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IMPACT OF GOVERNMENT REGULATION ON THE DEVELOPMENT OF CHEMICAL PESTICIDES FOR AGRICULTURE AND FORESTRY

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January 1981

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FOREWORD

As the Nation enters a period of increasing financial stress, due in part to government actions, including those taken by regulatory agencies, members of the public are becoming increasingly aware that the cost-benefit concept has application to government regulations. Regulations have benefits, but they also have costs. Through education regarding such matters, society will be enabled to adopt a position in which the benefits are well in excess of the costs.

Because of a desire to increase the general level of understanding regarding the impacts of government regulations on the development of agricultural chemicals, the executive committee of the Council for Agricultural Science and Technology (CAST) authorized the distribution of a mail ballot to members of the board of directors in November 1978 to determine whether a task force should be established to prepare a report dealing with the impacts. The board approved, and the task force was promptly established. The task force included expertise in agricultural economics, agronomy, animal science, dairy science, entomology, meat science, nematology, plant pathology, poultry science, range management, sociology, soil science, toxicology, and weed science.

This report, the second of two prepared by the task force, deals primarily with regulation of chemical pesticides for agriculture and forestry. The first, dealing with animal drugs and nutritional supplements and to a minor extent with pesticides used in animal production, was issued as Report No. 85 in October 1980.

The first draft of this report was reviewed by a subcommittee of the task force at a special meeting, and a revised version was sent to the headquarters office for editing. Editing was done by Dr. L. L. Danielson with assistance from the headquarters office, and the edited version was returned to the task force and the CAST executive committee for review and comment. Two more revised versions were then returned to the task force, and one was sent to the CAST editorial review committee for further comments before the final version was reproduced for publication.

On behalf of CAST, I thank members of the task force, the editorial review committee, and all the others who gave of their time and talents to prepare this report as a contribution of the scientific community to public understanding. Thanks are due also to the employers of task force members who made the time of their employees available at no cost to CAST. And finally, thanks are due to members of CAST. The unrestricted contributions they have made in support of the work of CAST have financed the report.

This report is being distributed to members of Congress, officials in the U.S. Department of Agriculture and the Environmental Protection Agency, the media, and institutional members of CAST. Individual members may receive a copy on request.

Charles A. Black
Executive Vice President
Council for Agricultural
Science and Technology

PREFACE

This is a report of the Task Force on the Impact of Government Regulation on the Development of Agricultural Chemicals. The Task Force has organized and focused its efforts in two areas: (a) chemicals used in animal production and (b) chemical pesticides for agriculture and forestry. The Task Force decided fairly early in its deliberations not to consider fertilizers.

This report has been prepared by the Task Force Subcommittee on Chemical Pesticides for Agriculture and Forestry. It has been read and approved by the membership of the entire Task Force.

The Task Force held meetings on January 29 and 30, 1979, in Washington, D.C., and on April 17 and 18, 1979, in Atlanta. The two subcommittees each held additional meetings to discuss and revise their findings. The Task Force held discussions with staff members of the Food and Drug Administration (Bureau of Foods and Bureau of Veterinary Medicine), the Environmental Protection Agency, the USDA Food Safety and Quality Service, the National Agricultural Chemicals Association, the American Feed Manufacturers Association, the Animal Health Institute, the Fertilizer Institute, and the Environmental Defense Fund. Consultations were held with individual government, industry, and university scientists by individual Task Force members. The Task Force has appreciated the interest and cooperation of the representatives of government, industry, public-interest groups, and individual scientists who have made the report of the Task Force possible. Any errors or misinterpretations of the information incorporated in this report are, however, the Task Force's own responsibility.

The Subcommittee on Chemical Pesticides for Agriculture and Forestry included Eldon I. Zehr (Chairman), Samuel R. Aldrich, Thomas Allen, Arnold P. Appleby, Gerald A. Carlson, Don A. Dillman, David A. Graham, Ronald J. Kuhr, John D. Radewald, and Robert J. Weir. The Subcommittee on Chemicals for Animal Production included Charles A. Lassiter (Chairman), Gerald A. Carlson, Edward C. Naber, Albert M. Pearson, Duane E. Ullrey, and Robert J. Weir.

Vernon W. Ruttan
Task Force Chairman

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SUMMARY

Cultural practices and biological techniques, including development of new plant varieties, are useful in controlling many pests and diseases of plants. These alternatives, however, are not always available, effective, or practical. Chemical pesticides are needed to maintain consistent control of plant pests and diseases when other methods are not appropriate. In recent years, the use of chemical pesticides has been subject to increasingly stringent regulations designed to protect the health of consumers and producers and to limit undesirable environmental impacts. This report examines the impacts of government regulation on the development of chemical pesticides for agricultural and forest uses.

Government regulation has created lengthy delays in registering and reregistering chemical pesticides. Moreover, it has caused sharply higher costs of developing new chemical pesticides and of defending chemical pesticides now marketed. These increased costs are passed on to users, including farmers, foresters, home gardeners, and industrial firms, and in the end lead to higher costs of food, fiber, ornamentals, and lumber to consumers.

The chemical industry has responded to increased stringency of regulation by hiring more employees and completing the additional testing required for registration. There is little evidence that government regulation is causing firms to abandon pesticide research and development in favor of more lucrative investments; in fact, pesticide chemical research and development expanded in real terms each year from 1967 through 1978. Chemical pesticides continues to be a growth industry. However, the percentage of funds allocated for synthesis, screening, and field development of new materials has decreased, while more funds have been spent meeting registration requirements.

The number of new compounds registered annually for commercial uses declined after responsibility for registration was transferred to the Environmental Protection Agency in 1970, and several years after the Federal Environmental Pesticide Control Act was enacted in 1972. Administrative difficulties encountered in registering new compounds are a continuing source of frustration for manufacturers and distributors of chemical pesticides as well as for researchers. Recent developments suggest that some of the problems associated with pesticide regulation are being resolved.

Shifts in emphasis of research and development in pesticides are a source of concern. As costs have risen, manufacturers have shifted their efforts toward major crops and major uses, with the result that chemicals having a broad spectrum of pesticide activity have been emphasized at the expense of chemicals that are more specific in their activity. This shift could be harmful to beneficial organisms and may affect the progress and development of integrated pest management, in which chemicals of specific activity are needed to avoid harm to beneficial organisms that contribute to control of the pests.

The outlook for biological control of plant pests improved substantially after certain important biological control agents were exempted from most pesticide registration requirements. Current regulations favor the development of biological control agents, except for certain chemicals of biological origin which remain subject to pesticide registration requirements. Since many of these, such as sex attractants, are of a highly specific nature, registration costs may be prohibitive. However, more lenient registration requirements now being developed may alleviate many of the problems in biological control.

Provisions of the Federal Pesticide Act of 1978 seem adequate to address the needs of pest management and biological control. Enlightened cooperation among federal regulatory agencies, university research and extension agencies, state and local governments, and manufacturers, distributors, and users of chemical pesticides could overcome the problems of minor uses and the need for pesticides with a limited toxicological spectrum.

Actions of regulatory agencies have not always contributed to their objective of reduced pesticide use. Sometimes chemicals removed from the market as a result of regulatory action have been replaced with chemicals that must be used in greater volume or more frequently or with greater hazard to achieve equivalent pest control. In some instances, government agencies appear not to have considered all the factual evidence before regulatory decisions were made. These incidents are unfortunate because they are not in the public interest, and they undermine confidence in the credibility of both the regulatory agencies and the pesticide industry to deal with problems of pesticide use in fairness to all parties concerned.

An important indirect cost of chemical pesticide regulation is the diversion of university and USDA scientists from innovative research and extension education. Personnel and funds diverted from agricultural research and extension are important long-range costs because returns to society from agricultural research and extension traditionally have been among the best of long-term public investments.

INTRODUCTION

Prior to the mid-1920s, technical progress in American agriculture was directed primarily to the achievement of increases in output per worker through advances in mechanical technology. During the last half century, advances in mechanical technology have been complemented by new biological and chemical technologies directed to improving the quality and increasing the output per unit of land area at reduced cost per unit of output.

Since the early 1960s, there has been heightened concern about the effect of the new technologies or innovations on the health and safety of agricultural producers and consumers and on the quality of the products and the environment. The result has been the emergence of a series of institutional changes represented by new laws and regulations designed to achieve more effective social control over the development and use of the innovations.

Both the drive for *technical innovation* leading to increased productivity of plants and animals and the drive for *institutional innovation* resulting in constraints on the development and use of the new technologies have been generated by powerful economic and social forces. Increasing scarcity of land and water resources, reflected in rising agricultural land values and rising costs of land improvement, is continuing to create a strong need for yield-increasing technologies in agriculture — for higher output per acre. The rising value that society is placing on health and environmental quality has led to a demand for more effective social controls over the development and use of new technologies.

