CMA
CHEMICAL MANUFACTURERS ASSOCIATION
Environmental Affairs

November 15, 1984

MEMORANDUM

TO: Risk Management Task Group

FROM: R. Garrity Baker RGB

SUBJECT: EPA Analysis of Risk Management Decisions

Please review the enclosed letter and study for the December 6 task group meeting. As the enclosed letter from G. Rodenhausen indicates, the task group should review the EPA study to help develop a task group project on risk management decisions.

The enclosed study compares the cost-effectiveness of risk management decisions in three EPA programs: National Emission Standards for Hazardous Air Pollutants (NESHAPs); drinking water; and pesticides. The study calculates the cost of regulations and the benefit that the regulation provides (in prevented cancer cases). These figures are used to compare the cost-effectiveness of the regulations in several different ways. If you are interested in reviewing the detailed analysis in the appendices to the enclosed report, please call and request a copy.

To provide a context of the laws which authorize the regulations in the EPA study, I have also enclosed CMA's "Comparative Overview of Federal Statutes." If you have any questions about the enclosed materials or the upcoming task group meeting, please call me at 202/887-1280.

cc: D. Carroll
C. Cathcart
C. Compton
S. Gaines
G. Ingle
R. Romano
R. Schumacher

CELANESE

October 18, 1984
GAR-374-84

Dr. Thomas J. Robichaux
Petrolite Corporation
369 Marshall Avenue
St. Louis, Missouri 63119

Re: Comparative Risk Management Study

Dear Buddy:

I would like to propose that at its next meeting the Risk Management Task Group form a work group to continue work on the comparative risk management study project.

The initial work group set up by CRAC--Janice Florin, Chris Cathcart, Sandy Gaines, Garrity Baker and myself--has held a number of exploratory discussions with EPA and consultants. These discussions have included Joe Merenda, Margaret Stasikowski, Ernie Abbott, Steve Weil, Dan Beardsley, Michael Gruber, Frank Kover, Mike Shapiro, Alan Farkas, Myron Weinberg and others.

The consensus seems to be that this is a project worth pursuing, but that we should await publication of several studies by EPA. First, OPPE is about to publish a two-phase comparative analysis of risk management decisions. The first is a quantitative analysis by Putnam, Bartlett and Hayes, and the second is a more qualitative analysis by Jellinek, Schwartz and Connelly. Also about to issue is a report on risk assessment and risk management by the Toxics Integration Task Force headed by Dan Beardsley. These three reports are all on point, and should be analyzed before we take any further steps.

The objectives identified in discussions which are worth pursuing are: trying to open up the "black box" of risk management decision-making by making criteria more

explicit; trying to make risk management decisions more consistent, objective and predictable; and trying to assess which statutory criteria work best or are most appropriate for regulation of health risks. All of these concerns are generated by the TSCA Section 9 referral issue and by the use of TSCA as an umbrella statute by EPA.

At the CRAC meeting on October 17 there was no objection to dissolving the CRAC work group making this a project for the Risk Management Task Group for 1984-85. The CRAC budget will hopefully contain $25,000 for possible work in this area.

Sincerely yours,

George A. Rodenhausen
Director
Environmental, Health
and Safety Affairs

GAR:js

cc: R. Garrity Baker
D. Christopher Cathcart
Ronald Condray
Janice D. Florin
Sanford E. Gaines
Risk Management Task Group

DRAFT

ANALYSIS OF COST PER HEALTH
RISK AVOIDED IN SELECTED
EPA STANDARDS AND REGULATIONS

Prepared By:

Putnam, Hayes & Bartlett, Inc.
1200 Eton Court, N.W.
Washington, D. C. 20007
(202) 965-7770

For:

Office of Policy, Planning and Evaluation
U. S. Environmental Protection Agency
Washington, D. C. 20460

September 28, 1984

TABLE OF CONTENTS

I. Introduction

Legislation such as the Clean Water Act, the Clean Air Act, the Toxic Substances Control Act, and the Safe Water Drinking Act specify criteria for the regulation of health risks. These criteria and the way EPA implements the legislation affect the cost and effectiveness of EPA regulations.

The purposes of this study are:

- To survey existing documentation of selected EPA decisions, proposals, and supporting studies to identify the costs of the regulation or standard, and the effectiveness of the regulation or standard as measured by reductions in health risk, specifically cancer;

- To calculate a cost-effectiveness ratio for each regulation or standard based on the cost and health risk reduction information obtained; and

- To compare the cost-effectiveness of the regulations and rejected alternatives, both within and across programs.

The following eight regulations were selected for review:

- Three NESHAPS regulations:

  - Benzene emissions from maleic anhydride plants

- Benzene fugitive emissions (decisions for new and existing sources)

- Vinyl chloride (two source categories)

- Two drinking water regulations:

  - Trihalomethanes

  - Inorganic chemicals (arsenic, cadmium, chromium, and lead)

- Actions taken concerning three pesticides:

  - Chlorobenzilate

  - Ethylene dibromide (EDB - three uses)

  - Dibromochloropropane (DBCP - eight uses)

In these eight regulations, cost-effectiveness values for 22 separate regulatory decisions and alternatives to those decisions are calculated.

The remainder of this report consists of two sections and eight appendices. Section II and its companion tables present the study's results and conclusions. Section III contains information on methodological issues, including sources of information and descriptions of computations performed. The eight appendices, one for each regulation, provide the supporting data, calculations, and information for this summary report. (The eight appendices are bound under separate cover.)

II. Results and Conclusions

This section is divided into five parts. Part A describes generally the decision-making procedures used by EPA in the eight regulations examined. Because the cost-effectiveness and risk data can be compared in several different ways, our data analysis is divided as follows: (1) Part B analyzes the data on a regulation-by-regulation basis; (2) Part C compares the regulations within programs, for example, for pesticides; and (3) Part D compares the regulations across programs. Finally, the results of the data analysis are summarized and general conclusions are developed.

Table 1 summarizes the basic data developed for this study and used in this section on data analysis. Drawn from the more detailed information contained in the eight appendices, Table 1 presents cost-effectiveness, risk reduction, and residual risk information on a regulatory option basis.

It is important to note at the outset that it is tempting to read more into the regulatory comparisons than the underlying data might warrant. The numbers presented in Table 1 should not be viewed as precise; they are EPA estimates, and in some cases, PHB estimates based on the EPA data provided (see Section III). As a result, comparisons are more appropriately made at a broad, order-of-magnitude level. In other words, a cost-effectiveness value of $8 million compared with another value of $10 million may not represent a significant difference; however, values that differed by a factor of 10 or 100 would be worthy of note.

