International Regulation of Toxic Chemicals

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INTRODUCTION

The technological revolution of the 20th century has been accompanied by a heavy reliance upon the development and use of a vast array of chemical substances. There are currently over a half-million chemicals produced throughout the world.¹ Approximately 10,000 are produced annually in amounts ranging between 500 and 1,000,000 kilograms.² Hundreds of new compounds are introduced each year and laboratory research continues apace on many thousands of others. Many of these substances have been extremely beneficial to modern society³ and may never pose significant health or safety risks. But the flood of new chemicals since World War II has also brought greatly increased risks to human health and the environment. In 1970, it was estimated that there were 12,000 toxic chemicals being utilized in the United States in industrial processing; in public health; in agriculture as pesticides and fertilizers; in foodstuffs as...
preservatives, coloring, flavoring, and sweetening agents; in packaging; in drugs and cosmetics; and in a host of other forms.4

It is the ubiquitous nature of many of the substances, and their capacity for causing subtle and latent effects on health and environment, which intensifies the dangers involved in their use. The threat to human health posed by some substances extends beyond the risk of direct and acute poisoning to the possibility of carcinogenic, mutagenic, and teratogenic effects.5 The threat to the environment is just as great. While many chemical substances can be comfortably assimilated into the environment in which they are used or disposed of, there is generally a threshold beyond which the impact of disposal becomes disruptive or even fatal. Large quantities of persistent chemicals are now being released into the environment where their cumulative, if not immediate, toxicity constitutes a major hazard to man and the ecosystem.6

Because of the ubiquitous nature of the chemicals and their cumulative


5. Simply stated, carcinogenic chemicals induce cancer, mutagenic chemicals induce heritable changes in genetic material, and teratogenic chemicals induce non-transmittable birth defects. See also note 93 infra. The majority of cancers in man are believed to be caused by chemical and other environmental agents. Hearings on Chemicals and the Future of Man Before the Subcomm. on Executive Reorganization and Government Research of the Senate Comm. on Government Operations, 92d Cong., 1st Sess. 103-04 (1971) (evidence given by the director of the National Cancer Institute) [hereinafter cited as Hearings on Chemicals]. See also note 6 infra. Yet in the United States, only 6,000 or so of the two million known chemicals have been laboratory tested for carcinogenicity. U.S. Council on Environmental Quality, Sixth Annual Report 32 (1975). For a detailed list of recognized, suspected, and potential carcinogens, see Hueper, Medicolegal Considerations of Occupational and Nonoccupational Environmental Cancers, in 5B Lawyers' Medical Encyclopedia §§ 38.45-.46 (C. Franke & R. Patterson eds. 1972).

6. The implications of these latent health and environmental risks are becoming more visible daily. Between 60% and 80% of all human cancers are believed to be environmentally induced. S. Epstein & R. Grundy, supra note 4, at 68. It should be noted, however, that the evidence for such conclusions “is in reality largely circumstantial, and . . . represents only the most satisfactory and logical explanation for the available data.” International Agency for Research on Cancer, Annual Report 22 (1976) [hereinafter cited as IARC Report]. Dr. Epstein has also estimated that 53 million, or 25% of the population in the United States will develop some form of cancer during their lives. The cancer-caused death rate appears to have tripled since the beginning of this century, in spite of major advances in diagnosis and treatment. 122 Cong. Rec. E939 (daily ed. March 1, 1976).

One industrial accident illustrating the serious threat posed by some modern chemical substances took place in the town of Seveso in northern Italy in 1976. The 16,400 residents of the town were evacuated following the accidental escape of about four pounds of the deadly chemical tetrachlorodibenzolparadioxin (TCDD). N.Y. Times, July 31, 1976, at 3, col. 5; The Economist, July 31, 1976, at 67. Over 1,000 people were treated for serious illnesses, 30 pregnant women underwent abortions to avoid giving birth to deformed babies, and scientists have recommended the complete destruction of all buildings, vegetation, and soil within a certain radius of the chemical factory. World Magazine, March 19, 1977, at 8. A British firm that had been manufacturing the same substance closed down voluntarily in 1976 for fear of a similar incident. Encyclopaedia Britannica, 1977 Book of the Year 322.
and latent qualities, the challenge of their regulation is essentially an international one. The fundamental unity of the global ecosystem is nowhere more evident than in the area of chemical use and disposal. Although some positive steps can be achieved with unilateral action, the inherent limitations of that approach require that strenuous effort be given to developing successful methods of international regulation.

This Article examines three aspects of the existing situation in an effort to highlight the obstacles to effective international regulation, the benefits to be derived from such regulation, and the means to hasten cooperation among nations. Section I reviews the present international setting of chemical assessment and control. The discussion underscores the many institutional factors that act as barriers to international regulation, including: the dismal quality of existing test data; the reluctance of manufacturers and national governments to make data available on an international level for fear of jeopardizing their competitive market positions; and the lack of the international chemical testing standards needed to overcome the scientific chauvinism of nations which refuse to rely on foreign data as the basis for a domestic regulatory decision.

Against the discouraging background of Section I, the second section recounts the accomplishments and the failings of existing bilateral and multilateral agreements. The section focuses on four current major international initiatives. These initiatives represent a significant improvement over most existing international regulatory efforts because they abandon the

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7. Perhaps the most striking example of the universal nature of toxic chemical problems can be found in the use of DDT. Since its introduction in 1942, DDT has been used extensively throughout the world to increase agricultural productivity and eradicate malaria and other diseases. Yet, because DDT is so pervasive, scientists endeavoring to confirm that it presents a severe and immediate threat to human health are now unable to turn to any uncontaminated control population in the world against which to measure its carcinogenic effects. Henahan, *Whatever Happened to the Cranberry Crisis—A Status Report on the Great Environmental Controversies*, *The Atlantic Monthly*, March, 1977, at 29-30. (Note, however, that while such toxic chemical problems need to be attacked on an international level, the best answer need not entail uniform international regulatory standards. See text accompanying notes 264-268 infra.)

The use of fluorocarbons, a class of man-made chemical compounds, provides a second example of the need for international action. Not until 1974 was their extensive use in aerosols, refrigerators, and air conditioning units linked to depletion of the vital ozone layer of the earth’s stratosphere. In 1973, 1.7 billion pounds of fluorocarbons were produced in 24 countries, and their use was worldwide. U.S. COUNCIL ON ENVIRONMENTAL QUALITY & FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY, FLUOROCARBONS AND THE ENVIRONMENT: A REPORT OF FEDERAL TASK FORCE ON INADVERTENT MODIFICATION OF THE STRATOSPHERE 1 (1975) [hereinafter cited as FLUOROCARBONS AND THE ENVIRONMENT]. Scientists now suspect that the destruction of the ozone layer could continue long after all fluorocarbon releases on earth have ceased, with the full impact not being realized for many years. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, FLUOROCARBONS: AN ASSESSMENT OF WORLDWIDE PRODUCTION, USE AND ENVIRONMENTAL ISSUES, FIRST INTERIM REPORT 2 (1976) [hereinafter cited as OECD, FLUOROCARBONS]. The problem is thus global in origin, in its eventual impact, and in its need for worldwide cooperation to develop an effective solution.

