The International Regulation of Pesticide Residues in Food

A Report to the National Science Foundation on the Application of International Regulatory Techniques to Scientific/Technical Problems

by

David A. Kay

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FOREWORD

This report is part of the first stage in a two-stage research effort under National Science Foundation Grant No. ERP73–02713 AO2. Our overall purpose in this research effort is to select, survey, and explore the possibilities of actively applying the spectrum of existing international management and regulatory techniques to the practical solution of six selected scientific and technological problems requiring international action, and to suggest in a systematic way circumstances and conditions under which these various techniques might be applied toward the resolution of specific technology-related transnational policy issues. A major political-technological challenge of the future is to develop approaches, policies and institutions capable of coping with the burgeoning number of issues and problems that cannot be successfully managed within the confines of individual states.

There has developed over the last few decades on the international scene a spectrum of regulatory procedures, techniques and approaches that are employed in a fragmentary way by various international entities concerned with widely differing, but generally highly specialized and nonpolitical subjects. These regulatory and management techniques have not been subject to a thorough evaluation of the dynamic forces relating to their development and application, nor to the development and testing of working hypotheses regarding the conditions of an effective or ineffective regulatory regime and the conditions which influence the transferability of regulatory and management techniques to other problem areas.

During the first stage of our work, we are concentrating on problem-oriented research focused on six technology-related transnational policy problems, of which the subject of this report is one. In each of these six areas we are attempting to grasp and project a decade or so ahead the evolving pattern of international scientific/technological relationships and to suggest a framework for their analysis that explores the range of possibilities for international action in each. In this problem-oriented report, and in the five others to be produced in this project, we are:

(a) Describing and analyzing the legal, political, economic, and scientific/technological dimensions of the policy area examined;

(b) Describing and explaining the extent of international management, control and regulatory techniques employed in the policy area;

(c) Defining the priority problems in the policy area for the ensuing decade;

(d) Evaluating the adequacy of existing techniques for coping with current and prospective problems;

(e) Identifying and evaluating alternative techniques.

Our research in the first stage is directed towards producing information, analysis and recommendations which will be of direct use to US decision-makers.

Once the first stage of this project has been completed we will, using the data collected in this first stage, begin the construction of a paradigm of international regulatory activity that will have explanatory power and analytical usefulness for the policymaker and scholar. In this stage we will be seeking to describe the range of techniques operative at the international level and to analyze these techniques with a view to proposing and initiating testing of working hypotheses concerning the conditions associated with:

(a) Norm creation

(b) Allocation of costs and benefits

(c) Compliance with agreed standards

(d) Expansion of management, control and regulatory techniques among scientific/technological areas.

In connection with the writing of this report, a number of debts of gratitude should be acknowledged. At every stage of our work, we received the full and extremely helpful cooperation of the operating agencies of the US government concerned with this problem. The officials of the Environmental Protection Agency, US Department of Agriculture and of the Food and Drug Administration gave unsparingly of their time, and without their assistance this report would not have been possible. We also received the valuable and full cooperation of the chemical industry and of its trade association, the National Agricultural Chemical Association. Finally, the assistance of the officials of various international and regional organizations who shared their views with us is gratefully acknowledged. As the author of this study, I owe a special debt of gratitude to Valerie Hood, my principal research assistant on this project, for the long hours of hard and often tedious work she put in on this project. In the end we all owe our appreciation to Judy de Lesseps and Dorothea Bodison for the seemingly endless typing and secretarial chores they have cheerfully undertaken.

The original version of this report was published by the National Science Foundation in January, 1975, and the recommendations should be read in that context.

This report does not purport to represent the views of The American Society of International Law (which as an organization does not take positions on matters of this kind). Similarly, the report's conclusions, findings, opinions or recommendations do not necessarily reflect the view of the National Science Foundation. The final responsibility for this report is, of course, fully borne by the principal investigator.

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Washington, D.C.
April, 1976

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THE INTERNATIONAL REGULATION OF PESTICIDE RESIDUES IN FOOD

Among the multitude of "crises" that governments find themselves faced with today, few have the immediate personal impact of the so-called food crisis. Evidence of this crisis can be found in such diverse phenomena as regional food shortages, long queues for sugar in England, sharply higher food prices in many states, and the renewed attention being given to agricultural exports as a major source of foreign exchange earnings. It is generally estimated that half of the world's present population has an inadequate diet and that a doubling of the world's food supply in the next thirty years would be required to achieve even a moderate advance in global nutritional levels. As indicated in Table I, agricultural products already play an important role in U. S. international trade, and this role will have to increase if global demand for agricultural products is to be met.