A. Decision-Making Procedures

The most systematic, clear-cut cost-effectiveness analysis was found in the three NESHAPS regulations. Because of this, relatively little derivation of cost and risk estimates by PHB was required for the NESHAPS.

The procedures used by EPA to make regulatory decisions were consistent among the three NESHAPS. In general, the process involved four steps. First, major emission sources were identified. Second, potential control technologies were examined for their feasibility and economic impact. Third, a control level was selected as BAT. Fourth, health risk analysis was performed for the BAT strategy and a small number of alternatives to ensure that the selected strategy provided sufficient protection of the public health.

For the two drinking water regulations, cost-effectiveness analysis appeared to be of less concern in the decision-making process than for the NESHAPS. For trihalomethanes, the decision was based on a balancing of public health considerations and the feasibility of achieving various maximum contaminant levels in the public water systems. In setting the inorganic chemicals standards, EPA did not perform any formal quantitative risk assessments. The MCL's established did not flow from risk analyses, but rather were identical to standards developed by the Public Health Service. It should be noted, however, that more quantitative drinking water re-studies are now being performed.

While not as systematic and thorough (for example, cases avoided were typically not computed) as the NESHAPS, the pesticide decision-making seemed to reflect some balancing of risks and benefits on a more general basis. For example, the option selected in the chlorobenzilate regulatory analysis reduced risks for the population with greatest exposure, but left risks where benefits of continued use of the pesticide were the greatest. EPA discussion in the documents surrounding the DBCP decision included statements about: (1) cancellation resulting in unacceptable adverse impacts on the economic benefits of a given DBCP use, and (2) cancellation of a given DBCP use being necessary in order to satisfactorily reduce risk. However, as will be discussed later in this section, the pesticide cost-effectiveness values exhibit wide variations and a number of inconsistencies.

B. Comparisons Among Alternatives for Each Regulation

Examining the NESHAPS regulations separately, the decisions made were fairly consistent. With one exception, the regulatory alternative eventually promulgated is the most cost-effective among the alternatives examined. This is also true of proposed regulations which were later withdrawn or significantly revised. The exception is the vinyl chloride PVC plants standard. In that case, the option selected is somewhat less cost-effective than the alternative option. While the selected option results in only a marginal increase in the number of cases avoided per year, it does reduce the maximum individual risk by a factor of three and the residual population risk by a factor of two.*

The drinking water regulations for inorganic chemicals did not include an options analysis of alternative standards. For trihalomethanes, the selected standard is only slightly less cost-effective than two rejected alternatives, and is twice as cost-effective as a third rejected alternative. While the selected option was slightly less cost-effective than two rejected alternatives, it also increased the cases avoided per year by 50 percent (from approximately 200 to 300).

Examining the pesticide regulations separately, the individual decisions made (on a use-by-use basis for EDB and DBCP) were generally consistent. As with NESHAPS, the regulatory option selected is the most cost-effective, with one exception. The exception is the preliminary

---

* The cost-effectiveness measure used here does not include all dimensions of decision-making. It calculates the cost per health risk avoided, but it does not address maximum individual risk or residual population risk.

notice of determination for EDB as a soil fumigant use. The selected option is many times less cost-effective than the rejected alternative. The selected option reduces risk by less than one case per year while the rejected alternative reduces risk by 180 cases per year. The explanation for this anomaly appears to lie in the fact that the selected option reduces occupational risk only; the rejected alternative would also have eliminated dietary risk for the general population. EPA was uncertain of its dietary risk estimates and may have felt that its estimate of 180 cases was unreliable.

As part of its amended notice of the intent to cancel DBCP registrations, EPA made decisions on the eight major uses of the chemical. While the decisions are consistent on a use-by-use basis, inconsistencies arise when comparing decisions across uses. The option selected for DBCP use on cotton resulted in a risk reduction of .001 cases per year at a cost per case avoided of $320 million. A rejected alternative for DBCP use on peaches resulted in the same risk reduction at the relatively low cost per case avoided of $10 million.

C. Comparisons Within Programs

The range in cost-effectiveness values for the promulgated NESHAPS regulations is two orders of magnitude (see Table 2). The values range from $ 09 million to $94 million. The least cost-effective of these values is a component of the vinyl chloride regulation applicable to plants which are generally located in low population areas. When cost-effectiveness is measured in terms of megagrams of pollutant removed, the two components of the vinyl chloride regulation are much closer in cost-effectiveness. Hence, the divergence in the cost-effectiveness is partly due to the range in population exposure.

In comparing promulgated NESHAPS regulatory alternatives with rejected alternatives, certain inconsistencies arise. For example, a regulation for controlling benzene emissions from maleic anhydride plants with a cost-effectiveness value of $55 million was rejected in 1984, while a regulatory alternative for controlling vinyl chloride emissions with a cost-effectiveness value of $94 million was promulgated in 1976. The vinyl chloride regulation did result in a greater reduction in the number of cancer cases per year (.52 versus .009 for the maleic anhydride alternative), but the pre-regulation population risk was less than one cancer case per year in both instances. It should be noted, however, that the pre-regulation maximum individual risk for the promulgated vinyl chloride alternative was two orders of magnitude larger than that for the maleic anhydride rejected alternative.

For the two drinking water regulations, relatively little comparison is possible because the inorganic chemicals standards promulgated did not use risk analysis as a basis for decision-making. As indicated in Table 2, however, the cost-effectiveness values of the selected trihalomethane alternative and for the group of four carcinogenic inorganic chemicals are very close ($71,000 and $95,000, respectively.)

Among the three pesticides, the cost-effectiveness values of the selected options vary widely. While the cost-effectiveness values for the selected options of chlorobenzilate and EDB are all under $1 million per case avoided, the DBCP values range from a few thousand dollars to $320 million. This wide disparity stems from two related considerations. First, the cost-effectiveness results are sensitive to the underlying EPA estimates of occupational versus dietary risk. The DBCP regulatory options analysis associated with the "amended notice of intent to cancel registrations" assumed that dietary risk was zero for six of the eight major uses. For the two uses with dietary risk, the cases avoided annually rose sharply and the associated cost-effectiveness value declined sharply.

The second reason for the DBCP disparity stems from the limitations of the data. For the six uses with occupational risk only, the baseline number of cases per year is understated since the estimates of worker risk are derived using only inhalation exposure to DBCP. Dermal and re-entry risks, which are probably at least as great as inhalation risk, could not be computed.