8. See text accompanying notes 226-279 infra.
piecemeal or categorical approach to chemical regulation and instead seek to
develop comprehensive data on the human health and environmental impact
of a wide range of chemicals. The four organizations are: (1) the Interna-
tional Agency for Research on Cancer (IARC), which is assembling
worldwide data on environmental causes of cancer, and seeks to provide
national governments and other international agencies with an expert, inde-
pendent assessment of possible human risks presented by numerous chemi-
cals; (2) the International Register of Potentially Toxic Chemicals (IRPTC),
which will help close the international information gap by providing
complete data on all potentially toxic chemicals; (3) the Organization for
Economic Cooperation and Development (OECD), composed of the non-
communist world's major chemical producing and consuming nations,
which has already achieved a high degree of international environmental
cooperation, and recently proposed a comprehensive, uniform approach to
the assessment and prevention of both short-term and long-term chemical
hazards; and (4) the European Economic Community (EEC), which regu-
lates the classification, packaging, and labeling of dangerous substances,
and has proposed a legal requirement that all new substances be thoroughly
tested, prior to marketing, for adverse health and environmental effects.

Section III analyzes the trade and economic implications of interna-
tional regulation that make nations reluctant to adopt or agree to more
stringent regulatory measures. Whether new restrictions deal with pre-
market testing and conditions of production, or prohibit specific substances,
their predominant impact is to create balance of trade problems and to
provide domestic manufacturers with incentives to relocate testing and
manufacturing facilities in countries with lower safety standards in order to
enjoy lower costs. While this Article argues for the adoption of uniform
international standards for testing and evaluating toxic chemicals as a means
of mitigating the adverse economic impact on environmentally conscious
nations, the short-term prospects for such an achievement are virtually
nonexistent. Section III discusses, as an alternative strategy, various unilat-
eral actions that nations wishing to obtain foreign compliance with domes-
tic health and environmental standards may undertake.

I
THE PRESENT INTERNATIONAL SETTING OF
CHEMICAL ASSESSMENT AND CONTROL

The major efforts to regulate potentially toxic chemicals have
originated in the developed countries of the Western world. This devel-
opment is a reflection of the fact that production and sales of chemicals are
concentrated in the U.S. and Western Europe. While international chemical
production is characterized by a very large number of firms—ranging in size
from some of the largest industrial enterprises in the world to small firms
producing special chemicals for limited outlets—thirty percent of the non-
Communist world's chemical sales are generated by only twenty companies, eight of which are based in the United States and the remainder in Western Europe. In 1972, U.S. consumption alone accounted for almost thirty-five percent of the non-communist world's total chemical sales of $159 billion. Western Europe accounted for a further thirty-eight percent.9

More recently, the countries of the Third World have come to rely increasingly upon chemicals to sustain the progress achieved in the Green Revolution and to raise living standards. Many developing countries are largely dependent on foreign sources for both their chemicals and their toxicological data. In many instances, the apparent benefits of certain chemicals are so significant, and the costs of thorough evaluation so prohibitive in the context of a developing economy, that little, if any, pre-use testing occurs.

Traditionally, economic considerations have motivated manufacturers in developed countries to export chemicals banned for domestic use to developing countries, regardless of the potential hazardous effects. However, as the potential dangers of unregulated toxic chemical use become more apparent, a growing mutuality of interest between developed and developing countries could emerge. Favorable trading relations might be placed in jeopardy through the discovery of hazardous effects for which a warning was not provided. Further, the developed world has a considerable interest in seeking to ensure that the imported raw materials, which are the sine qua non of much of their industrial activity, have not been exposed to persistent toxic substances.10

These trade considerations, and the increasing adverse health and environmental implications of chemical use,11 are factors that should stimulate the development of a broad international data base to facilitate the regulation of toxic chemicals. However, a useful international data base has not emerged due to stronger countervailing factors, such as: the unwillingness of manufacturers to conduct exacting tests and release information which might threaten their competitive position; the reluctance of national governments to release information potentially harmful to domestic industry; the inability of developing countries to devote resources to the production of comprehensive data; and the lack of international standards for chemical testing to promote a degree of uniformity and overcome the reluctance of national governments to rely on foreign data. A brief discus-

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Dieldrin used in Colombian forests penetrates into the wood of teak trees. The trees are cut and shavings from the logs are shipped to Canada for cow litter. The cows munch on the shavings and the result is an unacceptable level of Dieldrin in their milk.

11. See notes 6-7 supra, and accompanying text.
sion of the inadequacies of current chemical hazard testing and the obstacles to the international assimilation of the data will underscore the substantial nature of the task of compiling an international data base.

A. The Nature and Quality of Current Chemical Testing Data

The quality of results achieved in any regulatory program will rarely, if ever, be significantly higher than the quality of the information sources on which they are based. Thus, a comprehensive data base is a prerequisite to any attempt to regulate the production and use of potentially toxic chemicals. "The size and nature of the data base required for hazard assessment will vary with the type of chemical, the availability of pertinent information (toxicity, persistence, and so on) on known chemically related materials, and on the current and/or projected use."12 The first, and most fundamental, impediment to the development of an international data base is the inadequacy of the hazard testing done by the chemical industry.

The level of testing and assessment of new chemicals may vary considerably among manufacturers and among classes of chemicals. Generally, however, a threshold level of testing is essential to assess the utility and acceptability of the product when marketed, and the practicability of its production, packaging, storage, and transportation. Safety considerations constitute but one aspect of the pre-market testing, and in certain circumstances, may necessitate the collection of data to reveal whether any significant hazard is posed to the following: (1) laboratory workers developing the product; (2) production personnel; (3) treatment processes dealing with manufacturing wastes; (4) the natural environment, as a result of waste discharge; (5) consumers, through direct exposure as a result of use or foreseeable misuse of the product; (6) personnel involved in collection and disposal of the product after use; and (7) the environment and man through direct exposure resulting from the use, transport, accidental release, or disposal of the product.13

In addition to the pre-market considerations necessitating the collection of data on new chemicals, a variety of circumstances might compel the conduct of further tests upon a substance that is already on the market:

The development of new information may be necessitated by a change in use pattern or volume of production, by regulations concerning methods of disposal, or by evidence of undesirable effects to man or the environment during manufacture, use or disposal of the chemical.14

For all of these reasons, the chemical industry is the possessor of vast quantities of information relevant to the potential toxicity of its products.15

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12. NAS REPORT, supra note 3, at 146.
13. See OECD, CHEMICAL ASSESSMENT, supra note 9, ¶ 23.
15. In an effort to utilize some of this information, various industry establishments have now been formed, such as the Chemical Industry Institute of Toxicology.
The quantity of information available is but one virtue, for at all stages of chemical production and regulation, critical evaluation of the reliability of data is crucial. Data evaluation is a task often fraught with difficulty and controversy. Information on toxicity is never complete, and a degree of uncertainty in chemical assessment is inevitable in view of the variety of complex environmental interactions to which chemicals are subjected. In addition, the adequacy and accuracy of available information varies considerably from source to source.

The extent to which industry data is accurate and revealing of hazards associated with the use of a chemical depends on the nature of the product and on the disposition and size of the company developing the information, as recognition of the hazard will depend largely upon the specificity and sensitivity of the tests applied. Thus, the person who designs the testing system also substantially controls the findings of toxicity. Many of the large multinational chemical producers maintain their own research and testing laboratories. But a recent survey indicates that “the great majority of chemical companies is, in fact, too small to enable them to support in-house testing for human toxicity and ecotoxicity.” As a result, considerable reliance is placed upon external laboratories. The likelihood of comprehensive and impartial testing by these commercial laboratories has been questioned. At the same time, budget constraints coupled with a lack of expertise hamper governmental reviews.