Modern agricultural production in terms of its use of capital and technology is an industrial process. To increase production, farmers have resorted to heavier investments in machinery, improved seed varieties, and increased use of fertilizers and pesticides. Between 1960 and 1969 the production of synthetic organic pesticides in the United States increased by more than 40 percent and the dollar value of United States pesticide exports increased by more than 70 percent in this same period. In 1973 the United States sold abroad over $260 million worth of pesticides. Worldwide, the annual growth rate in the use of pesticides is approximately 10 percent. The Food and Agriculture Organization (FAO) has estimated that if the developing countries are to meet their food production requirements that between 1967 and 1985 they will have to increase their use of agricultural pesticides fivefold and that global use of agricultural pesticides will be approximately 7.5 million tons by 1985. While it is estimated that the

United States produces approximately 50 percent of all pesticides manufactured in the world, Table II shows that on an area of application basis, pesticide use is higher in Europe and Japan than in the United States.

Table II also demonstrates the dependence of modern agriculture upon the application of pesticides to reduce the food losses suffered from pests. High agricultural yields are directly associated with heavy use of pesticides. This is not surprising in view of the Food and Agriculture Organization's (FAO) estimate that pests destroy up to one-third of the world's food crops during growth, harvesting and storage. The success stories of the impact of the application of pesticides are numerous. The Ghanian cocoa crop was tripled in size by the application of an insecticide that controlled the capsid bug. In Pakistan an expenditure of $77,000 on insecticides increased the sugar crop by a third, producing an additional $7.2 million worth of sugar. Similar results can be found in the United States for every major agricultural product. The worldwide demand for more food from a relatively fixed agricultural land base would seem likely to insure the continued important role played by pesticides in agricultural production.

The earliest known pesticides * were organic materials of natural origin. It is alleged, for example, that Marco Polo brought pyrethrum to Europe from China where it was used to kill insects. By the mid-eighteenth century, crushed tobacco was being used in France to kill aphids, and this use rapidly expanded after the isolation in 1809 of nicotine, the active ingredient in tobacco. Petroleum oils were first used as insecticides in the eighteenth century and were widely used by the late nineteenth century. The mid-nineteenth century also saw the development of inorganic compounds, particularly the metal salts of arsenic, lead, mer-

* "Pesticides" is used in this report to mean any substance or mixture of substances intended for preventing or controlling any pest and includes any substance or mixture of substances intended for use as a plant growth regulator, defoliant or desiccant. The term excludes fertilizers and antibiotics or other chemicals administered to animals for other purposes such as to stimulate their growth or to modify their reproductive behavior. (This is the official definition of pesticide used by the Codex Alimentarius Commission.)

TABLE I

Agricultural Exports: Quantity Indexes, United States, 1959–73 [Calendar year 1967 = 100]

Year ending June 30	Total agricultural exports [1]	Animals and animal products	Meat and meat products [2]	Animal fats [2]	Dairy products	Poultry and poultry products	Cotton and linters	Tobacco unmanufactured	Grains and feeds	Vegetable oils and oilseeds	Fruits and vegetables
1959....	62	83	73	76	164	69	79	83	52	51	79
1960....	79	96	85	109	133	100	166	80	60	69	91
1961....	84	98	81	95	143	126	176	88	69	65	86
1962....	85	103	78	98	154	166	119	91	79	64	93
1963....	84	104	90	92	197	117	91	83	79	78	99
1964....	100	140	122	127	290	129	128	93	94	82	92
1965....	98	130	118	117	240	114	113	84	92	99	95
1966....	107	108	101	90	154	120	78	83	117	102	106
1967....	104	101	106	96	99	105	115	110	103	95	106
1968....	101	96	91	98	95	98	101	100	104	99	91
1969....	92	110	129	97	125	92	69	100	85	106	93
1970....	106	101	113	99	90	83	75	101	97	148	109
1971....	115	117	118	121	108	85	98	98	106	158	103
1972....	115	134	137	111	188	85	89	94	103	159	107
1973 [3]...	153	126	185	108	75	95	126	102	167	182	118

[1] Based on 359 classifications (commodity groups and total index include commodities shipped as food for relief or charity by individuals and private agencies).

[2] Included in "Animals and animal products."

[3] Preliminary.

Economic Research Service. Compiled from reports of the U.S. Department of Commerce. Data for 1924–58 in Agricultural Statistics, 1972, table 818.