As was the case with the NESHAPS, in comparing chosen pesticide options with rejected alternatives, certain anomalies arise. A rejected chlorobenzilate alternative was considerably more cost-effective than several DBCP options that were selected. Moreover, the reduction in cases per year for the rejected chlorobenzilate alternative (8.5) was considerably greater than those associated with several selected DBCP options (less than one case avoided per year). Again, this apparent discrepancy may be explained in part by the previously mentioned DBCP data limitations.

D. Comparisons Across Programs

Comparing the cost-effectiveness values across programs, one can see that the drinking water regulations are generally the most cost-effective, while the NESHAPS are generally the least cost-effective. The pesticide regulations exhibit the greatest variation in cost-effectiveness, and include the highest and lowest values for all eight of the regulations reviewed.

The NESHAPS regulations also result in the fewest number of cases avoided annually, typically less than one. As was the case with cost-effectiveness values, the pesticides also exhibit the greatest variation in number of cases avoided. Some selected DBCP options result in annual risk reductions of only .001 cases per year. On the other hand, the largest risk reduction in all of the regulations examined is associated with

DBCP use on vegetables (avoids 1,900 cases annually). As noted earlier, DBCP cost and risk estimates are especially sensitive to the issue of occupational versus dietary risk.

E. Conclusions

Recognizing the limitations of the data used in this analysis, a number of general conclusions can be drawn:

- Examining the eight regulations separately, the decisions made were fairly consistent. With a few exceptions, the regulatory alternative eventually selected is the most cost-effective among the alternatives examined. While the DBCP decisions are consistent on a use-by-use basis, inconsistencies arise when comparing decisions across uses. Some accepted alternatives are less cost-effective than other alternatives that were rejected.

- While the cost-effectiveness values for the two drinking water regulations are quite close, the values for both the NESHAPS and particularly the pesticides exhibit wide variation.

- When comparing selected alternatives with rejected alternatives within programs, inconsistencies arise. Some rejected alternatives are more cost-effective than those alternatives selected.

- Overall, the drinking water regulations are generally the most cost-effective while the NESHAPS regulations are generally the least cost-effective. This difference stems in large part from the large numbers of people exposed to water contaminants.

The significant difference in the exposed population results in a much larger pre-regulation number of cases for water contaminants.

- What constitutes an unacceptable level of pre-regulation and residual risk varies across regulations. For example, the residual risk (measured in terms of cases per year) for the selected trihalomethane alternative is much larger than the pre-regulation risk for DBCP use on pineapples. The maximum individual risks are similar. In spite of this, the pre-regulation risk for DBCP use on pineapples was considered unacceptably high and action was taken to reduce it.

III. Methodology

A. Selection of Regulations

The eight regulations analyzed in this study were selected using a two-step process. The first step involved identifying 20-25 regulations which potentially contained the necessary data for cost and risk estimates. This larger group was identified through telephone interviews with program office staff and through a review of regulatory agenda published in the Federal Register.

The second step involved choosing the smaller group of eight regulations for detailed study. Information obtained from the telephone discussions and from a review of regulatory materials was used in making this selection. In the selection process, it was important to ensure that the sample included several different programs and more than one regulation from each of those programs so that comparisons could be made both within and across programs. While the sample of eight is small, it does produce information on more than twenty separate regulatory decisions.

B. Sources of Information

Publicly available information was used in performing this study. This included Federal Register notices, Background Information Documents and Environmental Impact Statements, Position Documents, and other material available in the regulatory dockets and the EPA library. The sources relied upon in analyzing each regulation are referenced on the last page of each appendix.

In some cases, however, PHB was forced to derive cost and risk estimates based on the EPA data provided. Such calculated values are marked and explained in the appendices. Because very limited cost and risk data were available for the inorganics regulation, the most extensive derivations are contained in Appendix E. Other derived values include a 1984 cost estimate for the maleic anhydride regulation, certain health risk estimates for the vinyl chloride and benzene fugitive emissions regulations, and certain cost and population risk numbers for the pesticides.

It should also be noted that in some instances the source data and regulatory options were reorganized to allow for comparisons and to clarify the regulatory analysis. For example, three of EPA's regulatory alternatives for DBCP were combined into one option for the purposes of this analysis since EPA never showed any incremental cost attributable to two of those three alternatives. All such reorganizations are explained in detail in the appendices.

C. Comparability Issues

To ensure that the analysis performed for the eight regulations produced measures that were as comparable as possible, certain adjustments were made to the source data. These adjustments are described below.

All summary results were inflated to 1983 dollars. For the NESHAPS and drinking water regulations, this involved using the indices EPA typically has used in performing regulatory analyses for those programs. The index used for the NESHAPS was the Chemical Engineering plant cost index, and the index used in inflating the drinking water values was the Engineering News Record composite index for water and power construction costs. For the pesticides, the index for "prices paid by farmers for production items" presented in the Economic Report of the President was used.

In developing annualized cost estimates for the NESHAPS, EPA employed a capital recovery factor approach. This technique essentially spreads the upfront costs of capital equipment over a number of years by assuming an interest rate and an equipment life. This same approach was used in the drinking water and pesticide regulations wherever applicable.

In terms of risk measurement, all risk numbers refer to the lifetime probability of contracting cancer in the case of maximum individual risk and the number of cancer cases per year in the case of population risk. While EPA typically described health risks other than cancer in its regulatory analysis, only cancer risk was quantified. To the extent that other adverse health effects are present for a given pollutant, associated cost-effectiveness values are understated.

In spite of the numerous adjustments made to permit comparisons within programs and across programs, certain unavoidable comparability problems remain. In many instances, the pesticides' regulatory analyses did not present population risk. As a result, population risk estimates were derived by PHB using maximum individual risk, which overstates the number of cases per year. Pesticide regulations, particularly those which call for cancellation, potentially have added risk associated with the use of substitute pesticides. To the extent this may be the case, the relative cost-effectiveness of the

pesticide regulations are overstated. These remaining comparability issues, however, do not interfere with the ability to make broad comparisons across programs.

D. Development of Appendices

An appendix was developed for each of the eight regulations to present the results of our research and analysis. With one exception, the appendices were prepared in a standard format to facilitate comparisons among the data. The exception is the inorganics chemicals appendix which is presented in a substantially different format because the quantitative data were very limited and it was necessary to make a number of assumptions and derivations to estimate cost-effectiveness.

The other seven appendices begin with sections on background information, including a brief history of regulatory activity, and a description of regulatory options considered. Following these two sections are a number of standard tables presenting EPA cost/economic information, EPA effectiveness information, cost-effectiveness supporting calculations, and a summary of cost effectiveness values, both in 1983 dollars and the dollars of the original analysis. In those tables, the cost per case avoided was computed by dividing the annualized cost by the number of cases avoided annually. The incremental cost per case avoided was calculated relative to the pre-regulation case or relative to the next least stringent option considered for the regulation. Each appendix concludes with a section on effectiveness measures, a section highlighting key aspects of the regulatory decision, and a page listing the source documents for the analysis.