17. OECD, CHEMICAL ASSESSMENT, supra note 9, ¶ 61. The report cites the example of a medium-sized American chemical company, with a capital investment of $80 million, which employs only two full-time staff in environmental activities. The reasons are clear; a comprehensive toxicological testing program requires a sizeable professional, technical, and clerical staff, expensive laboratory equipment and testing apparatus, facilities for housing and performing tests with animals, as well as office space, and data storage and library facilities. Id. ¶¶ 62-64.
19. The recent experience of the U.S. Environmental Protection Agency in regulating pesticides is singularly instructive in this regard. See STAFF OF SUBCOMM. ON ADMINISTRATIVE PRACTICE AND PROCEDURE OF THE SENATE COMM. ON THE JUDICIARY, 94TH CONG., 2D SESS., THE ENVIRONMENTAL PROTECTION AGENCY AND THE REGULATION OF PESTICIDES (1976) [hereinafter cited as SENATE PESTICIDES REPORT].

In 1972, Congress gave recognition to the fact that many pesticides had been approved and registered for use on the basis of standards which were no longer appropriate. The Federal Environmental Pesticide Control Act, 7 U.S.C. §§ 136-136y (1970), required that the 50,000 pesticide products that had been registered over the past 30 years be reviewed and subjected to a re-registration process. The EPA Administrator was empowered to restrict, suspend, or cancel the use of any pesticide which he determined not to be performing its “intended function without unreasonable adverse effects” on human health and the environment. Id. § 136a. Confronted with such a massive task, EPA determined not to evaluate the safety testing data submitted by pesticide manufacturers. Prompted by a congressional investigation, EPA eventually acknowledged the lack of justification for such an approach:

We originally assumed that toxicological data in our files were derived from testing that generally was scientifically sound, that test procedures and results had been fully and accurately reported, that test reports generally had been reviewed in accordance
The quality of the hazard assessment data being generated must improve, as must the degree of scrutiny by independent sources. Possible solutions to these problems include requirements that data be developed and submitted in accordance with specified standards, that data be independently evaluated or verified by groups possessing the necessary expertise and resources, that a government agency be permitted to nominate a particular laboratory to evaluate data or conduct independent tests, and that the laboratories report directly to the government.

**B. Obstacles to International Data Acquisition**

The problem of poor data quality, resulting from inadequate testing and evaluation, is exacerbated by the reluctance of manufacturers and national governments to make data available for international use. A number of factors discourage the release of information by manufacturers. Foremost among these may be the inability to obtain patented rights to the substance, or to enforce a patent for a sufficient period of time after marketing to cover research costs and yield a satisfactory financial return. Reluctance also stems from the fact that data on newly developed chemical substances may be of assistance in the discovery of further products. Manufacturers are anxious to protect not only the chemical formulae they have developed, but, in addition, marketing information that can be crucial to achieving success.
in highly competitive markets. If the marketing information is made available, competitors may take unfair advantage of the situation. Finally, a company may wish to conceal data in order to avoid unwanted scrutiny of a product's potential toxicity.

As a result of this reluctance to make data available, it has been alleged that a "curious shroud of secrecy surrounds knowledge gained by the pharmaceutical industry about the effects of new drugs." There is good reason to believe that such an assessment is applicable throughout the chemical industry. This practice eliminates any of the potential assessment benefits which might be produced through scrutiny by the industry, academics, and users. Such secrecy or concealment is overcome, at least in part, at the national level by legislation requiring the provision of certain relevant information to the government. In the United States, for example, the Toxic Substances Control Act of 1976 authorizes the Environmental Protection Agency to obtain production, use, and other information on new and existing chemicals, and to require tests to be performed to determine the health and environmental effects of selected chemicals. However, the testing required is dependent upon a threshold finding that the substance may pose an "unreasonable risk," or that it will be produced in "substantial quantities." In Canada, reporting is mandatory for all new chemicals which are to be manufactured or imported in quantities exceeding 500 kilograms in one calendar year. The confidentiality of information collected in this manner is usually statutorily protected, although such a concession to industry is often unwarranted and unnecessary.

At the international level, it is not presently possible to compel chemical manufacturers to provide necessary data for inclusion in international
registers, although this result could be achieved through the adoption of an appropriate international convention. Accordingly, reliance must be placed upon the willingness of the industry and national governments to provide access to relevant data. However, national governments, like chemical manufacturers, may be unable—or unwilling—to contribute information to an international register. The inadequacy or nonexistence of pre- and post-market chemical assessment mechanisms in some countries ensures the inability of those countries to contribute data. Even among the major chemical producing nations, there is considerable variation in the amount of data available and the willingness to voluntarily contribute information to an international program. The confidential status of much of this information may prove to be a major obstacle. Moreover, national self-interest might dissuade a government from prompting the release of significant information by a large-scale domestic manufacturer.

To a certain degree, the success of any present or future international programs involving the collection of data on potentially toxic chemicals will depend upon the extent of cooperation in data collection by the participants, especially those representing the major chemical producing nations. Ultimately, however, the true success of any international data collection program hinges upon the willingness of national governments to utilize and rely upon data from foreign countries. At present, chemical research is being conducted all over the world, yet, in the absence of minimum international standards to provide assurance of the quality of the research, few countries make significant use of foreign data.

35. An indication of this reluctance to provide data can be gauged from the results of the World Health Organization's program to monitor the effects of certain substances on environmental health:

Over the four year period to the end of 1971, the British voluntary reporting rate was nearly ten times that of the United States on a per capita basis. American voluntary reporting of drug toxicity is the lowest, or nearly so, of all countries reporting to the W.H.O. monitoring project; the total number of reports from the whole of the United States for 1971 was one quarter the number reported from Canada.


36. India and several other developing countries have recently expressed concern over the inadequacy of pesticide supply statistics. Industry representatives indicated that publication of supply information was unacceptable in view of the “highly competitive situation” that existed. FOOD AND AGRICULTURE ORGANIZATION, REPORT OF THE AD HOC GOVERNMENT CONSULTATION ON PESTICIDES IN AGRICULTURE AND PUBLIC HEALTH 8-10 (1975) [hereinafter cited as FAO, PESTICIDES IN AGRICULTURE AND PUBLIC HEALTH].

37. “[T]he close association of the industry with national governments would lead one to suppose that governments themselves—especially when it comes to a question of export trade and ‘balance of payments’—take an interest in the protection of industrial interests . . . .” K. BRUUN, L. PAN, & I. REXED, THE GENTLEMEN’S CLUB: INTERNATIONAL CONTROL OF DRUGS AND ALCOHOL 159 (1975) [hereinafter cited as THE GENTLEMEN’S CLUB]. It is alleged that the attitude of the Swiss government towards control of the chemical industry “seems to serve the interests of Swiss drug manufacturers.” Id. at 130. Cf. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, THE CONTROL OF TRADE IN TOXIC CHEMICALS: THE SWISS EXPERIENCE (1976) (paper prepared by the Swiss government).
C. International Acceptance of Evaluations

The United States is a perfect example of a country that historically has been reluctant to accept foreign chemical evaluations and data. In the past, the U.S. Food and Drug Administration has been prepared to accept all foreign data, no matter how unreliable, for the purpose of establishing that a drug was unsafe, but has refused to accept any foreign data showing the efficacy of a drug. According to one industry representative, "under no circumstances will the FDA approve an NDA (New Drug Application) based solely on research done outside the United States." The major justification for such scientific chauvinism has been the desire to minimize the risks involved in the introduction of new chemicals to the American market. The philosophy underlying this approach has been criticized, and the costs against which its benefits should be weighed have been alleged to be enormous. While the debate about the stringency of U.S. standards continued to rage, FDA liberalized its policies relating to the acceptability of foreign chemical data in April, 1975. Continued large scale investment by U.S. corporations in overseas research is likely to strengthen the pressure for further liberalization.