This report attempts to assess the impact of the new regulatory regimes that have emerged over the last decade on innovation in chemical pesticides for agricultural and forest uses. This is only a small part of the broader issues referred to in the preceding paragraphs. The report is dedicated, however, to the proposition that it is in the interests of society to develop and use the potential opened up by advances in the application of new technologies to agricultural production as well as to manage this potential. Ideally, the societal payoff of advances in agricultural productivity, the health and safety of agricultural producers and consumers, and the quality of the environment will all be valued realistically as laws and regulations are developed.

Americans have been favored with an abundance and a wide variety of foods, and, as a consequence, the productivity of American agriculture is generally taken for granted. Part of the success of the American food production system stems from the natural fertility of many of the soils and from the ability of American farmers to produce large quantities of food with relatively little labor input. But even the most fertile soil must be protected from erosion and in time must be replenished with nutrients. Mechanized farming depends upon abundant and economical sources of energy. Farming efficiency has increased with size and specialization. But concentrated and continuous production of a single crop increases the potential for outbreaks of insects, weeds, disease organisms, and other pests. To support crop production and marketing activities, a strong agribusiness enterprise is necessary to provide equipment, seeds, fertilizers, pesticides, fuel, markets, and transportation. The results of agricultural research must be applied to sustain and increase the output of food, fiber, ornamentals, and lumber.

Production of crops and forest products is but one example of the interdependency among the several sectors of the American economy. Actions that affect one small segment often may have an impact on the whole of American society. Thus, chemical pesticides constitute only a small fraction of the total agricultural and forest products enterprise even though the annual business is valued in excess of $3 billion (National Agricultural Chemicals Association, 1978). However, disruption of the supply of these chemicals without suitable replacement would impact severely on the total supply of agricultural and forest products, and even more so on the stability of the outputs.

Stability of production is a quality that often is overlooked. The security and welfare of all nations is heavily dependent upon the assurance of a steady, reliable source of food. Threats of pests and diseases constitute one of the most destabilizing influences on crop production worldwide. Pest control practices, including pesticides, are very important for assurance of year-to-year stability of production (Carlson, 1979).

In the following discussion, the focus is primarily on the impact of government regulation on the development of chemical pesticides for agricultural and forest uses. Government regulation has important influences on commercial fertilizers as well, but the regulatory environment is so different that pesticides and fertilizers need to be considered separately.

Four major groups of chemicals other than fertilizers are used in production of crops and forest products: insecticides, herbicides, growth regulators, and chemicals for disease control which include fungicides, nematicides, and bactericides. Some of these chemicals are effective on more than one type of pest; e.g., some fungicides may also have nematicidal properties. In addition, predacides, rodenticides, piscicides, defoliants, and desiccants contribute significantly in some instances.

Insecticides are important for a steady supply of farm products year after year. They have helped to avoid frequent catastrophic losses of crops to plagues of insects. Together with similar methods for avoiding losses due to diseases, insecticides have enabled commercial production of fruits and vegetables on a much larger scale than was possible only a few decades ago. Sometimes insecticides have been used when they were not required, and some have been injurious to natural parasites and predators. Sometimes crop production has relied too heavily on the use of insecticides. Recent concepts of integrated pest management have the potential to reduce the scale and indiscriminant use of, but not the need for, insecticides.

Widespread use of herbicides is a more recent innovation than the use of insecticides. Herbicides, used to kill weeds, have become the most widely used pesticides in agriculture for several reasons. First, weed control with herbicides often is superior to that obtained by mechanical means alone, reducing competition of weeds for moisture and nutrients, and thus increasing crop yields. Second, fewer trips through fields are necessary, less labor is required, and savings in fuel and deterioration of equipment result. Third, herbicides do not physically disturb the soil, and they may be used in systems that leave residues of plant debris on the soil surface; thus they contribute to reduced water and wind erosion. And fourth, appropriate herbicides do not injure roots of crop plants as does cultivation; consequently, crop yields may increase.

Growth regulators have fewer general uses in agriculture, but are nonetheless important. Growth regulators may save much hand labor, as in removing excessive numbers of fruits on fruit trees. They are also used to adjust maturity dates of plants, and to help provide a uniform supply of produce for processing. Some are used as defoliants or desiccants to improve harvesting efficiency and quality of harvested products.

Chemical pesticides often are used to help control plant diseases and nematodes. Plants are especially vulnerable to diseases when grown together in large concentrations, as was evident in the potato famine in Ireland and other European countries in the 1840s, and more recently in the southern corn leaf blight epidemic in the United States. One basic feature of American agriculture is a high concentration of a single variety of plants in the limited geographic area to which it is best suited. Foods from these plants often must travel long distances to the consumer. Some require protectant chemicals as well as controlled environments to reduce spoilage in transit and during storage to assure adequate supplies throughout the year. An effective and diverse supply of chemical pesticides is needed to contain threatening plant diseases that might otherwise devastate American crops. Chemical pesticides are the principal means for effective control of certain plant diseases — notably those of fruits and vegetables — when plants are grown together in large concentrations.

One of the major reasons that new pesticide compounds are needed is that, in time, existing pesticides may lose their effectiveness. Resistance to most types of insecticides, to some kinds of miticides and fungicides, and possibly to certain nematicides has developed in some pest species in the past 20 years [see Brown (1971) and Ogawa et al. (1977) for a listing of resistant pest species, and Carlson (1977) for evidence on the effect of insect resistance on the demand for substitute insecticides]. There is also growing recognition of the effect of herbicides on selection of weed species which are more difficult to manage. Although such biological depletions can be limited by judicious use of current pesticides, new compounds must be developed continually to maintain effective means of pest control.

Numerous laws and regulations have been implemented to protect workers, consumers, and the environment from adverse effects of pesticides. These laws and regulations were necessary because many hazardous materials were being produced, distributed, and used without adequate investigation of their effects on human health and safety and on the environment. The primary purpose of the legislation was to correct such abuses. Now that safeguards have been implemented, perhaps it is time to evaluate their long-term effects.

Research and development are essential for improvement of chemical pesticides and their uses in agriculture and forestry. Agricultural research in the United States and worldwide has a high rate of return in increasing the output of food and fiber (Evenson et al., 1979; Nuckton, 1979). Chemical pesticides rendered ineffective through resistance mechanisms will need to be replaced. Through research, safer products can be developed. Chemical pesticides can be applied more efficiently and effectively, and they can be made more specific so that beneficial organisms are not harmed. Their persistence and threats to components of the environment can be reduced. More effective control of target pests can be obtained. Much of this research and development must be done by private industry cooperating with public and private research centers and with the federal and state governments. Does the present atmosphere encourage or hinder progress toward safer, more effective chemicals? What are the consequences of current government regulatory activities? What is the outlook for pesticides in the near future? We explore answers to these and other questions in the following pages.

Information on the impacts of government regulation on development of chemical pesticides for agriculture and forestry is sketchy and fragmented. Often it is based on conjecture, projection of short-term information to long-term trends, and on facts that can be interpreted several ways depending on the viewer's overall perspective. We attempted to overcome these problems by consulting with representatives of the chemical pesticide industry, the Environmental Protection Agency, the Environmental Defense Fund, and the Food and Drug Administration, and with respected colleagues in the scientific community. For published information we have relied heavily on reports published by the National Agricultural Chemicals Association and the Environmental Protection Agency. We also studied reports published by the National Academy of Sciences (1975), the National Research Council (1975, 1978), and a study report on the use of chemicals to control plant diseases prepared by the American Phytopathological Society (1979) for the Environmental Protection Agency, a report on research needs on pesticides (Glass, 1976), and newspaper and magazine articles. Finally, we have drawn on the expertise of our own committee members who, as research or extension specialists, are familiar with the problems of developing and registering new chemical pesticides for agricultural and forest uses.

IMPORTANT LEGISLATION DEALING WITH PESTICIDES

A number of important laws enacted since the Federal Food and Drug Act of 1906 regulate the manufacture, distribution, and use of pesticides. The federal laws most directly regulating pesticides are summarized in the Appendix. Additionally, a host of state laws regulates the use of pesticides in the various states. Most of these address certain state and local needs, and some (such as those regulating pesticide applicator registration) are mandated by federal legislation. Stringency of legislation generally has increased with time, especially during the last 10 to 15 years. The burden of proof of safety has shifted from government agencies to the manufacturers and distributors of pesticides. The formation of the Environmental Protection Agency in 1970, and important federal environmental legislation and regulations since that time have enormously increased the cost and complexity of pesticide registration. However, the Federal Pesticide Act of 1978 was an important step in recognition of problems of minor crop uses, conditional pesticide registration, and simplification of registration procedures. These provisions appeared to provide reassurance that government agencies would cooperate in expediting pesticide registration.