TABLE 1 -- SUMMARY OF RESULTS

I. NESHAPS

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness (1) $/Case Avoided ($ Millions)	Cost-Effectiveness (1) Incremental $/Case Avoided (2) ($ Millions)	Residual Risk (1) Risk Avoided(1) (Cases/Yr)	Residual Risk (1) Population Risk (Cases/Yr)	Residual Risk (1) Maximum Individual Risk ($\times 10^{-3}$)
Benzene (Health Endpoint is Leukemia)	Maleic Anhydride Emissions (1980)	97% control	Rejected	9.9	9.9	0.35	0.11	2.0
		97% + shut-down during malfunction	Proposed 1980	9.9	2.5	0.36	0.10	2.0
		97% + full back-up controls	Rejected	12	1400	0.37	0.098	2.0
		99% control	Rejected	17	16	0.38	0.080	0.55
	Maleic Anhydride Emissions (1984)	97% + shut-down during malfunction (3)	Rejected	55	55	0.009	0.020	0.81
	Fugitive Emissions-Existing Sources (1981)	70% control	Proposed 1981	16	16	0.46	0.19	18
		More stringent (80% control)	Rejected	37	270	0.49	0.16	15

(1) Throughout this table, values shown are midpoints of ranges presented in detailed tables in Appendices. All costs are expressed in 1983 dollars.

(2) Throughout this table, incremental values are comparisons with baseline (no regulation or no change in regulation) case or next least stringent option considered for the regulation.

(3) Re-evaluation of option proposed in 1980. Significant changes occurred in industry structure and in-place controls.

TABLE 1 -- SUMMARY OF RESULTS (continued)

I. NESHAPS (continued)

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness: $/Case Avoided ($ Millions)	Cost-Effectiveness: Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk: Population Risk (Cases/Yr)	Residual Risk: Maximum Individual Risk ($\times 10^{-3}$)
Benzene (Cont'd)	Fugitive Emissions-Existing sources (1984)	69% control	Promulgated 1984	1.6	1.6	0.31	0.14	45
		More stringent (72% control)	Rejected	15	440	0.32	0.13	42
	Fugitive Emissions-New sources (1981)	80% control	Proposed 1981	28	28	0.15	0.05	15
		More stringent (90% control)	Rejected	210	1500	0.18	0.18	6.9
	Fugitive Emissions-New sources (1984)	Final rule	Promulgated 1984	0.9	0.9	0.11	0.034	45
		More stringent	Rejected	11	550	0.11	0.032	42

TABLE 1 -- SUMMARY OF RESULTS (continued)

I. NESHAPS (Continued)

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness $/Case Avoided ($ Millions)	Cost-Effectiveness Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk Population Risk (Cases/Yr)	Residual Risk Maximum Individual Risk ($\times 10^{-3}$)
Vinyl Chloride (Health Endpoint is Liver and other cancers)	Emissions from EDC-VCM plants (1976)	90% overall reduction	Rejected	95	95	0.50	0.055	24
		94% overall reduction (including oxychlorination control)	Promulgated 1976	94	71	0.52	0.033	21
		97% reduction (including oxychlorination incineration)	Rejected	110	200	0.53	0.017	19
	Emissions from PVC plants (1976)	88% overall reduction	Rejected	9.9	9.9	14	1.9	150
		95% reduction	Promulgated 1976 (4)	10-32	14-310	15	0.80	59

(4) Ranges of values reflect substantially different technologies which may be necessary to achieve standards.

TABLE I -- SUMMARY OF RESULTS (continued)

II. Drinking Water

Pollutant	Regulation	Regulatory Option (5)	Decision	Cost-Effectiveness: $/Case Avoided ($ Millions)	Cost-Effectiveness: Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk: Population Risk (Cases/Yr)	Residual Risk: Maximum Individual Risk ($\times 10^{-5}$)
Trihalomethanes (Health Endpoint is Cancer)	National Interim Primary Drinking Water Regulations-Trihalomethanes (1979)	MCL = .10 mg/l Systems > 75,000	Rejected	.062	.062	200	460	41
		MCL = .15 mg/l Systems>10,000	Rejected	.056	.021	230	430	61
		MCL = .10 mg/l Systems >10,000	Selected	.071	.11	320	340	41
		MCL = .05 mg/l Systems>10,000	Rejected	.16	.23	430	230	20
Inorganic Chemicals (6) (Health Endpoint is Cancer)	National Interim Primary Drinking Water Regulations-Inorganic Chemicals (1975)	Arsenic MCL = 50 ug/l	Selected	.024	N/A	65	N/A	N/A
		Cadmium MCL = 10 ug/l	Selected	1.6	N/A	7.7	N/A	N/A
		Chromium MCL = 50 ug/l	Selected	.053	N/A	180	N/A	N/A
		Lead MCL = 50 ug/l	Selected	2.3	N/A	.35	N/A	N/A
		For all four	Selected	.095	N/A	250	N/A	N/A

(5) MCL refers to maximum contaminant level and "systems greater than" refers to systems serving more than the given number of people.
(6) The estimated cost-effectiveness for this regulation was derived by PHB based on very limited data. See Appendix E for details.

TABLE 1 -- SUMMARY OF RESULTS (continued)

III. Pesticides

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness (8) $/Case Avoided ($ Millions)	Cost-Effectiveness (8) Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk Population Risk (Cases/Yr)	Residual Risk Maximum Individual Risk (x 10^{-5}) (10)
Chlorobenzilate (Health End-point is Cancer)	Notice of Intent to Cancel Registrations (1979)	Cancel non-citrus; respirators	Selected (7)	0.8	0.8	0.40	8.1	18
		Cancel non-citrus; cabs	Selected (7)	12	2,700	0.40	8.1	.9
		Cancel non-citrus and Arizona citrus	Rejected	N/A	N/A	0.45	8.0	18 (7)
		Cancel all uses	Rejected	7.4	7.7 (9)	8.5	0	0
EDB (Health End-point is Cancer)	Preliminary Notice of Determination for EDB: Soil Fumigant Use (1980)	Register with restrictions	Selected	2,000	2,000	0.3	180	5.6
		Cancel use	Rejected	.17	.13	180	0	0
	Notice of Intent to Cancel Registrations: Soil Fumigant Use (1983)	Cancel use	Selected	.55	.55	65	0	0

(7) Grower was given his choice of protecting applicators either through respirators or through enclosed truck cabs.
(8) For all pesticides, cost-effectiveness values are lower-bound estimates since risk reduction estimates are upper-bound values because of the exclusion of the potential risk from substitute pesticides and the use of maximum individual risk figures in calculating total population risk.
(9) Calculated relative to control with respirator.
(10) For all pesticides, the most exposed group, which in some cases is workers and in other cases is the general population from dietary exposure.