There has been a major change in the geographical distribution of expenditures on chemical research and development in recent years. Facing a notable increase in chemical assessment activities in other nations, the United States will needlessly hinder its regulatory efforts unless it makes greater use of foreign data. At the same time that a sharp drop occurred in the growth rate in drug research and development in the United States, expenditure by other major drug producing countries increased enormously. As a result, total research and development expenditures by the member nations of the European Economic Community are now considerably in excess of those for the United States. In addition, research and devel-

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38. Prior to its 1975 policy change, FDA conceded that its access to data produced by drug studies performed outside of the United States has been limited largely to review of the published literature. As a result, in reviewing a New Drug Application (NDA) submitted for approval the agency has relied almost exclusively on clinical investigations performed in the United States. W. Wardell & L. Lasagna, supra note 26, at 156. Perhaps the ghost of the faulty foreign evaluation of thalidomide continued to haunt the corridors of FDA. See Ragolia, The FDA's Acceptance of Foreign Chemical Data, 30 Food, Drug & Cosm. L.J. 433, 434 (1975).


40. Id. at 434.


44. Id. at 148.
opment staffing in the Japanese pharmaceutical industry is currently three-fourths that of the United States. This situation is partly due to a very significant trend; U.S. based multinationals now perform much of their research and development through their overseas subsidiaries. Thus, in the first third of 1974, one-half of the new chemical entities produced by the fifteen largest U.S. firms were first tested abroad. At the same time, about one-eighth of the total investment in the chemical industry in Western Europe was made by U.S. firms.

A variety of international programs have been designed to facilitate the flow of technical data and information on chemicals. In many instances, these programs are coordinated by United Nations agencies such as the World Health Organization and the Food and Agriculture Organization, usually according to the purpose for which particular chemicals are used. Nevertheless, the extent to which foreign chemical evaluations are accepted varies greatly from country to country. It is perhaps inevitable that, for a variety of economic, social, and political reasons, countries are prepared to accept different levels of risk involved in the introduction of new chemicals. Thus, no matter how comprehensive the flow of information between two countries may be, their respective regulatory approaches to a potentially hazardous chemical may be quite inconsistent. Nonetheless, the information collected by manufacturers, researchers, and regulatory agencies must be viewed as a valuable world resource. A national agency which disregards foreign data, either through neglect or by the establishment of uniquely demanding standards, risks unnecessary expense and duplication, and almost certainly delays the completion of chemical evaluations. One of the major objectives of an international program in this field must be to minimize the potential isolationism, or scientific chauvinism, of national agencies.

45. Id.
47. OECD, Chemical Assessment, supra note 9, ¶ 12.
48. For example, the U.S. and Canada have concluded four separate bilateral agreements relating to food and drugs. They also participate, along with the United Kingdom, in the Tripartite Meetings—regular high-level conferences to discuss and exchange information on health issues. U.S. Food and Drug Administration, International Activities: A Situational Analysis 49-50 (1976) [hereinafter cited as FDA International Report]. Yet the Canadian and U.S. authorities reached different conclusions on the dangers to human health of amaranth, or Red Dye No. 2, which is extensively used in food. As a result of tests on rats indicating that the dye could be carcinogenic, FDA banned the use of the dye in future production. 41 Fed. Reg. 5823 (1976). In Ottawa, the Federal Department of Health refused to ban the dye, and stated in a news release that there was insufficient evidence available to justify a ban. Can. Envt’l L.A. Newsletter, Apr., 1976, at 18.
II
MULTILATERAL COOPERATION IN THE REGULATION OF
POTENTIALLY TOXIC CHEMICALS

The analysis in the first part of this Article delineated some of the institutional problems confronting attempts to develop internationally based data collection and evaluation programs. This section focuses upon four major international programs which seek to promote multilateral cooperation in the regulation of potentially toxic chemicals: the International Agency for Research on Cancer (IARC); the United Nations Environment Programme (UNEP); The Organization for Economic Cooperation and Development (OECD); and the European Economic Community (EEC). Before considering these initiatives in detail, this section will survey briefly some of the other bilateral and multilateral arrangements concerned with potentially toxic chemicals. The survey illustrates the circumstances under which international cooperation has occurred, and provides a background upon which to examine major current developments.

It should be noted at this point that with the exception of the proposed EEC directive, none of the international agreements discussed in this section contain provisions relating to legal enforceability in international forums. Nevertheless, their significance should not be underestimated. As one commentator recognized:

As long as they do last, even nonbinding agreements can be authoritative and controlling for the parties. There is no a priori reason to assume that the undertakings are illusory because they are not legal. To minimize their value would exemplify the old adage that "the best is the enemy of the good." It would seem wiser to recognize that nonbinding agreements may be attainable when binding treaties are not and to seek to reinforce their moral and political commitments when they serve ends we value.  

A. Bilateral Arrangements

Bilateral agreements are frequently used as a means of promoting the adoption of uniform standards. By reaching prior agreement as to the procedures to be followed in testing new or existing chemical substances, it is possible to reduce the incidence of unnecessary research duplication, minimize data collection and evaluation costs, and decrease the time lag preceding the introduction of a drug into a country with higher-than-average standards.  

50. One such initiative is currently being undertaken by FDA's Bureau of Drugs in the development of clinical guidelines for the conduct of investigational drug studies. The bureau will "use informal communications mechanisms to promote their adoption by other countries." FDA INTERNATIONAL REPORT, supra note 48, at 41.
Other types of bilateral arrangements include information exchange agreements, combined research programs, and scientific meetings to discuss topics such as discrepancies between national standards. These types of arrangements are usually important only to the major chemical producing and consuming nations. The vast majority of other countries remain unaffected by most specialist agreements. Even where bilateral agreements are of more general relevance, there may be a risk that the standards endorsed will be excessively stringent and unlikely to be appropriate for adoption on a broader scale by the less developed nations. Moreover, such agreements have to date focused almost exclusively on problems of short-term, rather than long-term toxicity.

B. Multilateral Arrangements

Multilateral cooperation to achieve global environmental objectives can be brought about in two ways. A single country may take the initiative to deal with a specific problem, or a number of countries may work together through existing international institutions. The former course of action is appropriate only where one country is responsible for all, or a large part, of a particular problem, or where unilaterally sponsored action is more likely to provoke cooperation in an area of general concern than multilateral action.

51. See, e.g., id. app. A (Bilateral Agreement Matrix); app. C (International Research Matrix).

52. However, not all specialist agreements are of as little general significance as, for example, the agreement between the United States and Brazil pertaining to the sanitary quality of chocolate liqueur imports. See id. at 60.

53. The agreements between the United States and six other countries relating to the quality of dry milk products, see id., serve as an example.

54. The classic example of this type of approach is the course of action mapped out in a report to the U.S. Council on Environmental Quality with regard to fluorocarbons. See FLUOROCARBONS AND THE ENVIRONMENT, supra note 7. The United States is responsible for just under half of the worldwide production of fluorocarbons. In response to the perceived threat to the ozone layer, the report recognized the desirability of concerted international action, but also outlined a more immediate unilateral strategy to promote global cooperation: Actions will include, but not be limited to, obtaining directly from individual countries information concerning fluorocarbon production and use; research and policy efforts directed at the fluorocarbon-ozone question; encouragement of and cooperation in non-duplicative research with individual countries or within international organizations; expressions of the U.S. concern on this matter in the Organization for Economic Cooperation and Development (OECD) and other organizations, with timely proposals for appropriate action to help bring about uniform treatment of this problem on a world-wide basis.