DECLINING PRODUCTIVITY OF RESEARCH AND DEVELOPMENT IN THE CHEMICAL PESTICIDE INDUSTRY[1]

Research and development (R&D) expenditures by the U.S. chemical pesticide industry have been expanding in real terms for the past 12 years. Although many new compounds were registered for use in this period, the numbers of new compounds and new uses of existing compounds registered have declined in recent years. In this section we examine data on R&D expenditures to determine whether pesticide innovation also has declined in recent years and, if so, to seek out the explanations for these changes.

[1]See also a publication by Eichers (1980).

Pesticide Research and Development Data

The pesticide industry is a small part of the U.S. chemical industry, and much of its R&D is conducted by divisions of large, diversified chemical and petroleum companies. Therefore, special data from these divisions are needed. This information is available primarily through the National Agricultural Chemicals Association (NACA), an association of pesticide firms. Some information is available from the Environmental Protection Agency. These sources were used in our assessment.

Past expenditures for R&D obtained from NACA surveys of its member companies are given in Table 1, column 2, in 1972 dollars. R&D has been expanding steadily, as shown in column 3 of this table. Although trends are difficult to identify over such a short period of time, growth of R&D is more rapid in the most recent (15.7 percent for 1976-1978) than in the earliest period (4.9 percent for 1967-1969).

As shown in column 4, Table 1, the dollar value of chemical pesticide sales rose rapidly in the early 1970s, and has risen each year since 1967. The increase reflects price increases, expansion of U.S. agricultural crop acreage, and intensification of pest control activities. Clearly, the market for registered chemical pesticides has been expanding rapidly, and this is one of the main incentives for R&D investments. Available information is insufficient to analyze the sales of new versus older compounds during this period.

The overall level of R&D activity as a percentage of sales is much higher for pesticides than the 2 to 3 percent average for U.S. industry in general (Mansfield, 1968). Although the ratio of R&D expenditures to total sales (Table 1, column 5) is influenced by the long time lags between R&D investments and prospective sales, it seems clear that the ratio of R&D expenditures to sales has been maintained.

R&D expenditures increased in real terms (Table 1), but types of expenditures changed from 1967 through 1978 (Table 2).[2] The percentage of the total R&D investment spent for synthesis, screening, and field testing decreased, while the percentage spent for registration, administration, residue analysis, and environmental testing rose dramatically in recent years. However, funds spent for synthesis and screening also rose in real terms. Although the number of compounds screened for pesticide activity rose between 1967 and 1978, the number of compounds screened per employee declined (Column 4, Table 3).

The proportion of R&D funds spent to support and continue registration of commercial products increased from 13 percent in 1967 to 23 percent in 1970, but declined to 10 percent by 1978 (Column 5, Table 3). Expanding registrations for old products and development of new products consumed an average of 23 and 63 percent of R&D expenditures in recent years, while about 14 percent of expenditures were for continuing registration of compounds in commercial use (National Agricultural Chemicals Association, 1978).

The final two sets of general information are on the amount of time required to register compounds, and annual numbers of new compounds and new use registrations. Both EPA and NACA were able to provide information on these items. Before examining this information one must have some measures of R&D productivity.

Table 1. U.S. agricultural research and development expenditures for chemical pesticides for agriculture and forestry based on annual surveys of the National Agricultural Chemicals Association member companies (National Agricultural Chemicals Association, 1978)

Year	Total R&D (mil. $) (1)	Deflated R&D[a] (mil. $) (2)	Growth in R&D (%) (3)	Total chemical pesticide sales[b] (mil. $) (4)	Total R&D ÷ total sales[c] (5)	No. of companies (6)
1967	52.4	66.3		639	8.2	33
1968	56.2	68.1	2.7	691	8.1	33
1969	65.2	75.2	10.4	692	9.4	33
1970	69.9	76.4	1.6	722	9.7	33
1971	87.7	91.4	19.6	1044	8.4	36
1972	98.5	98.5	7.7	1154	8.5	36
1973	110.7	104.5	6.1	1417	7.8	36
1974	134.8	115.8	10.8	1956	6.9	37
1975	160.5	126.1	8.9	2471	6.7	37
1976	219.7	164.1	30.1	2657	7.9	37
1977	250.1	177.0	7.9	3115	8.1	37
1978	289.6	193.3	9.2	3607	8.1	36

[a]Deflated by the 1972 GNP deflator.

[b]Total chemical pesticide sales include foreign and domestic sales and domestic sales from foreign production.

[c]Based only on those companies providing information on total research and development and total sales. This column may not agree with column 1 ÷ column 4.

Measures of Research and Development Productivity

Productivity of R&D may be measured in several different ways. An important factor in the evaluation is the comparatively long time required to register and develop new chemicals. Bailey (1972) and Grabowski et al. (1978) used new discoveries registered in year "t" divided by average R&D expenditures 4 to 6 years earlier in their economic analyses of the pharmaceutical industry. The number of employees per new product or new use registration, with appropriate time lags, may also be used as a measurement.

In Table 4, four measures of pesticide R&D productivity are given. The first two are expenditures for R&D per new chemical pesticide entity registered based on expenditures that occurred 4 to 6 years earlier. The NACA and EPA information on registered new compounds (Table 5, columns 5 and 6) is used. The third measure is the number of professional R&D employees per new compound, and the fourth is R&D expenditures per new-use registration. Each of the four productivity measures shows 3 years of fairly stable

[2]Data from NACA surveys are difficult to compare over a period of years. Where known, changes in definitions are noted in footnotes of Tables 1 and 2. However, this information seems to be more complete than that used elsewhere (Lee and Aspelin, 1978; Arthur D. Little, 1975).

Table 2. Percentages of research and development expenditures allocated according to function by American manufacturers of chemical pesticides for agriculture and forestry[a]

Year	Synthesis and screening (1)	Field testing and development[b] (2)	Toxicology and metabolism[c] (3)	Formulation and process development (4)	Registration and administration[d] (5)	Environmental testing and residue analysis[e] (6)
1967	34	30	13	17	5	1
1968	34	31	12	18	5	0
1969	33	31	12	19	5	0
1970	31	32	13	18	6	0
1971	29	33	12	18	5	3
1972	27	34	13	17	5	4
1973	25	34	14	17	5	5
1974	23	29	13	20	11	4
1975	22	29	13	21	10	5
1976	19	23	11	20	11	16
1977	21	20	13	20	10	16
1978	22	20	13	21	9	15

[a]From NACA industry surveys of 33 to 38 companies, 1967 through 1978 (National Agricultural Chemicals Association, 1978).

[b]Does not include residue analysis.

[c]Includes environmental and wildlife toxicology in 1976 through 1978.

[d]Registration only until 1974; administrative costs were included in 1974 and thereafter.

[e]Primarily environmental testing after 1970, and environmental testing and residue analysis in 1976 through 1978. Residue analysis was explicitly listed as a category only in 1976 through 1978. If it existed prior to this time, it may have been distributed among various categories.

Table 3. Professional employees of U.S. manufacturers of chemical pesticides for agriculture and forestry as related to compounds screened and maintenance of pesticide registration[a]

Year	Number of companies (1)	Total prof. employees[b] (2)	Thousands of compounds screened (3)	No. of compounds screened/employee (4)	Percent of R&D for registration maintenance[e] (5)
1967	33	2127	60	28.2	13
1968	33	2234	59	26.4	15
1969	33	2383	61	25.5	18
1970	33	2394	63	26.3	23
1971	36	2504	-[d]	-	17
1972	36	2661	-[d]	-	17
1973	36	2866	-[d]	-	17
1974	37	4191	71	16.9	14
1975	36	4421	85	19.2	13
1976	38	5247	93	17.1	13
1977	38	5120	91	17.1	12
1978	36	5088	84	16.5	10

[a]From NACA industry surveys of 33 to 38 companies, 1967 through 1978 (National Agricultural Chemicals Association, 1978).

[b]After 1973 the figure includes employees at non-U.S. locations.

[c]Companies were asked what percent of their R&D expenditures was for maintenance of registration of existing products.

[d]Not available.

Table 4. Productivity measures for research and development for U.S. manufacturers of chemical pesticides for agriculture and forestry, 1973-1978

Year	R&D expenditure per new chemical pesticide entity[a] NACA (mil. $) (1)	EPA[b] (mil. $) (2)	R&D employee years per new chemical pesticide entity (EPA)[b] (3)	R&D expenditures per new-use registration (EPA)[bc] (thousand $) (4)
1973	9.98	9.98	321.1	18.47
1974	9.15	9.15	292.1	26.12
1975	8.10	8.10	242.7	28.42
1976	22.19	12.68	358.9	46.11
1977	32.71	49.01	1338.5	134.24
1978	53.13	35.42	1079.7	236.16

[a]Based on the deflated R&D expenditures of column 2, Table 1. R&D expenditures are average values for 4 to 6 years earlier. The numbers of new chemical pesticide entities are from columns 5 and 6 in Table 5. The number of new chemical pesticide entities assumed for 1973 in column 1 is 7, the same as the number (from column 6 in Table 5) used in calculating column 2.