TABLE 1 -- SUMMARY OF RESULTS (continued)

III. Pesticides (Continued)

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness: $/Case Avoided ($ Millions)	Cost-Effectiveness: Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk: Population Risk (Cases/Yr)	Residual Risk: Maximum Individual Risk ($\times 10^{-5}$)
EDB (continued)	Preliminary Notice of Determination for EDB: Spot Grain Fumigant Use (1980)	Register with restrictions	Rejected	.15	.15	8	160	540
		Cancel use	Selected	.05	.05	170	0	0
	Notice of Intent to Cancel Registrations: Spot Grain Fumigant Use (1983)	Cancel use	Selected	.01	.01	800	0	0
	Notice of Intent to Cancel Registrations: Quarantine Fumigation (1983)	Cancel use	Selected	.11	.11	320	0	0
DBCP (11) (Health Endpoint is Cancer)	Amended Notice of Intent to Cancel Registrations: DBCP Use on Peaches (1978)	Worker restrictions	Selected	7.1	7.1	.062	.001	7.3
		Cancel irrigation	Rejected	10	220	.063	0	0
		Cance use	Rejected	60	N/A	.063	0	0

(11) Eight major uses of DBCP are presentec. Occupational risk for all eight major uses; dietary risk only for peanuts and vegetables.

TABLE 1 --SUMMARY OF RESULTS (continued)

III. Pesticides (Continued)

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness: $/Case Avoided ($ Millions)	Cost-Effectiveness: Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk: Population Risk (Cases/Yr)	Residual Risk: Maximum Individual Risk ($\times 10^{-5}$)
DBCP (continued)	Amended Notice of Intent to Cancel Registrations: DBCP Use on Citrus (1978)	Worker restrictions	Selected	1.9	1.9	.049	.001	
		Cancel irrigation	Rejected	6.6	240	.050	0	0
		Cancel use	Relected	260	N/A	.050	0	0
	Amended Notice of Intent to Cancel Registrations: DBCP Use on Vineyards (1978)	Worker restrictions	Selected	2.1	2.1	.189	.004	12
		Cancel irrigation	Rejected	6.0	190	.193	0	0
		Cancel use	Rejected	160	N/A	.193	0	0
	Amended Notice of Intent to Cancel Registrations: DBCP Use on Pineapples (1978)	Worker restrictions	Selected	160	160	< .001	< .001	19
		Cancel irrigation	N/A	N/A	N/A	N/A	N/A	N/A
		Cancel use	Rejected	130,000	N/A	< .001	0	0

TABLE 1 -- SUMMARY OF RESULTS (continued)

III. Pesticides (Continued)

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness: $/Case Avoided ($ Millions)	Cost-Effectiveness: Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk: Population Risk (Cases/Yr)	Residual Risk: Maximum Individual Risk ($\times 10^{-6}$)
DBCP (continued)	Amended Notice of Intent to Cancel Registrations: DBCP Use on Soybeans (1978)	Worker restrictions	Selected	120	120	.013	< .001	18
		Cancel irrigation	N/A	N/A	N/A	N/A	N/A	0
		Cancel use	Rejected	2,600	N/A	.013	0	0
	Amended Notice of Intent to Cancel Registrations: DBCP Use on Cotton (1978)	Worker restrictions	Selected	320	320	.001	< .001	19
		Cancel irrigation	N/A	N/A	N/A	N/A	N/A	N/A
		Cancel use	Rejected	3,700	N/A	.001	N/A	0
	Amended Notice of Intent to Cancel Registrations: DBCP Use On Peanuts (1978)	Worker restrictions	Rejected	460	460	.004	100	3.3
		Cancel irrigation	N/A	N/A	N/A	N/A	N/A	N/A
		Cancel use	Selected	.1	.1	100	0	0

TABLE 1 -- SUMMARY OF RESULTS (continued)

III. Pesticides (Continued)

Pollutant	Regulation	Regulatory Option	Decision	Cost-Effectiveness: $/Case Avoided ($ Millions)	Cost-Effectiveness: Incremental $/Case Avoided ($ Millions)	Risk Avoided (Cases/Yr)	Residual Risk: Population Risk (Cases/Yr)	Residual Risk: Maximum Individual Risk ($\times 10^{-5}$)
DBCP (continued)	Amended Notice of Intent to Cancel Registrations: DBCP Use On Vegetables (1978)	Worker restrictions	Rejected	160	160	.013	1,900	61
		Cancel irrigation	N/A	N/A	N/A	N/A	N/A	N/A
		Cancel use	Selected	.01	.01	1,900	0	0

SL 102752

TABLE 2

COST-EFFECTIVENESS OF

PROMULGATED REGULATIONS[1]

Regulation	Cost per Cancer Case per Year Avoided (1983 Dollars)
Drinking Water - Trihalomethanes	71,000
Drinking Water - Inorganics	95,000[2]
Pesticides - EDB (range over three uses)[3]	10,000 - 550,000
Pesticides - DBCP (range over eight major uses)[4]	10,000 - 320,000,000
Pesticides - Chlorobenzilate	800,000
NESHAPS - Benzene Fugitive Emissions for New Sources (1984)	900,000
NESHAPS - Benzene Fugitive Emissions for Existing Sources (1984)	1,600,000
NESHAPS - Vinyl Chloride Emissions from PVC Plants (1976)	10,000,000
NESHAPS - Vinyl Chloride Emissions from EDC-VCM Plants (1976)	94,000,000

---

1 For the three pesticides, cost-effectiveness values are from position documents and other documents associated with the "notice of intent to cancel registrations" for the pesticide.

2 The estimated cost-effectiveness of the inorganics regulation was derived by PHB based on very limited data. See Appendix E for details.

3 Spot grain use: $10,000; Quarantine use: $110,000; Soil use $550,000.

4 Vegetables: $10,000, Peanuts: $100,000; citrus: $1,900,000; Vineyards: $2,100,000; Peaches: $7,100,000; Soybeans: $120,000,000; Pineapples: $160,000,000; Cotton: $320,000,000.