Id. at 18-19. Within a year of this report, and within two years of the publication of the first scientific paper postulating the adverse effects of fluorocarbons, a large number of international organizations were involved in activities investigating the implications of fluorocarbons. These organizations included the Organization for Economic Cooperation and Development, the United Nations Environment Programme, the International Council of Scientific Unions, the World Meteorological Organization, the International Civil Aviation Organization, the Economic Commission for Europe, and the European Economic Community. Thus, the action initiated by the U.S. government seems to have been effective in mobilizing international concern.
INTERNATIONAL CHEMICAL REGULATION

However, the vast majority of multilateral activities relating to the assessment and regulation of potentially toxic chemicals has resulted not from the action of a single country, but instead has developed within the framework of existing international institutions. The United Nations Conference on the Human Environment recommended that "governments use the best practicable means available to minimize the release to the environment of toxic or dangerous substances" and in doing so should "take into account the relevant standards proposed by competent international organizations." Similar calls to cooperative action in the environmental and scientific spheres were included in the Final Act of the Conference on European Security and Cooperation, concluded in Helsinki in 1975. The result is a complex diversity of U.N. agencies and regionally oriented organizations which are involved, to varying degrees, in international efforts to scrutinize the production and use of toxic chemicals. To illustrate the fragmentation of responsibility which has occurred, the activities of some of these groups will be briefly surveyed.

1. United Nations Environment Programme (UNEP)

UNEP was established subsequent to the 1972 United Nations Conference on the Human Environment to promote international environmental cooperation and to act as a catalyst, stimulator, and coordinator for the work of other agencies and programs. Its major undertaking is the development of the Earthwatch system, which is designed to provide early warning of significant environmental risks and opportunities, and to ensure that governments have access to the best available environmental data. Earthwatch is made up of the Global Environmental Monitoring System (GEMS), the International Referral Service (IRS), and the International Register of For a discussion of the possible international implications of unilateral declarations of national policy or intent, see Rubin, The International Legal Effects of Unilateral Declarations, 71 Am. J. Int'l L. 1 (1977). Rubin is highly critical of an opinion by the International Court of Justice, where the Court held that when it is the intention of the State making the declaration that it should become bound according to its terms, that intention confers on the declaration the character of a legal undertaking, the State being thenceforth legally required to follow a course of conduct consistent with the declaration. Nuclear Test Cases (Australia v. France), (New Zealand v. France), [1974] I.C.J. 253, 267, 457, 472.

56. Id. recommendation 72.
59. See text preceding note 103 infra.
60. See text preceding note 103 infra.
Potentially Toxic Chemicals (IRPTC). The latter is analyzed in detail later in this Article.  

2. Codex Alimentarius Commission

The Commission was established in 1962 to implement the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Food Standards Programme. Its purposes are to protect the health of consumers and to ensure fair practices in the trade, to promote coordination of all food standards work undertaken by international governmental and nongovernmental organizations, to determine priorities and initiate and guide the preparation of draft standards, to finalize standards, and, after acceptance by governments, to publish them as either regional or worldwide Codex standards. Since 1962, the Commission has submitted over 130 standards to member governments. Its work has involved consideration of food additive labeling, food sampling and analysis, pesticide residue problems, and food composition, contamination, and hygiene problems. These activities were further expanded in response to several specific recommendations by the Stockholm Conference.

3. WHO Environmental Health Criteria Programme

The Environmental Health Criteria Programme seeks to develop "criteria documents" which bring together all known information on every aspect of a particular chemical substance. A number of documents have

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61. See text accompanying notes 95-109 infra.
63. H. Roberts, FDA Views on Codex 4 (paper presented at seminar on U.S. Codex Alimentarius, Washington, D.C., Aug. 2-3, 1976). FDA has fully accepted only three of the Codex standards. A majority of the standards have been less stringent than those promulgated by FDA. FDA INTERNATIONAL REPORT, supra note 48, at 41.
65. The Conference recommended that internationally co-ordinated programmes of research and monitoring of food contamination by chemical and biological agents be established and developed jointly by the Food and Agriculture Organization of the United Nations and the World Health Organization, taking into account national programmes, and that the results of monitoring be expeditiously assembled, evaluated and made available so as to provide early information on rising trends of contamination and on levels that may be considered undesirable or may lead to unsafe human intakes. The Stockholm Declaration, supra note 55, recommendation 78. In response, see FOOD AND AGRICULTURE ORGANIZATION, WORLD HEALTH ORGANIZATION & UNITED NATIONS ENVIRONMENT PROGRAMME, REPORT ON METHODS OF SAMPLING AND ANALYSIS OF CONTAMINANTS IN FOOD (FAO Food Control Series No. 3, 1976).
been published recently relating to lead, mercury, polychlorinated biphenyls (PCBs), and nitrates. Other documents in preparation relate to, *inter alia*, cadmium, germanium, manganese, photochemical oxidants, and titanium. The Programme has twenty-three national "focal points" which are responsible for collecting information.

4. **WHO/FAO Pesticides Programs**

As early as 1953, WHO published a monograph on the toxic hazards of certain pesticides to man. Since that time, it has undertaken a variety of programs relating to the control and regulation of pesticides, and has cooperated with FAO in the preparation of the Codex Alimentarius Commission’s recommended international maximum limits for pesticide residues. A considerable amount of information relating to toxicity has been generated in the course of tests and studies of the effects of pesticides. However, it is difficult to determine the extent to which the information is disseminated and utilized on an international basis.

5. **WHO Pharmaceutical Certification Scheme**

A scheme to certify the quality of pharmaceutical products in international trade was adopted by the World Health Assembly in May 1975. The scheme applies only to medicines intended for human use, and depends entirely on the voluntary cooperation of participating countries. It does not have the status of a treaty or convention, and is no more than a general step in the direction of an international drug registration program. Under the scheme, a certificate for a specific product issued by the competent authority of the exporting country indicates: (1) that the product has been authorized for sale or distribution within the exporting country; and (2) that the manufacturing plant in which the drug was produced has been regularly inspected and has complied with WHO’s requirements for good practices in the manufacture and quality control of pharmaceuticals. Importers of drugs that are found to be defective may request that an inquiry be conducted by the competent authorities of the exporting country. Similarly, the latter

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69. In 1967, there were at least 27 international organizations specifically concerned with various aspects of pesticide use and control. WHO, Control of Pesticides, *supra* note 67, at 6.

70. Information on the WHO Pharmaceutical Certification Scheme is taken from WHO Pharmaceutical Certification Scheme, 10 J. World Trade L. 185 (1976).

71. Or, if the drug has not been authorized for domestic distribution, the certificate will state why authorization has been withheld.
should notify the importing country of any serious defects which are discovered prior to export. Finally, the certificate will also include data on packaging, labeling, the nature of the container, date of manufacture, the results of any analysis, and other relevant data.

The scheme is thus quite comprehensive and, if voluntarily adhered to by a significant number of countries, could set a useful precedent for the regulation of other forms of potentially toxic chemicals.

6. **North Atlantic Treaty Organization Committee on the Challenges of Modern Society**

The Committee was established by the North Atlantic Treaty Organization (NATO) in 1969 “to explore ways in which the experience and resources of the Western nations could most effectively be marshalled toward improving the quality of life.” It has sought to avoid duplication of existing regional or international environmental programs and is currently studying various aspects of hazardous waste management, including the disposal of toxic chemicals.