[b]EPA values for new chemical pesticide entities were corrected for the reporting period as indicated in footnote *c*, Table 5. EPA data were derived from the National Academy of Sciences (1975), President's Science Advisory Committee, Panel on Chemicals and Health (1973), and Aspelin (1979).

[c]EPA new-use registrations were adjusted for the fiscal year time change.

Table 5. Time required for registration, and number of new registrations of chemical pesticides for agriculture and forestry, 1967-1978[a]

Year	Registration time for new products, NACA data: Submission to approval (months) (1)	Discovery to market (months) (2)	Registration time for new products and new uses, EPA data: Total time (months) (3)	Agency review (months) (4)	New chemical pesticide entities: NACA (number) (5)	EPA[e] (number) (6)	New-use registrations (EPA)[e] (number) (7)
1967	7[b]	60[b]			8	9	
1968					12	9	
1969	18[c]	70[c]			10	9	3,437
1970	11	77			11	3	1,029
1971						1	1,662
1972						7	3,077
1973	22	80				7	3,784
1974	18	97	9	3.2	8	8[d]	2,804
1975	14	93			10	10[d]	2,850
1976	14	74			4	7	1,925[d]
1977	29	110	19	7.2	3	2	730[d]
1978	32	69			2	3	450

[a]National Agricultural Chemicals Association (NACA) (1978) data are from industry surveys of 33 to 38 companies. EPA data are from President's Science Advisory Committee, Panel on Chemicals and Health (1973), National Academy of Sciences (1975), and Aspelin (1979).

[b]Average for 1963 through 1967.

[c]Average for 1967 through 1971.

[d]Figures listed are adjusted for change in reporting time.

[e]Fiscal year accounting.

output and then a rapid increase in expenditures per unit of discovery and registration. Expenditures and employees per new discovery actually fell in the mid-1970s before rising rapidly. The decline in R&D productivity for new compounds is observed in only the last 3 years. Because the numbers are very large, it appears certain that pesticide R&D productivity has declined rapidly in terms of both new compounds and new formulations or new uses of existing compounds.

There is some indication that the 1978 amendments to FIFRA which allow "conditional pesticide registrations" may have reversed the recent downward trend in registrations. Preliminary indications are that six or seven compounds were registered by EPA in calendar year 1979. If this estimate is correct, productivity for 1979 would be expected to improve according to the EPA figures (Table 5) and assumed rates of R&D expansion.

Alternative Explanations of the Productivity Decline

Several possible reasons are given in other studies for declines in chemical R&D effectiveness. Among those relevant to pesticides are: (a) measurement problems, (b) depletion of the stock of potentially discoverable pesticide compounds, (c) reduced demand for chemical pesticides, and (d) increased stringency of government regulations. These explanations will be examined in turn to see if items *a* through *c* explain the declines observed in Table 4. Finally, various measures of government regulatory stringency will be compared with the numbers of new pesticides discovered and registered for use in recent years.

Measurement Problems

One important measurement problem is how to determine which new compounds are agricultural and forest pesticides. Different definitions lead to different numbers of registrations. The EPA figures for new chemical pesticide entities registered from 1967 through 1974, as given by the National Academy of Sciences (1975), differ from data published by the NACA (Table 5). Another type of measurement problem is that the number of new compounds registered by EPA may not be an adequate measure of R&D output in that the number may not reflect the spectrum of pesticidal activity or the potential sales. Conceivably, a given registration may have a much more significant impact on sales volume and pest control than most products registered previously. This may be true also for new use registrations. EPA, industry, and pest-management researchers agree that only major-pest, major-crop registrations are being sought at present. Because new registrations require very large inputs of time and expense, more and more crops are being added to the so-called "minor-use" category (pesticides for use on minor crops or for minor uses on major crops).

New, potentially useful processes and development also may be discovered, which are not measured by numbers of products registered. Additionally, new uses for pesticides frequently are found after a pesticide is registered, but registration for these new uses is not pursued because the return would be too small. The Federal Pesticide Act of 1978 provides for use of a registered product to control a pest not specified on the label, but such additional uses cannot be recommended by extension personnel or farm advisers under current regulations.

Depletion

The depletion explanation for declining R&D productivity is that, as the search process proceeds, discovery of new pesticides becomes more difficult. This process was found to be a significant factor in declining returns to pharmaceutical R&D in both the United States (Bailey, 1972) and Great Britain (Grabowski et al., 1978).

Discovery and registration of new pesticides appear not to be declining worldwide. Although little information is available on registration of pesticides in foreign countries, *Farm Chemicals* magazine (Anonymous, 1978) surveyed "leading producers from the U.S., Europe and Japan." In 1976 and 1977, seven new agricultural compounds were registered in the United States, but 19 new compounds were registered in other countries. *Farm Chemicals* reported also that foreign companies screened approximately 5400 compounds per company, while U.S. companies screened an average of about 3000 compounds per company in recent years. Moreover, in comparison with pesticide firms in the United States, foreign companies appear to be devoting a larger share of R&D expenditures to product expansion and maintenance of existing products than for new product development. Of approximately 180 commercial herbicides available in the world, at least 30 are not registered for use in the United States according to our information.

According to the preceding evidence, depletion of the stock of potentially beneficial compounds does not seem to be a major hindrance to R&D productivity. More research is needed to document the timing of discovery, commercial importance, and degree of duplication of compounds used in foreign countries compared with pesticides registered in the United States. However, the threat that other nations may surpass the United States in developing new agricultural chemicals looms larger as regulation becomes relatively more stringent in the United States.

Demand for Pesticides

In general, U.S. pesticide sales seem to be expanding (see Table 1, column 4). As an EPA report states (Lee and Aspelin, 1978): "The U.S. pesticide producing industry is a growth industry based on the past record, and is expected to be in the future as well." The number of firms registered for the first time with EPA as a pesticide manufacturer remained steady in recent years. Values of agricultural and forest products to be protected are increasing. A statistical analysis of the data in Table 1 suggests that pesticide firms expand R&D investment following years of high pesticide sales. Each of these factors indicates a steady or growing demand for pesticides and pesticide investments. However, the growth in demand does not preclude the possibility that regulation or one of the other factors has slowed pesticide innovation from a given level of R&D. Also, investments in R&D might have been higher with less regulation.

Regulatory Stringency

The effect of regulatory stringency can be examined in several ways. As a measure of regulatory stringency in the pharmaceutical industry, Bailey (1972) used the coincidence of the timing of legislative changes with productivity declines, while Grabowski et al. (1978) used the months of delay from new drug submission to approval. Delay time is especially important to R&D rate-of-return computations. Regulatory impact may be measured also by levels of R&D expenditures and shifts among functions and types of products (Table 2).

As indicated elsewhere, major changes in pesticide legislation and registration occurred in 1947, 1970, 1972, and 1978. EPA assumed the registration responsibility in 1970, and changes in FIFRA were made in 1972 and 1978. We examine here the R&D expenditures and registration responses for 1971, 1973, and 1979 for evidence of effects of the changes that occurred in 1970, 1972, and 1978. Other effects of the changes in legislation and regulation might not surface for years but would be difficult to isolate because of the possible influence of other factors on investment.

The numbers of registrations of new chemical pesticide entities and of new uses seem to have decreased substantially following the movement of registrations from USDA to EPA in 1970 and 1971 (Columns 6 and 7, Table 5). Following the 1972 amendments that required reregistration of all pesticides there was an increase in new-use registrations. Preliminary indications are that the 1978 amendments may have helped to increase new-entity registrations during 1979.

Industry R&D investment response to pesticide legislation is mixed. The year 1970 was a period of very low investment, but in 1971 R&D investment expanded at the highest rate during the 1967 to 1975 period (Table 1). In 1973, following the 1972 FIFRA amendments, R&D expansion was the smallest since 1970, but the slow-down was temporary.

Perhaps a more direct measure of EPA regulatory stringency is the time required for pesticide registration approval (Table 5). EPA and NACA data are divergent, in part because EPA figures show registration times for new products and registered new uses, whereas NACA data include only new products. There is much year-to-year variation in these delay times. However, for the past 12 years the trend is to longer periods of time for all phases of testing and approval. EPA sources (Lee and Aspelin, 1978) indicate that in 1977 only about 7 of 19 months required for registration (Table 5) involved agency review time, but this claim is disputed by industry sources (National Agricultural Chemicals Association, 1978).