CHEMICAL MANUFACTURERS ASSOCIATION

COMPARATIVE OVERVIEW OF FEDERAL STATUTES

Several private organizations and government agencies have recently begun to explore the question of how the different federal laws manage risks to public health or the environment. At the same time, significant issues have arisen about the relationship between two or more government agencies addressing the same risks or risks created by the same substance. As a preliminary step to an understanding of the complex legal and institutional relationships that exist within the federal government's management of chemical risks, CMA's Office of General Counsel has prepared a synopsis of ten laws primarily directed to the protection of public health and the environment. This synopsis simply portrays the statutory directives in each law; it does not attempt to interpret those directives or to explain how they have been applied by the agencies.

SL 102754

Formerly Manufacturing Chemists Association—Serving the Chemical Industry Since 1872
2501 M Street, NW • Washington, DC 20037 • Telephone 202/887-1100 • Telex 89617 (CMA WSH)

Table of Contents

1. TOXIC SUBSTANCES CONTROL ACT

New Chemicals

I. Section 5(a) -- New Uses

A. Threshold for Action

Foreseeable new uses may present risks not evaluated during PMN review.

B. Risk Management Option

Require submission of PMN 90 days prior to manufacture of a chemical for a "significant" new use.

II. Section 5(e) - Regulation Pending Development of Information

A. Threshold for Action

1. May present an unreasonable risk.

or 2. Presents or may present significant or substantial human exposure or substantial release to environment.

B. Risk Management Option

Issue an order to PMN submitter to prohibit or limit manufacture, processing, distribution, use, or disposal.

C. Factors

1. Sufficiency of information to make a reasoned evaluation of chemical's effect.

2. Extent of exposure that may occur from manufacture, processing, distribution, use, or disposal.

III. Section 5(f) -- Protection Against Unreasonable Risks

A. Threshold for Action

Presents or will present an unreasonable risk before a section 6 rule can protect against such risk.

B. Risk Management Option

1. Issue a proposed rule under section 6(a), effective immediately, to limit amount

SL 102756

manufactured or to impose any section 6 controls except a ban.

2. Issue a proposed order or seek a court injunction to prohibit manufacture.

C. Factors

1. Effects and magnitude of exposure (human or environmental).

2. Benefits of substance and availability of substitutes.

3. Economic consequences of rule.

4. Timing - risk may occur before section 6 rule can be issued.

Existing Chemicals

I. Section 6(a) - Scope of Regulation

A. Threshold for Action

Presents or will present an unreasonable risk.

B. Risk Management Options

Apply least burdensome requirement(s):

1. Prohibit manufacture, processing, or distribution; or limit amount.

2. Prohibit manufacture, processing, or distribution for a particular use; or limit amount.

3. Adequate warnings and instructions on substance or article containing substance.

4. Manufacturer or processor retain records or conduct tests.

5. Prohibit or regulate manner or method of use or disposal.

6. Require manufacturer or processor to give notice of risk to distributors and public, and to replace or repurchase substance.

C. Factors

1. Effects and magnitude of exposure (human or environmental).

2. Benefits of substance and availability of substitutes.

3. Economic consequences of rule.

II. Section 6(b) - Quality Control

A. Threshold for Action

Manufactured or processed in a manner which unintentionally presents or will present an unreasonable risk.

B. Risk Management Option

The Administrator may order manufacturer or processor to submit quality control procedures; review procedures; or give notice of risk to processors, distributors, or the public.

III. Section 6(d) - Effective Date

A. Threshold for Action

Unreasonable risk of serious or widespread injury.

B. Risk Management Option

Make a proposed rule under section 6(a) effective immediately upon publication in the Federal Register.

C. Factors

1. Determination that the activity is likely to result in unreasonable risk.

2. Public interest requires an earlier effective date.

Imminent Hazards

I. Section 7(a) - Actions Authorized and Required

A. Threshold for Action

Presents imminent and unreasonable risk of serious or widespread injury.

B. Risk Managment Option

Commence a civil action for seizure of an imminently hazardous chemical; for relief against the manufacturer, processor, user, or distributor; or for seizure and relief.

C. Factors

Injury to health and the environment is likely to result before a final rule under section 6 can protect against such risk.

Cost-Benefit Analysis Requirement

No formal cost-benefit analysis is required in TSCA. As the House Report states:

> "the bill is not to be construed as a direction to [EPA]...to make any statement of findings in addition to those required by specific provisions of the bill or to involve [EPA]...in any cost-benefit justifications." (Legislative History, p. 471.)

Nevertheless, EPA must always consider the "economic consequences" of its actions as generally required in section 2(c) ("The Administrator shall consider the..economic...impact of any action...") and as specifically required elsewhwere (e.g., section 6(a) -- use the "least burdensome requirements," and section 6(c) -- consider the "reasonably ascertainable economic consequences").

SL 102759

2. CLEAN AIR ACT

I. Pollutants from Numerous Diverse Sources

A. Threshold for Action (Section 108)

May reasonably be anticipated to endanger public health or welfare.

B. Risk Management Option (Section 109)

The Administrator shall prescribe national primary and secondary ambient air quality standards for such pollutants.

1. Primary standards shall protect public health with an adequate margin of safety.

2. Secondary standard shall protect the public welfare from known or anticipated effects.

C. Factors

1. Variable factors (e.g., meteorology) which may alter the effects on public health.

2. Types of air pollutants which may interact to produce an adverse effect on public health.

3. Any known or anticipated adverse effects on welfare.

II. Hazardous Air Pollutants (Section 112)

A. Threshold for Action

Causes or contributes to pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness.

B. Risk Management Option

The Administrator shall establish emission standards for each hazardous air pollutant.

C. Factors

Provide ample margin of safety to protect public health.

III. Chlorofluorocarbons (Section 137)

A. Threshold for Action

Substance, process, or activity may reasonably be anticipated to affect the stratosphere, and as such affect public health or welfare.

B. Risk Management Option

The Administrator shall promulgate regulations to control the substance, practice, process, or activity which may affect the stratosphere and endanger public health.

C. Factors

1. Feasibility

2. Costs

3. Exempts medical products for which there is no substitute.

IV. Motor Vehicle Emissions (Section 202)

A. Threshold for Action

May reasonably be anticipated to endanger public health or welfare.

B. Risk Management Option

The Administrator shall prescribe standards applicable to the emission from vehicles of any air pollutant which causes or contributes to air pollution.

C. Factors

1. Cost of compliance.

2. Noise, energy, and safety factors associated with the application of the technology.

V. Fuel and Fuel Additives (Section 211)

A. Threshold for Action

May reasonably be anticipated to endanger public health or welfare.