7. **International Chemical Industry Associations**

The inability of international agencies to compel cooperation by chemical manufacturers highlights the significance of trade associations in the development of international regulatory programs. The existence of such groups is now a common feature of the international chemical industry. Their objectives are to coordinate and promote representation of the industry’s viewpoint at the international level, to facilitate the pooling of resources for research and other activities, to maximize collaboration, and to avoid duplication of effort. As a consequence of the large corporations’ scale of operations, they inevitably must dominate the membership and financing of the trade associations, while many small enterprises remain unrepresented. Promotion of the views of individual multinational corporations is achieved through their participation, often within national delegations, in international conferences discussing aspects of chemical regulation. There is also a significant flow of high-level personnel between


74. Prominent among the industry groups are the European Council of Chemical Manufacturers’ Federations, the International Association of the Soap and Detergent Industry, the Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry, and the International Petroleum Industry Environmental Conservation Association. OECD, **CHEMICAL ASSESSMENT**, supra note 9, §§ 69-71.

75. **NAS REPORT**, supra note 3, at 103.

76. For example, the president of the Manufacturing Chemists Association (U.S.A.) “has been directly involved in some phases of the United Nations Environment Program, and currently is exploring how MCA members may assist in the International Register of Potentially
private enterprise and international regulatory agencies.\textsuperscript{77} One recent study that analyzed the role of pressure groups in drug regulation concluded that "during the last decade the pharmaceutical industry has organized itself internationally to enable it to safeguard its interests in the face of international controls."\textsuperscript{77}

On the positive side, growing international awareness of the health and environmental implications of the chemical industry's activities has drawn an appropriate response from many trade associations.\textsuperscript{79} Thus, devices such as "international safety sheets"\textsuperscript{80} have been designed to enable manufacturers to ensure that certain minimum health and safety standards are followed. Unfortunately, the associations are, by their nature, slow moving and prone to adopt a relatively negative posture:

[T]hey take positions that are of necessity consensus positions, usually at the level of a common denominator: this may insulate the [regulatory] agency from information an individual corporation is developing at the leading or cutting edge of a relevant field.\textsuperscript{81}

Yet, the success or failure of international regulation will depend largely on the extent to which individual manufacturers and trade associations can be persuaded, or cajoled, to contribute data and cooperate with suggested regulatory measures.

C. Major Initiatives in the International Chemical Regulation Field

The above overview of bilateral accords concerned with potentially toxic chemicals demonstrates that, although such agreements are frequently used, they have little impact beyond the signatories because of their specificity or stringency. Multilateral agreements, which have evolved primarily through existing international organizations such as the United Nations or NATO, affect more nations. Unfortunately, these agreements have taken a piecemeal approach to the evaluation and control of hazardous chemicals. The result is a confusing multiplicity of organizations, each with a narrow perspective on what is essentially a unified threat to human health and the environment.

\textsuperscript{77} THE GENTLEMEN'S CLUB, supra note 37, at 155.

\textsuperscript{78} Id. at 161.

\textsuperscript{79} For example, the European Council of Chemical Manufacturers' Federations has recently established a Working Party on Protection of the Environment. OECD, CHEMICAL ASSESSMENT, supra note 9, ¶ 69.

\textsuperscript{80} See id. at apps. I-VI.

\textsuperscript{81} NAS REPORT, supra note 3, at 103.
Examined below are four major programs which show promise of overcoming the disadvantages of bilateral and multilateral agreements.

1. **International Agency for Research on Cancer (IARC)**

In the early 1960s, a group of French *savants* proposed the establishment of an international cancer research organization, to be funded by an appropriation of one-half of one percent of the military budget of the nations of the world. Shortly thereafter, in 1965, the Eighteenth World Health Assembly established the International Agency for Research on Cancer (IARC) within the overall framework of the World Health Organization. IARC is based in Lyon, France, and has additional research centers in Nairobi, Singapore, and Jamaica. It has an annual budget in excess of six million dollars, and has collaborated with WHO in drawing up a broadly based long-term plan for international cooperation in cancer research, largely modeled on the programs of the U.S. National Cancer Institute and the Council for Mutual Economic Assistance (COMECON).

IARC has sought not to duplicate the work being performed by national institutions, although international coordination of these activities is an important aspect of its work. Much of its research efforts have been focused upon environmental carcinogenesis, a field which it considered to be "inadequately developed at the national level, and [where] an international research programme with a coordinated multidisciplinary laboratory and epidemiological approach" would be of great value.

In 1967, IARC commenced its program to study chemical carcinogenesis with research on the effects of DDT upon animals. Since that time, four different aspects of the program have developed: the collection of carcinogenicity data in a series of monographs on the evaluation of the carcinogenic risk of chemicals to man; the evaluation of the significance for man of experimental data; the long-term testing of environmental chemicals which are of particular socio-economic importance; and the development of rapid screening tests for potential chemical carcinogens.

The objective of the series of monographs is to provide government authorities with expert, independent, scientific opinion on environmental carcinogenesis, by assembling all available data and evaluating it in terms of possible human risks. To overcome many of the difficulties inherent in the evaluation of diverse sources of technical, experimental, and epidemiological...
chemical data, IARC establishes "working groups" of international experts who serve in individual, rather than official, capacities. Their published reports do not include recommendations for preventive or legislative measures. Such matters are considered to be decisions most appropriately made on the basis of risk-benefit assessments by individual governments and/or broadly based international agencies. By the end of 1976, working groups had screened all relevant epidemiological, experimental, production, and occurrence data for a total of 296 chemicals. Unequivocal or strong circumstantial evidence of carcinogenicity to animals and/or man was found for 163 of the 296.

IARC has already undertaken a number of surveys to ascertain the nature and extent of carcinogenicity testing being carried out by individual institutes or agencies around the world. It also serves as the Secretariat for the International Association of Cancer Registries, which was established in 1969. The Association publishes standardized cancer incidence figures from approximately eighty population groups collected by registries in twenty-eight countries. Despite the coordination achieved through the registries, there remains a marked absence of epidemiological data. In order to remedy this defect, IARC has recently proposed the establishment of an International Cancer Surveillance Network to be developed under IARC's auspices. The proposal makes no mention of UNEP's proposed International

88. INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, SOME CARBAMATES, THIOCARBAMATES AND CARBAZIDES [IARC Monograph on the Evaluation of Carcinogenic Risk of Chemicals to Man No. 12, 1976] [hereinafter cited as SOME CARBAMATES, THIOCARBAMATES AND CARBAZIDES]. However, it is possible that IARC finds such a deferential approach more pragmatic than ideal.

[It is highly desirable that regulatory actions be governed, wherever possible, by scientific evaluation of available data rather than by sometimes ill-informed pressures from the general public as well as from scientific and political circles. IARC REPORT, supra note 6, at 21. The U.S. experience somewhat contradicts this disparaging view of the role of public interest pressure groups. In the United States, such groups have played an important role in drawing attention to dilatory agency response to highly persuasive scientific indicia of toxicity. The statement also ignores the inherently political nature of a majority of decisions relating to chemical regulation resulting from less than perfect scientific data.

89. An analysis of the evaluations of substances made by working groups is as follows:
Chemicals evaluated: 296
Chemicals carcinogenic to man: 20
Chemicals definitely carcinogenic in experimental animals only: 143
Chemicals for which data were inadequate for evaluation or indicated a possible carcinogenic effect: 110
Chemicals for which the available data did not reveal a carcinogenic effect: 23
This information is based on summaries of data reported in the first 12 volumes of the IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man. See IARC REPORT, supra note 6, at 86; SOME CARBAMATES, THIOCARBAMATES, AND CARBAZIDES, supra note 88.

90. INT'L AGENCY FOR RESEARCH ON CANCER INFORMATION BULL., March, 1976, at 6. The survey covers information from 89 institutes in 19 countries, and includes a total of 828 chemicals.