The delay time involved under alternative regulatory schemes is uncertain. The reduced efficacy testing requirements of the 1978 amendments to FIFRA probably will not reduce efficacy testing needed for company investment decisions. Delay times and levels of pesticide industry R&D expenditures the following year are difficult to interpret. Funds spent to generate additional data required for registration might be offset in part by less investment in the search for new compounds. Clearly, the increased delay times in 1977 and 1978 are concurrent with the greatest R&D expenditures per unit of output as shown in Table 4.

The final indication of regulatory impacts on R&D expenditures is the shift in uses of R&D funds. In the functional division of expenditures for the NACA member companies (Table 2), the most striking feature is the decline through time of the share of funds devoted to innovative or discovery activities. Synthesis, screening, and field testing (Columns 1 and 2) show a sizeable decline from about 65 percent of R&D expenditures in the late 1960s to about 42 percent in the late 1970s. There has been a slight increase in expenditures for formulation and process development. The most sizeable expenditure gains are in registration and administration, environmental testing, and residue analysis. The combined total was 6 percent or less prior to 1971 and 24 to 27 percent since 1975. This increase can be attributed to a combination of increased public concern and increased stringency of the regulatory regimes.

Some pesticide R&D expenditures are difficult to categorize. In recent years, new categories such as residue analysis, environmental chemistry, and other expenditures have claimed an increasing share of expenditures. Regulations and additional testing requirements contributed to the expansion of expenditures in this area (Lee and Aspelin, 1978, p. 34). Part of the increase in testing costs is due to the recent rapid increase in cost of laboratory animal studies. Private laboratory estimates of per-test costs have risen about seven-fold in the 1973 to 1979 period, largely because salaries of pathologists and toxicologists increased 25 to 40 percent in 2 to 3 years, and laboratory practices have become substantially more complex (for example, more tissues must be examined). EPA (Johnson, 1978) estimates the average cost of a chronic feeding study to be $150,000. A 1978 private laboratory estimate is $150,000 for a mouse test and $230,000 for a rat test

(Ruttan et al., 1980).

Under FIFRA, EPA is responsible for putting its data requirements for registration in written form. Guidelines for registering pesticides were proposed by EPA in July 1978 (Fowler, 1978), and an economic impact analysis of the guidelines was published on September 6, 1978 (Johnson, 1978). The guidelines add certainty to testing requirements in the future. The EPA economic analysis estimated future registration costs by tabulating expected costs for: (a) incremental cost of guidelines (new tests and laboratory practices), (b) the cost of submitting data to meet current standards, and (c) the value in current prices of acceptable data already submitted to EPA in support of a registration. The latter two items pertain to reregistration only, while the first item is for new registrations. The EPA estimate for the cost of registration for an "average" new compound is about $390,000.[3]

FMC Corporation (1978) has prepared a rebuttal to the EPA economic analysis. FMC's analysis contends that two major difficulties are present in the EPA analysis. First, FMC's "average" product is a high-volume product which requires more extensive testing than does EPA's average product. Second, testing costs per new ingredient, particularly in the product chemistry and the human domestic hazard category, are underestimated by EPA. Both the number of tests required and the cost per test are estimated to be higher by FMC than by EPA.[4] The FMC cost figures are $1.3 million for the "average" EPA product and $2.9 million for the "average" FMC product.

In Brief

This evaluation indicates that there is some possibility that depletion and emphasis on pesticides with potentially large sales volume may explain some of the recent rise in costs per new pesticide registered. But the rise in safety testing costs and registration delay times in 1977-1978 occurred at the same time as the rise in costs per pesticide approved. The shift of resources from discovery activities to safety testing has decreased the number of compounds screened. All of this has been taking place in a rapidly expanding pesticide sales environment. The private benefit of getting a new compound approved is very high, but the probability of a success is falling, and costs of new compound development are rising rapidly. Whether or not the conditional registration and efficacy testing waivers of the 1978 FIFRA amendments can offset these increased regulatory costs will be critical for the next few years.

ADDITIONAL IMPACTS OF PESTICIDE REGULATION

Examination of the effects of government regulation on innovation in the pesticide industry projects an image of an industry grappling with sharply higher costs of development, but one in which industry seems to be coping with the problem by passing increased costs on to the user and consumer. Increased cost of chemical pesticides that will be passed on in the form of higher prices to consumers is one obvious impact of government regulation. There are other, more subtle but perhaps more harmful costs that must be considered in the overall evaluation.

Diversion of Effort of Scientists in the Public Sector

Scientists at the agricultural experiment stations in various states and in the U.S. Department of Agriculture are involved in the development of new chemical pesticides for agricultural and forest uses. However, developing these new chemicals is only a small part of the total research effort at these institutions. One recent effect of increasing government regulation has been to increase the amount of time these publicly supported scientists must allocate to defending needed agricultural chemicals and to making adjustments in pest control practices as important chemicals are removed from the marketplace or are restricted in use patterns. These and other scientists also must respond to government requests for information, train pesticide applicators, assist in obtaining information needed for registration, make residue analyses, and perform many other pesticide-related activities. Although some of the required investigations would be done as a part of comprehensive research on pesticides, a substantial portion must be diverted from other needed areas of research.

In an attempt to obtain some understanding of the impact of regulations on university research, extension, and teaching, we examined the repercussions of the Federal Environmental Pesticide Control Act of 1972

[3]An "average" product is typical in terms of volume and range of uses across crops, locations, and target pests.

[4]According to FMC, its average chronic feeding study cost $420,000, compared with the private laboratory estimate of only $150,000 for a mouse test and $230,000 for a rat test.

(FEPCA, amended FIFRA) from 1972 to 1978 in the New York State College of Agriculture and Life Sciences at Cornell University (including the agricultural experiment stations at Ithaca and Geneva and Cooperative Extension). This law, more than any other, has placed additional responsibilities on plant protection scientists. Some of the more relevant features of FEPCA in this regard include: (1) establishment of new intrastate and interstate requirements for registration of all pesticides, (2) classification of pesticides for general or restricted use and training and certification of those who use restricted materials, (3) state registration of pesticides under certain circumstances (section 24c), (4) emergency exemptions from normal registration procedures (section 18), and (5) establishment of an RPAR (rebuttable presumption against registration) system for determining whether a pesticide's registration or reregistration would cause unreasonable adverse effects on the environment.

The most dramatic change since the enactment of FEPCA has been the increase in faculty and administrative effort in behalf of minor crops, section 18 and section 24c registrations, and the National Agricultural Pesticide Impact Assessment Program as part of the RPAR process. Many faculty members currently spend 3 days per month on pesticide registration activities, or 15% of their total effort. During the 1972-1978 period, a total of one scientist-year was devoted strictly to section 18, section 24c, and RPAR affairs. In the same period, a total of 6.8 years of work was accumulated by technical and clerical staff hired largely to facilitate work in this area. The total administrative time required per year for pesticide regulatory matters has more than doubled since 1972.

Extension education carries the heaviest workload for registration requirements. Faculty members whose responsibilities are entirely or predominantly in extension are most severely affected. Moreover, faculty efforts in behalf of pesticide registration often receive less than adequate recognition from university administrators. Sometimes, therefore, motivation may be a problem for those who must carry the load for pesticide regulatory matters. In an environment where research resources have not been expanding there is considerable competition for faculty members' efforts. If current regulatory demands continue, more resources are needed for RPAR activities.

Certification of restricted pesticide users and associated training programs have had the second largest impact. The simple exercise of preparing and administering examinations consumed about 1.2 years of scientist and supporting staff time during the 1972-1978 period. Another year was accumulated by college staff who toured the state presenting training sessions, but this could be justified as normal extension duty. Preparation of certification manuals, preparation of training aids, and legislative liaison work have required about 7 scientist-years and 9 staff-years of effort.

A survey of faculty research full-time equivalents spent on chemical control of insects, pathogens, and weeds indicated very little change from 1972 to 1978. During the same time, there was about a 10% increase in efforts on nonchemical control of pests. However, the technical support which assisted these research programs showed a 15% decrease for chemical control and a 100% increase in nonchemical control. The number of chemicals tested for efficacy, residues, and yield was similar in 1972 and 1978. However, no distinction was made between the number of new chemicals tested and the number of old chemicals tested for new uses.

The impact of FEPCA on teaching programs has been small, although regulatory history, pesticide certification, pesticide safety, and registration requirements formed a part of at least seven courses. The time involved has increased substantially since 1972 and amounted to part of a lecture in some courses to five full class periods in one course.[5]

Although these data are very limited and insufficient to draw extensive conclusions, indications are that during the 1972-1978 period a total of at least 10 scientist-years and 16 support-years was spent at the New York State College of Agriculture and Life Sciences on regulations imposed by FEPCA. A similar survey of the South Carolina Agricultural Experiment Station, Clemson University, revealed similar impacts on faculty and staff resources.