B. Risk Management Option

The Administrator may control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of the fuel or fuel additive.

C. Factors

1. Medical and scientific criteria.

2. Other technologically or economically feasible means.

3. Substitutions

4. Economic date

VI. Aircraft Emission Standards (Section 231)

A. Threshold for Action

May reasonably be anticipated to endanger public health or welfare.

B. Risk Management Option

The Administrator shall issue emission standards.

C. Factors

1. Technology

2. Cost of compliance

3. Aircraft safety

Cost-Benefit Analysis Requirement

Throughout the Clean Air Act, the economic "cost of compliance" is given appropriate consideration before a regulation may be authorized (e.g., Sections 157, 202, 211, and 231).

SL 102762

3. CLEAN WATER ACT

I. Water Quality Standards (Section 303)

A. Threshold for Action

Revision of state water quality standards or adoption of new standards.

B. Risk Management Option

Standard shall protect the public health or welfare, enhance the quality of the water and serve the purposes of the Act.

C. Factors

Use and value of water for:

1. Public water supply
2. Propagation of fish and wildlife
3. Recreation
4. Agriculture
5. Industry
6. Navigation

II. Toxic and Pretreatment Effluent Standards (Section 307)

A. Threshold for Action

Will cause death, disease, behavior abnormalities, cancer, genetic mutations, physiolgical malfunction, or physical deformation, in organisms or their offspring.

B. Risk Management Option

The Administrator may impose more stringent effluent standards on toxic pollutants which may cause an unreasonable risk.

C. Factors

1. Toxicity, persistence, degradability of pollutant, usual/potential importance of the affected organisms.

2. Extent to which effective control is being or may be achieved under other regulatory authority.

III. Oil and Hazardous Substance Liability (Section 311)

A. Threshold for Action

Present an immminent and substantial danger to the public health or welfare.

B. Risk Management Option

The President shall prohibit the intentional or unintentional discharge of oil or hazardous substances into navigable waters in such quanitites as may be determined to be harmful.

IV. Thermal Discharges (Sections 303 and 316)

A. Threshold for Action

Thermal discharge controls in permits are not stringent enough to assure the protection and propagation of a balanced indigenous population of shellfish, fish, and wildlife.

B. Risk Management Option

State shall identify waters with thermal discharge problems. Such designation will lead to thermal load allocations for sources discharging to these waters.

Cost-Benefit Analysis Requirement

Section 302 (Water Quality Relation Effluent Limitations) states:

> "Prior to the establishment of any effluent limitation...determine the relationship of the economic and social costs of achieving such limitation, to the social and economic benefits to be obtained..."

4. SAFE DRINKING WATER ACT

I. Public Water Systems (Section 1412)

A. Threshold for Action

May have any adverse effect on the health of persons.

B. Risk Management Option

Establish by rule recommended maximum contaminant levels.

C. Factors

Set at level at which no known or anticipated adverse effects occur and which allows an adequate margin of safety.

II. State Programs for Underground Injection Control (Section 1421)

A. Threshold for Action

Presence of contaminant from underground injection may adversely affect the health of persons.

B. Risk Management Option

Publish proposed regulations for State underground injection control programs.

C. Factors

1. Consider varying geographic, hydrological, or historical conditions in various States.

2. Avoid unnecessary disruption of State control programs.

3. Ensure protection of underground sources of drinking water.

III. Interim Regulation of Underground Injections (Section 1424)

A. Threshold for Action

Would create a significant hazard to public health.

B. Risk Management Option

Prohibit an area from operating new underground injection wells.

C. Factors

Sole or principal drinking water source for an area becomes contaminated.

IV. Emergency Powers (Section 1431)

A. Threshold for Action

May present an imminent and substantial endangerment to the health of persons.

B. Risk Management Option

1. Issue orders necessary to protect user's health.

2. Commence civil action for relief.

C. Factors

1. Presence of contaminant in or likelihood that it will enter a public water system.

2. Appropriate action has not been taken by State and local authorities.

Cost-Benefit Analysis Requirement

Section 1442(a)(3) authorizes the Administrator to "conduct studies on the costs of carrying out regulations prescribed under section 1412." These studies should analyze "anticipated costs of compliance with revised national primary drinking water regulations...methods of paying costs of compliance...advantages and disadvantages of each of the methods..."

5. RESOURCE CONSERVATION AND RECOVERY ACT

I. Identification and Listing of Hazardous Waste (Section 3001)

A. Threshold for Action

1. May cause or contribute to an increase in mortality or serious irreversible, or incapacitating reversible, illness; or

2. Pose a substantial present or potential hazard to human health and the environment.

B. Risk Management Option

The Administrator shall promulgate criteria for identifying and listing hazardous wastes.

C. Factors

Flammability, toxicity, corrosiveness, persistence.

II. Standards Applicable to Generators of Hazardous Wastes, Transporters, and Treatment, Storage, and Disposal Facilities (Sections 3002-3004)

A. Threshold for Action

May be necessary to protect human health and the environment.

B. Risk Management Option

The Administrator shall promulgate regulations establishing standards for solid wastes which may cause a risk when improperly treated, stored, transported, or disposed of.

C. Factors

1. Performance and design requirements (for treatment or storage).

2. Non-numerical health and environmental performance criteria (for land disposal).

Cost-Benefit Analysis Requirement

While the statute does not require a formal cost-benefit analysis, States are expected to analyze "economic feasibility of" and the "economic impediments to" the development of facilities and programs to conserve resources which contribute to the waste stream (section 4003(b)).

6. COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT

I. Designating Hazardous Substances and Reportable Quantities (Section 102)

A. Threshold for Action

May present substantial danger to the public health or welfare or the environment.

B. Risk Management Option

Administrator shall promulgate and revise regulations designating compounds, mixture, solutions, and substances as hazardous substances, and shall promulgate regulations establishng the quantity of any hazardous substance released.

II. Response Authorities (Section 104)

A. Threshold for Action

May present an imminent and substantial danger to the public health or welfare.

B. Risk Management Option

The President is authorized to remove or arrange for the removal of, and provide for remedial action of any hazardous substance, or take any other response measure consistent with the national contingency plan.

C. Factors

1. Release or substantial threat of release of any hazardous substance; or

2. Release or substantial threat of release of any pollutant or contaminant.

III. Abatement Action (Section 106)

A. Threshold for Action

May be an imminent and substantial endangerment to the public health or welfare or the environment.

B. Risk Management Option

The President may require the U.S. Attorney General to secure from the district court relief necessary to abate danger or threat.

C. Factors

Actual or threatened release of a hazardous substance from a facility.