91. IARC REPORT, supra note 6, at 29.
92. Id. at 25.
Register of Potentially Toxic Chemicals (IRPTC). Ideally, the establishment of a network of national laboratories should be undertaken in close coordination with the IRPTC, which could assist in identifying those chemicals which are internationally perceived to present the greatest problems. While carcinogenicity is the most persistent and widespread by-product of toxic chemicals, it is not the only aspect of the international chemical situation in need of coordinated epidemiological study. In addition to the apparently significant relationship between mutagenic and carcinogenic effects, it would seem desirable that a network of the magnitude of that proposed by IARC should address itself to as many aspects of chemical toxicity as possible. A narrower emphasis, restricted to carcinogens, will only tend to perpetuate the existing fragmented approach to the problems of toxicity in chemicals.

2. The International Register of Potentially Toxic Chemicals (IRPTC)

A development with great potential for rectifying many of the problems of international chemical regulation is the proposal to establish, under the auspices of the United Nations, a register of all chemicals which have been objectively assessed to possess either toxic, or potentially toxic properties.

a. Origins

The International Register of Potentially Toxic Chemicals (IRPTC) had its genesis in a suggestion by the Scientific Committee on Problems of the Environment (SCOPE) in preparation for the United Nations Conference on the Human Environment, held in Stockholm in 1972. The proposal to establish an International Registry of Data on Chemicals in the Environment was endorsed by the Conference as part of what later became the Earthwatch program. It was to be based on "a collection of available scientific data on some carbamates, thiocarbamates and carbazides, supra note 88, at 17.

93. It has been observed that a very high percentage of carcinogens are known to be mutagens, and vice versa, although the exact level of correlation is still under investigation. In discussing sources of funding, IARC notes that the proposed network "could also contribute to other studies which might develop in fields such as congenital abnormalities or drug effects." Nothing more specific is discussed. IARC REPORT, supra note 6, at 26.


95. SCOPE is a Committee of the International Council of Scientific Unions. At about the same time as the SCOPE suggestion, the U.N. Advisory Committee on the Application of Science and Technology to Development (ACAST) also considered the establishment of such a Register. Tenth Report of ACAST, 55 U.N. ESCOR, Supp. (No. 6) para. 48, U.N. Doc. E/5288 (1973).

96. See text accompanying notes 58-61 supra.
the environmental behavior of the most important man-made chemicals and containing production figures of the potentially most harmful chemicals, together with their pathways from factory via utilization to ultimate disposal or recirculation.98

The Stockholm Conference focused the attention of the subsequently established United Nations Environment Programme (UNEP) on a variety of urgent concerns ranging across the entire international environmental spectrum. However, the records of UNEP’s governing council indicate that member governments have attached an especially high priority to the establishment of IRPTC.99 As a result, considerable progress has been achieved despite the magnitude of the proposed undertaking.

An international workshop held at Bilthoven, in the Netherlands, in January, 1975, recognized the difficulties inherent in attempting to assemble the information required:

Data on properties may be separated from biological effects data. The use of trade names makes it difficult to associate commercial products with toxicological data. Negative results of toxicological tests are often not reported at all. Information on production and use, if it exists, is not associated with scientific data. Moreover, the existing data are often found in forms that are not utilizable by decision-makers.100

b. Objectives

While the ultimate objective of IRPTC is to reduce the health and environmental hazards presented by chemicals, its immediate aim is to facilitate universal access to existing scientific and regulatory data. IRPTC proposals make little distinction between problems of short-term acute toxicity and longer-term toxicity. In practice, IRPTC’s initial focus will probably be to concentrate upon the short-term effects, as those effects are easier to assess and will provide earlier results which can be used to justify continued financial support for the agency. Its other stated objectives include: encouraging international cooperation in determining the impact of chemicals on man and the environment; encouraging and developing a more open relationship between industry and regulatory authorities, both in industrialized and developing countries, in order to make relevant data more readily available; and providing essential data for the operation of the early warning capability being developed within UNEP’s Earthwatch program.101

98. The Stockholm Declaration, supra note 55, recommendation 74(e).
100. Bilthoven Report, supra note 95, para. 11.
101. Id. paras. 12-13.
c. **Structure**

The Bilthoven Workshop rejected the possibility of establishing a single, all-embracing, central register, and opted instead for a decentralized system consisting of a network of cooperating data collection points and a "central unit." The latter will coordinate the use of information held by network partners and will maintain its own files identifying all chemical substances and the sources where relevant information can be obtained. The central unit will also provide a mechanism for the review of the quality of the data and the overall functioning of the system. In addition, each participating country will be required to nominate a specific individual, or institution, as the IRPTC national correspondent. By the end of 1976, the organizational headquarters had been established in Geneva and a variety of preliminary projects had been undertaken.

d. **Institutional Framework**

In practice, IRPTC will be closely linked to the two other major components of the UNEP Earthwatch program—the International Referral System (IRS) and the Global Environmental Monitoring System (GEMS). It is GEMS' responsibility to monitor the presence of various chemicals in the environment. Relevant information gathered by GEMS at its monitoring stations will be incorporated into the Register and, in the absence of adequate information on a particular chemical, a specific GEMS monitoring program will be sought. IRS is founded on a network of national and international focal points and seeks to provide a worldwide exchange of sources of environmental information. IRPTC will be involved only with specific substance-oriented inquiries. General chemical information that is unsuitable for IRPTC will be retained by IRS. In addition to its efforts to coordinate its work with UNEP, IRPTC will seek to collaborate with the multiplicity of United Nations agencies and outside groups working in the chemical field.

e. **Approach**

The enormous volume of the data which could eventually be expected to be stored in the Register has necessitated an initially selective approach. There will be an "intensive programme" with comprehensive data on a

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102. *Id.* para. 18. It was thought that, while a single central file might be the most efficient approach, there would be "legal, administrative, economic and technical considerations" that might preclude some sources from contributing all of their data to a central system. *Id.*


104. *Id.* paras. 15, 17. IRPTC will not duplicate the work already being done on the hazards of radioactivity by the International Atomic Energy Agency, the International Radiation Protection Association, and the U.N. Scientific Committee on the Effects of Atomic Radiation. It will merely note that a substance contains radioactive nuclides, without incorporating specific data.
relatively small number of chemicals, and an "extensive programme" listing a restricted number of attributes of as many chemicals as possible. The approach, however, will be flexible and will vary according to specific needs and circumstances. A UNEP Task Team Report has proposed use of the following criteria to ascertain which substances deserve priority treatment: physical volume; relevant physical and chemical properties; established distributive mechanisms; estimated exposure of humans; risk to humans; impact on other living organisms; impact on the abiotic environment; needs of priority users; degree of public concern; significance of the chemical to society.105

The Bilthoven Report recommends that, unlike existing programs, IRPTC should not arbitrarily include in its program only those chemicals that are more narrowly conceived to be environmental in use and impact, such as pesticides and industrial effluents, while excluding other chemicals, such as drugs and food additives.106 Such attempts to distinguish between different chemicals according to their use are often counter-productive and foster information gaps in the context of a comprehensive program of this nature. This is a significant point of departure from many of the other international programs relating to potentially toxic chemicals.

f. Types of information

The Register will include information about the physical and chemical properties of substances and all aspects of their known toxicity. It will also attempt to trace the progress of potentially toxic chemicals through the environmental pathways which they may follow. This endeavor will be promoted by the compilation of statistics relating to their production, transportation, use, and disposal. Emphasis will also be placed on the accumulation of information for use in emergency situations, such as major oil spills, chemical explosions, and other chemical-related accidents.