[B3393]

Agricultural Imports: Quantity Indexes, United States, 1959–73 [Calendar year 1967 = 100]

Year ending June 30	Total agricultural imports [1]	Complementary imports [2]	Supplementary imports [3]	Animals and animal products	Dairy products [3]	Hides and skins [3]	Meat and meat products [3]	Wool excluding free in bond [3]	Grains and feeds	Vegetable oils and oilseeds	Sugar, molasses, and sirups	Tobacco unmanufactured
1959..	91	99	84	79	51	197	62	100	200	74	97	83
1960..	92	103	81	69	51	179	56	89	185	77	101	85
1961..	88	101	75	64	58	141	54	77	168	78	87	88
1962..	96	102	88	89	60	162	75	108	173	82	90	89
1963..	100	106	95	101	61	141	93	124	110	87	99	85
1964..	96	105	88	91	62	152	93	86	215	81	78	83
1965..	90	95	85	81	62	144	71	124	124	93	82	91
1966..	103	111	95	106	69	141	90	166	95	92	83	88
1967..	100	98	100	102	113	108	97	104	105	101	101	95
1968..	105	104	105	108	94	121	107	115	92	97	102	111
1969..	107	103	110	115	122	102	115	100	96	105	103	103
1970..	111	104	116	121	116	32	128	81	131	104	107	103
1971..	111	101	118	118	124	83	128	47	136	111	113	109
1972..	116	108	122	117	117	71	134	29	145	119	118	127
1973 [4].	121	112	128	127	137	54	144	25	122	129	109	122

[1] Based on 430 classifications. [2] Supplementary agricultural imports consist of all imports similar to agricultural commodities produced commercially in the United States, together with all other agricultural imports interchangeable to any significant extent with such U. S. commodities. Complementary agricultural imports include all others, about 98 percent of which consist of rubber, coffee, tea, cacao beans, raw silk, wool for carpets, bananas, and vegetable fibers.

[3] Included in "Animals and animal products." [4] Preliminary.

Economic Research Service. Compiled from reports of the U. S. Department of Commerce. Data for 1924–58 in Agricultural Statistics, 1972, table 819.

[B3392]

TABLE II

Areas and Countries in Order of Pesticide Use Per HA and of Major Crop Yields

Area or country	Pesticide (g/ha)	Yield (kg/ha)
Japan	10,790	5,480
Europe	1,870	3,430
United States	1,490	2,600
Latin America	220	1,970
Oceania	198	1,570
India	149	820
Africa	127	1,210

Source: (Industrial Production and Formulation of Pesticides in Developing Countries, Vol. I: General Principles and Formulation of Pesticides, Kenneth C. Walker, "International Aspects of Pesticides," United Nations, New York, 1972, p. 15.)

[B3388]

cury, copper and zinc, as pesticides. Lead arsenate was used in 1892 in Massachusetts against that perennial scourge, the gypsy moth.

The modern era of pesticide use really began with the Second World War. Sources of several of the naturally occurring organic pesticides, such as pyrethrum, were interrupted by the war, and modern organic chemistry was just getting into full stride as the war broke out. DDT was discovered to have insecticidal properties in 1939, and a crash effort was undertaken to push its use during the war by the United States. Its successes during the war against typhus and malaria created great enthusiasm for its commercial use when the war concluded. Subsequent research to develop new pesticides led to the development of a variety of organochlorine, organophosphate and carbamate pesticides. It is estimated that there are now in the United States some 900 active pesticide chemicals formulated into over 30,000 preparations.

While the important contribution made by pesticides to increasing agricultural yields has generally been recognized, concern has grown in recent years as to the potentially harmful effects on man of such pesticides. Pesticide residues remain in minute quantities in almost all crops grown under modern methods. During the last decade the residues left in food by the modern biologically active pesticides, beginning with DDT and the dangers presented by the possible incorrect application of such pesticides, have been recognized as potentially serious public health problems. Table III sets forth in summary form the generally

TABLE III

Recognized Potential Side Effects of Pesticides in the Environment

Environment Element	Potential Side Effect
1. Abiotic Environment	Presence of residues in air, water, soil
2. Plants	Presence of residues; damage due to phytotoxicity; plant changes (e. g. due to use of herbicides)
3. Animals	Presence of residues in domestic animals and wildlife; physiological effects (e. g. non-viability of bird eggs); mortality of certain wildlife species; mortality in beneficial insects, predatory and parasitic insects; insect population changes
4. Man	Presence of residues in tissues and organs; effects of occupational exposure
5. Food	Presence of residues
6. Target Organisms	Development of resistance

Source: N. Van Tiel, "Pesticides in Environment and Food," Environmental Quality and Safety, Vol. I., p. 181, (Stuttgart: Georg Thieme Publishers), 1972.

