requires may include the following information:

(A) the common or trade name, the chemical identity, and the molecular structure of each chemical substance for which such report is required, insofar as known to the person making the report or insofar as reasonably ascertainable;

(B) the categories or proposed categories of use of each such substance, insofar as known to the person making the report, or insofar as such are reasonably ascertainable;

(C) reasonable estimates of the amounts of each substance manufactured, imported, or processed for each such use; and

(D) a description of any byproducts resulting from the manufacture, processing, distribution in commerce of each such substance, insofar as known to the person making the report or insofar as reasonably ascertainable.

(2) For purposes of this subsection, the term "byproduct" means a chemical substance which is produced or results as a consequence of the manufacture, importation, processing, or distribution in commerce of some other chemical substance.

(b) INVENTORY -- The Administrator shall compile and publish a listing of each chemical substance which any manufacturer, processor or importer reports (under this section) is manufactured, processed or imported into the United States. A chemical substance shall be included in such listing as of the earliest date (as determined by the Administrator) on which such substance was manufactured in or imported into the United States.

(c) SUBMISSION -- Any test data or other information required to be developed pursuant to this Act shall be submitted to the Administrator promptly. The Administrator may require the submission of preliminary and other reports during the course of any monitoring or testing.

(d) RECORDS -- Any person who manufactures, processes, or distributes in commerce any chemical substance shall maintain records of adverse reactions to human health or the environment alleged to have been caused by the chemical substance. Such records may consist of, but not be limited to, consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce by individuals or governmental agencies.

(e) HEALTH AND SAFETY STUDIES -- Any person who manufactures, processes, or distributes in commerce any chemical substance shall report to the Administrator --

(1) all health and safety studies in progress on or initiated after the date of enactment of this Act, conducted by or for the person; and

(2) a list of all health and safety studies conducted by or for such person 40 years prior to the date of enactment of this Act. Such list shall be submitted to the Administrator within 180 days after the date of enactment of this Act. The Administrator, on the basis of the lists submitted, may request submission of any study appearing on such list.

(f) COMMENTS -- Whenever the Administrator determines that such action would be necessary to assist him to carry out his responsibilities and authorities under this Act, he may, by publishing a notice in the Federal Register, invite and afford all interested persons an opportunity to provide information and comment in writing respecting the health or environmental effects of a chemical substance. Such an invitation and opportunity shall not be deemed a proceeding for purposes of section 15(a)(2) of this Act.

Authorization for Appropriations

Section 26:

(a) There is authorized to be appropriated to the Administrator, for purposes of carrying out this Act, not to exceed $11,100,000 for the fiscal year ending June 30, 1976, not to exceed $2,600,000 for the transitional quarter ending September 30, 1976, and not to exceed $10,100,000 for the fiscal year ending September 30, 1977. No part of the funds so authorized to be appropriated shall be used to construct any research laboratories.

(b) The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit test data under sections 4 and 5 of this Act to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of $2,500. In setting such a fee, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost of the Administrator of reviewing such data. Such rules may provide for sharing such a fee, in any case in which the expenses of testing are shared under section 4(d) of this Act.

(c) Whenever the Administrator submits, in connection with this Act, any budget requests, supplemental budget estimates, legislative recommendations, prepared testimony for congressional hearings, or comments on legislation to the President or to the Office of Management and Budget, he shall concurrently transmit a copy thereof to the Congress. No officer or agency of the United States shall have any authority to require the Administrator to submit budget requests or estimates, legislative recommendations, prepared testimony for congressional hearings, or comments on legislation relating to this Act to any officer or agency of the United States for approval, comments, or review, prior to the submission of such recommendations, testimony, or comments to the Congress.