Some states are affected more than others by regulatory-related activities. If the two institutions surveyed represent an average rather than the exception, however, at least 500 scientist years may have been diverted to regulatory-related activities at state experiment stations in the United States during 1972-1978. These surveys do not include estimates of the amount of research time that is devoted to subjects inspired by regulatory concerns. We have not been able to estimate the magnitude of the diversion of USDA scientists.

The influence on agricultural productivity resulting from the recent diversion of scientific effort to regulatory activities has probably been relatively small to date because the major innovations that increase agricultural productivity generally require more than 10 years from conception to extensive implementation. In the long run, however, the diversion of scientific effort to regulatory activities will be very costly to the U.S. public. The reasons are that, in addition to paying the cost of the regulatory activities, the public will lose the benefits of the scientific output that would otherwise result. The annual rate of return to the U.S. public from investment in agricultural research is approximately 50% (Evenson et al., 1979).

[5]In some institutions, new curricula are being offered in pest management.

Effects of RPAR on Pesticide Use Patterns

The "rebuttable presumption against registration" (RPAR) procedure was developed to review thoroughly the status of agricultural chemicals that might have potential for serious harm to humans or the environment as a basis for determining whether registration of those chemicals should continue. We have reviewed some of the effects of this procedure in the preceding pages. Also, we have noted the demands that this procedure places upon state experiment station scientists.

When a chemical pesticide is removed from the market or when its use is severely restricted, one effect is the substitution of older, less effective chemicals if these are available. These substitutes often must be used in greater volume because more pesticide is required to obtain equivalent pest control. Therefore, the overall effect may be to increase the volume of pesticide used.

An important example is the recent decision of the Environmental Protection Agency to suspend the registration of 1,2-dibromo-3-chloropropane (DBCP)[6] for health and safety reasons for all nematicide uses except for nematodes on pineapple. Replacements for DBCP as a preplant treatment on peaches on the East Coast will require four to seven times as much material for equivalent control (Table 6). If ethyl-4-(methylthio)-*m*-tolyl-isopropylphosphoramidate (fenamiphos) is approved for use on peaches, the amount of active material per acre per application will be less than that of DBCP; however, fenamiphos will require annual application (DBCP is applied biennially), and it is less effective than DBCP for control of ring nematodes.

The cost of treatment ($27-$45 per acre for DBCP in 1974 — Table 6) was modest relative to gains realized in terms of expanded productivity and prolonged tree life. During the 5-year period from 1974 to 1979, the retail prices of fumigants increased two to four times. However, because of the loss of DBCP, the cost increase of *preplant* treatments was even greater — from $27-$45 per acre in 1974 to $125 or more in 1979. Some of this increase was due to inflation and some to rising prices of petroleum, but a substantial fraction represented the cost of regulation being passed on to farmers. In this instance, more material is needed at greater cost, with less effective nematode control and greater expenditure of energy in the more frequent application of treatments. Additionally, the hazard to applicators is increased because of the more frequent applications of alternative nematicides required to provide control.

The use of DBCP was suspended also for established citrus, deciduous fruits, and vines, which are important in the West. DBCP was used no more frequently than once in 3 years for citrus, whereas the potential alternative nematicide must be applied annually. No nematicide or cultural practice now available is as effective as DBCP for prolonging the life of groves and vineyards. Unpublished studies by the California Department of Food and Agriculture indicate that, with suitable precautions, DBCP can be applied without hazard to workers, but the Department considers that it is unlikely to pursue further the use of DBCP because traces of the compound have been found in certain well waters.

Most agricultural scientists are pleased to cooperate with federal regulatory agencies in their requests for information and consider it a part of their responsibility to the general public. However, agricultural scientists have at times been made to feel that they were wasting their time by such cooperation. Some recent actions of EPA reinforce the widespread belief that facts developed from careful scientific investigation are often not heeded when regulatory decisions are made.

For example, the costly and tedious RPAR process may be triggered on the basis of tenuous information or poorly performed experiments, and, when decisions are made, the findings in the RPAR process may be ignored

[6]DBCP was widely used as a nematicide because it was very effective at low rates, was reasonably priced, and was of low toxicity to plants. It was used as a preplant treatment for some crops and was the only chemical in the fumigant class that was available for use on established crops such as peaches, pineapple, and additional fruits and nuts.

Table 6. Per acre material costs of nematode control on peach trees in 1974 and 1979 with selected chemicals used in South Carolina

Chemical and rate of formulated product per acre	Treatment mode	Material cost per acre[a]	
		1974	1979
DBCP (3-5 gallons)[b]	Preplant and postplant	$27- 45	$ 79-115
Ethylene dibromide (12-20 gallons)	Preplant	84-140	140-200
1,3-dichloropropene (21-35 gallons)	Preplant	35- 50	125-210
Fenamiphos 15G (60-100 lb)[c]	Preplant and postplant		100-165

[a]Cost is variable depending on soil type and whether broadcast or strip treatments are used.

[b]Registration of DBCP was suspended in November 1979.

[c]Not currently registered for use on peaches; has potential for postplant treatments.

in favor of information that is scientifically indefensible. In the recent EPA decision to suspend selected usages of the herbicide 2,4,5-T, carefully developed studies made as part of EPA's RPAR process (USDA, 1979) were ignored. Instead, EPA relied on a retrospective epidemiological study it conducted in a forested area in Oregon where certain women claimed that use of 2,4,5-T in forest management was a cause of an excessive number of spontaneous abortions. In the 6-year period included in the study, 2,4,5-T was used in significant quantities in 30 months, but EPA claimed a significant increase in the rate of spontaneous abortions in only 1 month. A subsequent examination of EPA's data (Newton, 1979) showed that in this month there were ten cases, but in eight of these the women involved were from areas in which there was no known use of 2,4,5-T during the entire 6-year period. The EPA study was reviewed by Health and Welfare Canada and Agriculture Canada, and, on April 19, 1979, they stated, "The recently released reports that prompted the U.S. decision appear to be inadequate to support the regulatory action taken." The Department of Public Health, Division of Public Health, New Zealand (1979), reached a similar conclusion. This and additional evidence was reviewed by Crosby et al. (1979). EPA's own Scientific Advisory Panel to the Federal Insecticide, Fungicide, and Rodenticide Act recommended that no hearing be held for the registered uses of 2,4,5-T because "no evidence of an immediate or substantial hazard to human health or the environment" was found (Torgeson et al., 1979). In the legal arena, a U.S. District Court upheld the suspension decision, but explained that "the Court is not empowered to substitute its judgment for that of the EPA," adding that "...the Court will frankly concede that it arrives at this decision with great reluctance and would not in its judgment have ordered the emergency suspensions on the basis of the information before the EPA" (Harvey, 1979). Nonetheless, EPA still does not admit that it acted on invalid evidence (Johnson, 1980) and persists in its emergency suspension of 2,4,5-T.

Integrated Pest Management

Integrated pest management (IPM) involves the integrated use of all applicable pest control principles and practices. IPM includes the use of chemical pesticides, but only as they are needed, and with management of their application to limit the harm done to beneficial organisms. Frequently this requires pesticides that are selective for the target pest. The property of a narrow spectrum of pesticidal activity necessarily limits the numbers of uses of a pesticide to one or a few crops and to one or a few pests.

One of the most important and far-reaching effects of spiraling costs of developing new chemical pesticides is the effect on chemicals having a narrow spectrum of activity. In most instances, costs to industry do not justify the development of such chemicals. This situation restricts the development of IPM systems now for minor crops, and it may eventually have severely restrictive effects on IPM systems for crops of large acreages as well.

A major research objective is to reduce pesticide use. There are several approaches. One is to search for new compounds that are effective at lower rates of application. This approach reduces the volume of pesticide applied to a crop — a practice which reduces cost and residues. Another is to combine pesticide use with other pest control practices, or to eliminate pesticides altogether. A third is to investigate the biology of pests and its interaction with pest control measures so that the most effective control practices can be applied at the most opportune time. A fourth is to develop pest-resistant crop varieties that require less help from pesticides and other control practices.