Cost-Benefit Analysis Requirements

Section 104(c)(4):

"The President shall select appropriate remedial actions determined to be necessary to carry out this section...which provide for that cost-effective response which provides a balance between the need for protection of public health and welfare and the environment at the facility under consideration, and the availability of amounts from the Fund established under title II to respond to other sites which present or may present a threat..."

Section 105:

"The President shall revise and republish the national contingency plan for the removal of oil and hazardous substances...which shall include at the minimum:

(2) methods for evaluating, including analyses of relative costs, and remedying any release or threats of releases from facilities which pose substantial danger to the public health or the environment.

(7) means of assessing that remedial action measures are cost-effective over the period of potential exposure to the hazardous substance or contaminated materials."

7. FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

I. Registration of Pesticides (Section 3(c)(5)(C))

A. Threshold for Action

Unreasonable adverse effects on man or the environment.

B. Risk Management Option

The Administrator shall deny registration for a pesticide which poses an unreasonable risk.

C. Factors

Economic, social, and environmental costs and benefits.

II. Suspension (Section 6(c))

A. Threshold for Action

Poses an imminent hazard.

B. Risk Management Option

The Administrator may suspend registration of a pesticide immediately if continued use would be likely to result in unreasonable adverse effects on the environment.

C. Factors

Likelihood that serious harm will occur during pendency of the cancellation proceedings.

III. Packaging Standards (Section 25(c)(3))

A. Threshold for Action

To protect children and adults from serious injury or illness.

B. Risk Management Option

The Administrator shall establish standards with respect to the package, container, or wrapping in which a pesticide is enclosed for use or consumption if accidental ingestion or contact may result in serious injury or illness.

Cost-Benefit Analysis Requirement

While no formal cost-benefit analysis is required, the Administrator takes into account the "economic, social, and environmental costs and benefits of the use of any pesticide" in order to determine whether the pesticide poses an "unreasonable risk to man or the environment." (Section 3(bb)).

8. OCCUPATIONAL SAFETY AND HEALTH ACT

I. Safety and Health Standards (Section 6(b)(5))

A. Threshold for Action

Must protect health to the extent feasible.

B. Risk Management Option

The Secretary shall set standards dealing with toxic materials or harmful physical agents which most adequately assure that no employee will suffer material impairment of health or functional capacity.

C. Factors

1. Latest available scientific data

2. Feasibility of standards

3. Other health and safety laws

II. Emergency Temporary Standards (Section 6(c)(1))

A. Threshold for Action

Grave danger.

B. Risk Management Option

The Secretary shall provide for an emergency temporary standard to take immediate effect upon publication in the Federal Register.

C. Factors

1. Exposure to substance or agents determined to be toxic or physically harmful or from new hazards, and

2. Emergency standard is necessary to protect employees from such danger.

III. Inspection, Investigation, and Recordkeeping (Section 8(f)(1))

A. Threshold for Action

Threat of physical harm or imminent danger.

SL 102773

B. Risk Management Option

An employee or representative of employees may request an inspection.

C. Factors

1. Belief of existence of a violation of a safety or health standard, or

2. Belief of existence or a danger.

Cost-Benefit Analysis Requirement

As determined in American Petroleum Institute et al. v. OSHA, 581 F.2d 492 (1978):

> "[Section 6(b)(5) of the OSH Act] does not give OSHA the unbridled discretion to adopt standards designed to creat absolutely risk-free workplaces regardless of cost..." (at 502)

In AFL-CIO v. Marshall, 617 F.2d 636 (1979), the Court states:

> "OSHA agrees that a systematic evaluation of costs and benefits is to be encouraged within the limits of available estimation techniques, yet it contends that such analysis is not required...We agree." (at 663)

SL 102774

9. FEDERAL FOOD, DRUG, & COSMETIC ACT

Food

I. Emergency Permit Control (Section 344)

A. Threshold for Action

May be injurious to health.

B. Risk Management Option

Secretary shall promulgate regulations to issue temporary permits to manufacturers, processors, or packers governing the contaminated class of food.

C. Factors

1. Determination that distribution in interstate commerce of contaminated food may be injurious.

2. Injurious nature cannot be adequately determined after the food has entered interstate commerce.

II. Establishment of Tolerances (Section 346a.(b))

A. Threshold for Action

Necessary for protection of public health.

B. Risk Management Option

The Secretary shall promulgate regulations establishing tolerances with respect to the use of poisonous or deleterious pesticide chemicals.

C. Factors

1. Necessity for production of an adequate, wholesome, and economical food supply.

2. Other ways in which consumers may be affected by the poisonous or deleterious substance.

3. The opinion submitted with the certification of usefulness.

SI 102775

III. Food Additives (Delaney Clause) (Section 348(c))

A. Threshold for Action

Found to induce cancer when ingested by man or animal.

B. Risk Management Option

The Secretary shall not establish regulations prescribing the conditions of use for the additive.

C. Factors

Residue of additive is found in any edible portion of, or food yielded from, consuming animals.

Drugs and Devices

I. New Drugs (Section 355)

A. Threshold for Action

Imminent hazard to the public health.

B. Risk Management Option

The Secretary may suspend approval of an application for the introduction of a new drug into interstate commerce.

C. Factors

1. Safety of the drug for use under conditions of the application.

2. Evidence that the drug will not have the effect is purports to have.

3. Application contains any untrue statement of material fact.

II. New Animal Drugs (Section 360(b))

A. Threshold for Action

Imminent hazard to the health of man or animal.

B. Risk Management Option

The Secretary may suspend approval of an application of the introduction of a new animal drug.

C. Factors

1. Safety of the drug for use under the conditions of the application.

2. Evidence that the drug will not have the effect it purports to have.

3. Application contains any untrue statement of material fact.

Cost-Benefit Analysis Requirement

No formal requirement in this statute.

SL 102777

10. HAZARDOUS MATERIALS TRANSPORTATION ACT

I. Designation of Hazardous Materials (Section 1803)

A. Threshold for Action

May pose an unreasonable risk to health and safety or property.

B. Risk Management Option

The Secretary shall designate a quantity and form of material or group or class of materials as hazardous upon finding that the transportation in commerce may pose a risk.

II. Imminent Hazard (Section 1810(b))

A. Threshold for Action

Imminent hazard.

B. Risk Management Option

The Secretary may petition the appropriate district court for an order suspending or restricting the transportation of a hazardous material if he has reason to believe a hazard exists.

C. Factors

Substantial likelihood that serious harm will occur prior to completion of a formal proceeding to abate the risk.

Cost-Benefit Analysis Requirement

No formal requirement in this statute.

SL 102778