recognized harmful side effects that may result from the pesticides in the environment. During the last ten years in many countries, including the United States, the impact of pesticides on man and the environment became a major topic of public discussion and eventually led to new legislation designed to regulate the use of pesticides. The national regulatory practices concerning pesticides that have developed during this last decade differ considerably. In many countries procedures have been developed for experimentation and field testing of new pesticides prior to approval for their general use, but only a few nations systematically examine new pesticides themselves or conduct their own toxicological studies. Registration schemes to control the pesticides approved for use have been adopted by most developed nations, but they present bewildering variations in the manner in which they operate and in the data they require for the approval of a pesticide. In the United States, the EPA draft document of guidelines for pesticide registration is over 300 pages long; in the Federal Republic of Germany a potential registrant must answer seventy questions on the composition, analytical method, toxicology and crop residues of a new pesticide, but only fifteen questions in the Netherlands. The Japanese insist that some of the long-term toxicological work required for registration of a new pesticide must be carried out in Japan even if it is repetitious of other work already performed in another state. Registration, while the most common form of national pesticide control, has several limitations. In the first instance, registration provides no insurance against either accidental or intentional misuse of a pesticide by the ultimate user either in excessive amounts or on unapproved crops. Such misuse could obviously lead to unsafe residue levels. Secondly, since states have different registration requirements and pesticides may be registered in one jurisdiction but not another, national registration systems provide no protection on food imports. States also differ considerably in their approach to the control of pesticide residues in food. Both the United States and Canada have comprehensive laws establishing procedures for setting maximum pesticide residue levels in foods, but the United Kingdom only controls pesticide residues indirectly through the general provisions of its Food and Drug Act and a Voluntary Pesticides Safety Precautions Scheme. Legislation designed to control pesticide residues in food is now found in the following nineteen countries: Australia, Argentina, Austria, Belgium, Canada, Czechoslovakia, Colombia, Denmark, Finland, Netherlands, Luxembourg, Japan, New Zealand, Poland, Sweden, Switzerland, West Germany, Soviet

Union, and the United States. Spain is in the process of introducing comprehensive pesticide legislation. Indirect control over pesticide residues is achieved through legislation regulating the sale and pre-harvest use of pesticides in Brazil, Ecuador, France, Italy, Philippines, South Africa, Thailand and the United Kingdom. A majority of countries, however, still has no legislation specifically controlling pesticide residues in food. Even in those countries with national tolerance schemes, their administration requires costly sampling and analysis efforts to detect violations of the tolerances in imported food coming from jurisdictions with differing pesticide regulations. Table IV illustrates the wide variation that exists on selected pesticide residues among those countries which have comprehensive residues legislation. A few countries make an attempt to license and control the conditions of use of certain pesticides. This is particularly the case with aerial applications of pesticides. A final topic addressed by national legislation is the content of labels and advertising for pesticides.

Inevitably such national attempts at the regulation of pesticides have reflected the complexity of the multitude of interests affected. Among these interests are agricultural producers, the pesticide industry, public health authorities, the scientific community, consumer and environmental interests, and government agencies concerned with all of these issues. Although national regulatory requirements do differ, often considerably, it is possible to construct a general model of the process followed in bringing a chemical from its discovery to marketing and thus illustrate the complexity of the interests involved. In its simplest form this is a three-stage process, consisting of (1) Research, (2) Development, and (3) Evaluation and Marketing. The pesticide industry is a very closed industry when it comes to providing research and development costs and specific product production and sales figures. In the United States, for example, sections 8 and 10 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. § 135) prohibits federal disclosure of any such information on a specific company or product basis that is provided it by the industry. However, our survey data indicates that on the average the industry screens about 10,000 chemical compounds for suitability as a pesticide at the research stage for every successful pesticide and that the research cost for each product is on the average somewhere between eight to ten million dollars. Table V, based on a survey in 1968 by Arthur D. Little of over 30 agricultural chemical manufactures gives some insight into the relative cost and risks of failure at each stage in the development of a pesticide. These costs have not been adjusted to reflect the impact of inflation between 1968 and 1975, however, our rough estimate is that they would have to be adjusted upwards by between 50 to 60 percent to reflect current price levels. In the research and evaluation stage biological and toxicological studies, of course, have to be performed to indicate the impact of the pesticide on the target organism, but a great deal of effort is also expended on identifying the potential impact of the pesticide on the environment. A method of analysis must be found for identifying the chemical and its residues. It is generally required by registration authorities that this method be easily reproducible and have a high sensitivity level. In the case of each crop on which the pesticide is to be used, several hundred samples may be required to provide decay curves and confirmation of the safe residue level. Since pesticide residue levels may vary with climate, agricultural practices, and soil types, these analytical samples often have to be prepared for each country in which registration is sought. It is estimated that about eight man years are required for residue and metabolism analysis before a pesticide can be registered. In the development and evaluation stages data must be gathered on the storage properties (the general acceptable minimum being two years), and on the use patterns to be followed in the application of the pesticide, and on the labelling and production information to be supplied with the pesticide. In a regulatory environment on the order of complexity of the United States, the average length of time required from discovery until registration is currently seven to ten years. Many chemicals obviously do