Government regulations may have important impacts on attempts to reduce overall pesticide usage. This point is well illustrated by a report which our committee received from Dr. D. L. Kittock, a colleague formerly in the U.S. Department of Agriculture, who is now retired. The following is quoted from this report:

> We have been working on chemical termination of cotton for control of pink bollworm for 8 years. This involves treating cotton plants in the fall with a single application of a relatively non-toxic plant growth regulator or mixture of two plant growth regulators to stop fruiting. If the application is properly timed, we prevent formation of bolls that will not mature before frost, but do not affect those that will mature. The lack of immature bolls in the fall denies the overwintering generation of pink bollworm's food source and habitat. We have been able to reduce the overwintering generation of pink bollworm 90 to 95% by use of chemical termination with little or no effect on lint yield. This should delay population build-up the following summer by at least one generation which is about 30 days or five insecticide applications. We have not been able to adequately test the effects of chemical termination on pink bollworm population the season following treatment. In order to do so it will require treatment of several thousand acres in an isolated area because of the pink bollworm moth's ability to fly long distances and reinfest fields. Treatment of a large acreage will require obtaining an experimental label with allowable tolerances on at least one suitable plant growth regulator.
>
> We have identified four plant growth regulators that are fast acting and effective for chemical termination. They are: (1) 2,4-D at 1 pound/40 acres, (2) dicamba at 1 pound/20 acres, (3) silvex at 1 pound/20 acres, and (4) Pennwalt's TD-1123 at 1 pound/acre. We have ruled out use of 2,4-D because it severely reduces germination and emergence of seed and makes leaves, flowers, and squares stick, which presumably adds to the dust problem under attack by OSHA. Silvex was ruled out by EPA this spring. We had hoped to get an experimental label on dicamba with tolerance this year. However, in recent conversation with Velsicol Corp., we found that they do not wish to pursue registration of dicamba. Last Friday, I was told Pennwalt had decided to discontinue development of TD-1123.

Government regulations affected only silvex directly. However, government regulations inhibited Velsicol and Pennwalt because of the high cost of testing that is required for registration.

The economic and environmental cost of these decisions could be quite high. One-half of all insecticide use in the U.S. is by agriculture. One-half of that (25% of the total) is used on cotton. Chemical termination theoretically should be as effective for control of boll weevil as well as pink bollworm. Therefore, under best possible results it might reduce insecticide use on cotton up to 80% or a 20% reduction of total U.S. insecticide use. Of course, it is possible that the technique may not work at all on a field scale. Most likely the technique will have some value and reduce insecticide use somewhere between 0 and 20%. We may never know if we can't test the concept.

Other examples could be cited. New bactericides to replace streptomycin and oxytetracycline which are used to control bacterial diseases of plants are not being developed because of prohibitive costs. Concerns have mounted about the use of antibiotics such as streptomycin and oxytetracycline for plant disease control because of fears that resistance to these chemicals might be transmitted to pathogens of humans and animals. The lack of alternatives to these antibiotics is a matter of serious concern to plant pathologists and farmers.

The problems just described are similar to those encountered with so-called "minor uses" of chemical pesticides on crops of limited value or acreage and on major crops for pest control needs which are significant only in limited areas. The problem of minor uses was the subject of another CAST Report (Upchurch et al., 1977). The Federal Pesticide Act of 1978 was an important step forward in dealing with the minor use problem, and, if fully implemented, will help to alleviate some of the problems in innovation that hinder development of pesticides needed to support IPM. The provisions of this law for conditional registration and data requirements for minor use pesticides will be especially helpful if regulations are implemented to encourage the registration of pesticides that have a narrow spectrum of activity. Cooperation of federal and state agencies in granting tolerances for emergency uses under section 18 provisions and in developing state registrations under section 24c provisions also would be very helpful in solving these problems.

Biological Control

Biological control means the use of biological agents to control pests. It is not necessarily nonchemical in nature, because some biological control agents are chemicals produced biologically. There are several classes of biological control agents.

Parasites and predators are living organisms that attack and destroy pests. They include microorganisms such as bacteria, viruses, nematodes, or fungi, but they may be larger living organisms such as parasitic wasps, beetles, or birds.

Antagonists may control pests by secreting biologically active compounds which are inhibitory. For example, marigolds secrete substances which inhibit certain nematodes. The crown gall disease of woody and herbaceous plants may sometimes be controlled by a bacterium that is antagonistic to the bacterium causing crown gall.

Sex pheromones are chemicals that may be used to disrupt mating patterns of insects. Resistance mechanisms sometimes can be utilized through genetic manipulation to increase the natural resistance of plants to pests.

Biological control agents are valuable in overall pest control strategy. Like chemical pesticides, however, they have limitations. They are generally more difficult to develop and use than are chemical pesticides. As is true of chemical pesticides, biological control agents may lose effectiveness with time because the pests develop resistance to them. Although nonliving chemical biological control agents disappear from the environment, like chemical pesticides, this is not necessarily true of living biological control agents. Depending on the organism and the circumstances under which it is used, living biological control agents may persist longer in the environment than do chemical pesticides, and they are more difficult to eliminate if their presence is found harmful. In fact, living biological agents may increase in the environment.

How do government regulations affect innovation in biological control? Until recently, agents for biological control were required to undergo the same kinds of tests that were required for new pesticides. However, current federal regulations (Jellinek, 1979) do not restrict the movement of parasites and predators within the United States. Movement from outside the United States is subject to quarantine laws, but registration as a pesticide is not required. The movement of antagonistic microbes within the United States is not restricted unless the microbes are classified as pests. However, sex attractants and other types of chemicals produced by biological agents are subject to pesticide regulations. Since most chemicals of this nature are specific in their activity, their commercial development is not financially attractive at present. At least one source (Tucker, 1978) indicates that federal regulations have already prevented the development of certain biological agents, such as juvenile hormones and parasitic microbes, for insect control. Liberalized regulations for biological agents in the natural environment which might be developed for biological control are being studied.

Technological Leadership

Agricultural scientists who test new pesticides have noticed that the proportion of new test chemicals originating from outside the United States is increasing. This may not be a matter of serious concern, but it raises certain troubling questions. Are chemical manufacturers finding costs of developing agricultural chemicals outside the United States low enough to focus on the market abroad rather than on the United States? Is it becoming more attractive to market new chemicals abroad before undertaking development of them in the United States? If so, American farmers might find themselves at a significant disadvantage in pest control compared with farmers in other countries. Could the technology to discover and develop chemicals for biological control and integrated pest management flourish abroad while being restricted in the United States? There are indications that advances in pesticide innovation in the United States may be lagging behind those of other developed nations (Anonymous, 1978).

CONCLUDING REMARKS

Increasingly stringent regulation of agricultural chemicals in recent years has required private industry to verify the safety of both new and old chemical pesticides. This procedure is very expensive. Generally, industry has been able to pass on part or all of these costs of regulation to users. Costs of regulation do not appear to have greatly inhibited the search for new compounds, but some research and development funds have been diverted from synthesis, screening, and field testing to other activities (Table 2). However, the effects in agriculture are not uniform. One effect has been to encourage the development of chemical pesticides having a broad spectrum of activity at the expense of compounds with more specific activity that would be useful in IPM.

If current trends in regulation continue, one long-term effect will probably be reduced respect for pesticide regulations among users. If, for instance, the trend continues toward registration of broad-spectrum chemical pesticides on major crops only, the temptation to engage in illegal use of pesticides will increase. Farmers and gardeners confronted daily with pest control problems will become less concerned with use of chemicals in accordance with label directions if they know that the chemicals will work for crops not on the label, especially if they believe that label restrictions are based on economic reasons rather than safety considerations. Vigorous implementation of the "minor use" and conditional registration provisions in the Federal Pesticide Act of 1978 would help to overcome this problem.

The Federal Pesticide Act of 1978 contains a number of provisions for registration and use of pesticides which are helpful to agricultural, forest, and business interests. Wise use of this law by all parties involved in the registration, production, and use of pesticides would go far toward alleviating many difficult problems associated with pesticides.

Certain important issues relating to government regulation have not been addressed in this review. Some of them defy attempts at a complete assessment because of their complexity and lack of reliable data; nevertheless, they should be kept in the public view because they are very important. Examples of questions that are of concern in analyses of regulations are these:

1. What is the impact of substituting a highly toxic, nonpersistent chemical pesticide (such as parathion) for a persistent chemical pesticide of low mammalian toxicity (such as DDT) or vice versa? How is the hazard of the former to humans evaluated against the hazard of the latter to the environment?
2. Is development of safer, more effective chemical pesticides unduly inhibited by existing regulations? Do current regulatory activities overemphasize the regulatory process and underemphasize the objectives of regulation?
3. Is chemical pesticide use increasing or decreasing as a result of government regulation? Some uses seem to be increasing as a result of government regulation.
4. Would less government regulation spur the development of safer, more effective pesticides, or would the effect be injurious to humans and the environment?
5. Are the costs of government regulation to industry, agriculture, and forestry, and eventually the consumer, justified by the benefits obtained? How can risks of pesticide manufacture and use be balanced against the risks of regulation?
6. What incentives are needed to bring about more effective collaboration among the several public and private institutions involved in pesticide research, production, and regulation?

An assessment of the impacts of government regulation on the development and use of agricultural chemicals is not complete unless long-term effects are considered. Answers to these questions will become clearer as time progresses.

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APPENDIX

The Federal Food and Drug Act of 1906

Generally referred to as the Pure Food Act, this law was designed to prohibit the use in food of chemicals known to be harmful to humans. Under this law the burden of proof of the harmful or poisonous effect of any chemical rested with the Food and Drug Administration (formerly the Bureau of Chemistry).

The Federal Insecticide Act of 1910

An act for preventing the manufacture, sale, or transportation of adulterated or misbranded insecticides and fungicides, for regulating traffic thereof, and for other purposes.

The Federal Food, Drug and Cosmetic Act of 1938

This act was passed by Congress on June 25, 1938, and became effective one year later. It superseded the 1906 Food and Drug Act.

It prohibited the unnecessary addition of poisonous substances to food and set forth the procedures for establishing tolerances for instances in which such substances could be used without endangering human health. No tolerance could be established unless the chemical in question could be used in such a way that the public health would be protected.

Under this Act the Food and Drug Administration could not bar the use of a chemical unless it could prove that the chemical was harmful. Hearings were held in 1944 and 1950 for the purpose of establishing tolerances. All chemicals and tolerances established by these hearings were for fruits and vegetables.

This Act provided that tolerances be established for pesticide residues in foods where these materials were necessary for the protection of the food supply.

The Federal Insecticide, Fungicide and Rodenticide Act of 1947 (FIFRA)

This Act was passed on June 15, 1947, and became effective one year later.

It superseded the Insecticide Act of 1910 and extended coverage to include herbicides and rodenticides.

It further established regulations relating to the certification of the usefulness of chemicals in agriculture and required registration of all compounds with the Secretary of Agriculture. A tolerance or exemption from a tolerance continued to be requested under the provisions of the 1938 Food, Drug and Cosmetic Act.

The 1947 FIFRA placed the responsibility for registration with the manufacturer. It specified requirements for safety precautions in applying and handling agricultural chemicals and required requests for continued registration on a 5-year basis.

The Act provided that all material sold in interstate commerce must be correctly labeled and that the label must be registered and approved by the USDA.

It also provided penalties for misbranding and unregistered uses being recommended on the labels.

Public Law 518

Also called the "Miller Amendment" or the "Miller Pesticide Residue Amendment."

Public Law 518, the Miller Amendment to the Food, Drug, and Cosmetic Act, was passed July 22, 1954, and provided that any raw agricultural commodity may be condemned as adulterated if it contains any pesticide chemical whose safety has not been formally cleared, or which is present in amounts exceeding established tolerances.

This law places the responsibility on the manufacturer for clearing all legal requirements for use of agricultural chemicals with the USDA and the FDA.

It requires that a specific tolerance be established for each use to be made of any chemical, or the establishment of an exemption from a tolerance where exemptions can be justified.

It gives the Secretary of Health, Education and Welfare the power to establish such residue tolerances and spells out in detail the procedure to be followed.

It further requires each product to carry on the label full and specific instructions for use so as to meet the legal residue tolerances specified by the Food and Drug Administration.

The Department of Agriculture enters the picture to certify that the chemical is useful for the production of the crop in question, and that the tolerance proposed by the petitioner reflects the maximum amount of residue likely to result when the pesticide is used in the manner proposed.

The Food Additives Amendment

Also referred to as the Williams Bill (H.R. 13254), it is an Act passed on September 6, 1958, amending the Food, Drug and Cosmetic Act.

It prohibits the use of substances in food until they have been adequately tested to establish their safety. It distinguishes between food additives and food components which are not additives. Lists of substances regarded as safe and substances proposed or being regarded as safe are cleared and periodically publicized by the Food and Drug Administration.

It regulates the additives in processed food and covers any material "intentionally" or "incidentally" added to foods.

It specifies that no food additive shown to increase the incidence of cancer in humans or animals can be considered safe (the Delaney Clause).

The Nematicide, Plant Regulator, Defoliant and Desiccant Amendments of 1959

This Amendment, passed in August 1959, amended the Federal Insecticide, Fungicide and Rodenticide Act to include nematicides, plant regulators, defoliants, and desiccants under the provisions of the 1947 Act.

Pesticide Regulation Amendments, September 6, 1963

This Amendment requires warning statements on labels along with the words "Keep Out of Reach of Children" and also eliminates from the labels of all economic poisons such claims as "Safe," "Non-Poisonous," "Non-Toxic," "Non-Injurious," and "Harmless."

Public Law 88-305, May 12, 1964

This Law requires pesticide labels to bear a registration number furnished the manufacturer at the time the pesticide is approved for registration.

It eliminates the controversial "registration under protest" clause of the 1947 Federal Insecticide, Fungicide and Rodenticide Act. Under this clause it was formerly possible to register chemicals under protest even though the Secretary of Agriculture felt more information on the chemical was needed. This was long considered a major loophole in the law.

Formation of EPA — 1970

Established a new agency, the Environmental Protection Agency. Most pesticide regulatory responsibilities were transferred from USDA and FDA to EPA.

The Federal Environmental Pesticide Control Act of 1972 (FEPCA)

Legislation was signed into law on October 21, 1972. This Act substantially amended the 1947 Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

It extends the requirement for registration to *all* pesticide products sold or distributed in the United States, not just those sold in interstate commerce.

It prohibits the use of any registered pesticide in a manner inconsistent with the label.

Pesticides must be classified into "general" use or "restricted" use categories. Restricted use pesticides may be used only by certified applicators.

It specifies civil or criminal penalties for violations of the Act.

Federal Pesticide Act of 1978

This Act amended the 1972 FEPCA. Several major features include:

Compensation for data requirements: Data compensation has been a major concern to both holders of the data and those who wish to use it. Reactions from the initial registrants and the potential users have been generally favorable to the compensation for data amendments. Assurance of a period of exclusive use and compensation should encourage the development of new products.

State pesticide authority: States have primary enforcement responsibilities, subject to certain important preconditions, with increased authority to approve federally registered pesticides for additional uses to meet local needs for use within that state.

Use inconsistent with labeling requirements: The 1978 law specifies that certain uses would not be considered inconsistent with labeling. These include (a) use against a target pest not specified on the label unless the label specifically states that the pesticide may be used only for pests identified on the label, (b) mixing a pesticide with fertilizer unless specifically prohibited by the labeling, (c) use of a pesticide at less than the label dosage, concentration, or frequency, (d) employing any method of application not prohibited by the label, or (e) any use that the EPA administrator determines to be consistent with the purposes of the Act. The Administrator had until May 31, 1979, to require definite label amounts of dilution for a pesticide used for agricultural or forest purposes.

Conditional registration in absence of data for complete registration: Conditional registration could be granted for: (a) a new pesticide or proposed new use which is identical or substantially similar to current registrations, for which approval would not significantly increase the risk of an unreasonable adverse effect on the environment, (b) new uses of currently registered products, subject to similar qualifications, and (c) active ingredients not contained in any currently registered products, but only to permit use of the product for a period of time sufficient to obtain the required data, and after the Administrator has determined that there would be no unreasonable risk and that the use is in the public interest.

Data requirements for minor use pesticides: Consideration will be given by the Administrator to the incentives for undertaking the development of required data for minor use pesticides. This will include appraisals of volume, pattern, and extent of use; the impact of the cost of meeting registration requirements; and the degree of exposure to humans and the environment. New rules such as waiving efficacy requirements under certain conditions, increasing state authority to register pesticides, easing labeling requirements, and allowing conditional registration should help alleviate the minor pesticide use problem.

Waiver of data requirements pertaining to efficacy: The Administrator may waive efficacy data requirements for any pesticide registration application. The 1978 Act further provides that if a pesticide is found to be efficacious by any state, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in that state.

Other features of the Federal Pesticide Act of 1978 include simplification of registration procedures, changes in classification from restricted to general use, continued state authority to certify applicators prior to completion of reregistration, permits for experimental use, and consideration of a generic approach to registration. In general, the Act was amended in an effort to streamline the pesticide regulatory process, encourage pesticide research and development, and provide greater pesticide use flexibility for growers.

Other Laws

Other laws that relate to pesticide regulation are the Federal Seed Act, 7 U.S.C. §§1551 et seq.; the Endangered Species Act, 16 U.S.C. §§1531 et seq.; the Hazardous Materials Transportation Act, 49 U.S.C. §§1801 et seq.; the Federal Water Pollution Control Act, 33 U.S.C. §§1251 et seq.; the Occupational Safety and Health Act, 29 U.S.C. §§651 et seq.; the Resource Conservation and Recovery Act of 1976, 42 U.S.C. §§6901 et seq.; and the Toxic Substances Control Act, 15 U.S.C. §§2601 et seq.