It had originally been proposed that the Register should "provide information concerning national, regional and global policies, regulatory measures, criteria studies, international standards and recommendations, and . . . serve as a basis for draft model legislation."107 However, the enormity of such a task is likely to ensure that IRPTC's activities are confined to referring inquiries to the relevant sources of legal information and fostering efforts to draft model legislation.

g. Data evaluation

The difficulties inherent in evaluating large quantities of data derived

105. Id. para. 30.
107. Id. para. 15(d). Cf. Nairobi Report, supra note 95, at para. 14 (since legislative or regulatory information may be lengthy, use of an international referral system to refer certain questions to individual countries would reduce the need for excessive storage capacity).
from a variety of sources, without the benefit of uniform assessment standards, have been discussed earlier. IRPTC will rely upon existing agencies such as WHO, UNEP, and IARC, wherever possible, to assess and evaluate relevant data. Ultimately, however, the onus will be on the user to evaluate the information provided by IRPTC.

h. Conclusion

IRPTC will play a much-needed role in helping to close the international information gap, which has grown larger as the number and volume of potentially toxic chemicals have increased. It will enable governments and industries in all participating nations to make full use of available information, and will reduce the need for uninformed decision making. IRPTC will also help to avoid unnecessary duplication of research and data storage facilities. It remains to be seen whether it can expand and develop to the stage where its international toxicity standards will command widespread recognition. The experience of the Codex Alimentarius Commission in its related endeavors, undertaken on a smaller scale, does not warrant optimism as to the time scale within which IRPTC is likely to begin to achieve the broader objectives noted above. Nevertheless, in the short run, there is no doubt that it can play an extremely valuable role in disseminating information on a limited range of potentially toxic chemicals.

The ultimate success of IRPTC will depend to a large degree on the extent to which it obtains the cooperation of manufacturers, researchers, and existing international organizations that may be interested in protecting their own more specialized spheres of influence in the field of chemical assessment and regulation.

3. The Organization for Economic Cooperation and Development (OECD)

To date, OECD has achieved a greater degree of international environmental cooperation than any other international group. Since the establishment of its Environment Committee in 1970, OECD has effectively promoted the acceptance of the "polluter pays principle," produced a major "Declaration on Environmental Policy," and specifically focused upon the issue of chemicals in the environment. In many of its endeavors, the organization has worked in cooperation with the specialized agencies of the

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108. See text accompanying notes 16-22 supra.
110. OECD was established in 1960 and its current membership includes Australia, Austria, Belgium, Canada, Denmark, Finland, France, the Federal Republic of Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, OECD AND THE ENVIRONMENT 4 (1976) [hereinafter cited as OECD AND THE ENVIRONMENT].
111. Id. at 12-14.
United Nations and the European Economic Community. Perhaps its most tangible achievement to date has been to restrict the manufacture and use of polychlorinated biphenyls (PCBs) to use for very specific purposes in all twenty-four of the OECD nations.\textsuperscript{112}

The non-Communist world's twenty largest chemical manufacturing corporations are all based within member countries of the OECD.\textsuperscript{113} Its members are also prolific users of chemical products,\textsuperscript{114} making them especially susceptible to any resulting deleterious environmental effects. The organization is therefore uniquely placed to consider the adoption of optimum procedures designed to minimize the adverse effects of chemical manufacture and use on man and the environment.

At the first ministerial level meeting of the OECD Environment Committee,\textsuperscript{115} in November, 1974, the OECD Council recommended: (1) that data relating to the manufacture, import, and sales of chemicals be collected; (2) that procedures be developed to facilitate the assessment of potential environmental effects of chemicals; and (3) that the effects of chemicals on humans and the environment be assessed prior to marketing.\textsuperscript{116} The major objective of the recommendation is to stimulate a concerted approach by member countries to prevent the unintentional environmental ill-effects of chemicals.\textsuperscript{117} Its timing was appropriate in view of the fact that it coincided with consideration by a number of countries, including the United States, of legislative measures to control potentially toxic chemicals. The November, 1974 recommendation is significant in its emphasis on the need for a comprehensive and unified approach to assessing the implications of chemicals for man and the environment. This suggested policy is in contrast to the widely adopted compartmentalized approach. This latter approach had considered chemicals primarily in the context of particular uses, concentrating heavily on chemicals intended for direct consumption by man, such as pharmaceutical products and food additives, and on chemicals that humans were likely to consume indirectly, such as pesticides, deter-

\textsuperscript{112} OECD Council Decision, Protection of the Environment by Control of Polychlorinated Biphenyls (Feb. 13, 1973), \textit{reprinted in id.} at 17-19. The Council resolved that the use of PCBs "should be controlled by international action in order to minimize their escape into the environment pending the realization of the ultimate objective of eliminating entirely their escape into the environment." \textit{Id.} The decision was unanimous, and has since been adopted in national legislation in all member countries.

\textsuperscript{113} See OECD, \textsc{Chemical Assessment}, \textit{supra} note 9, at 8-9.

\textsuperscript{114} See id.

\textsuperscript{115} The governing body of the OECD, the Council, is assisted in its work by a number of specialist committees covering such areas as Economics Policy, Development Assistance, Technical Cooperation, and the Environment. These committees may, in turn, establish even more specialized groups such as the Chemicals Group. The Council, which may meet at the ministerial or official level, usually acts unanimously and can make decisions that are binding on member states. \textit{See A. ROBERTSON, EUROPEAN INSTITUTIONS: CO-OPERATION, INTEGRATION, UNIFICATION} 79-84 (2d ed. 1966).


\textsuperscript{117} \textit{Id.} at 37-38.
gents, and animal feeds. Under the compartmentalized approach, the broader environmental implications of chemical use and disposal were of only incidental significance, despite the possibility that such use might cause extensive harm to materials and biological systems that are beneficial to man’s survival.

As part of its 1974 resolution, the OECD Council also directed its Environment Committee to consider methods designed to achieve “greater collaboration and harmonization in respect of national assessment” of chemicals. As a result, the OECD Chemicals Group has recently considered a set of draft “Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment.” If adopted by the full Council, the guidelines will represent a major step towards the extension of regulatory measures from certain product groups to chemicals in general and the coordinated consideration of environmental and human health factors. The draft urges member countries to take the guidelines into account in establishing new procedures, or extending existing procedures, for assessing the effects of chemicals.

The guidelines represent an attempt to establish a common denominator for chemical regulation acceptable to countries at significantly different stages of economic development. At one point, the draft specifies examples of different regulatory options which may be adopted involving different degrees of stringency and implementation costs.

At the same time, the guidelines attempt to reconcile disparate national approaches to the assessment and introduction of new chemicals. The draft notes that the economic and technical resources available for assessment procedures are limited and, accordingly, recommends that assessment priority be given to: (1) new chemicals; (2) existing chemicals being used for distinctly new purposes or in considerably increased quantities; and (3)
existing chemicals that are newly suspected of being harmful to health or the environment. 121 It suggests that a two-phase approach be adopted in the assessment of chemicals. 122 The first assessment would seek to determine the general likelihood of health and environmental hazards presented by a chemical. Suggested basic data requirements for this stage of assessment are included in the guidelines. 123 The second phase, involving more detailed and intensive testing programs, is to be undertaken where the initial assessment indicates that a substance is hazardous to human health or the environment. 124

The guidelines do not establish a comprehensive mechanism for international cooperation in the conduct of assessment procedures, nor is there any attempt to standardize the evaluative criteria to be applied to chemical substances. However, they do urge the establishment of an integrated approach to assessment "with optimum co-ordination between expert groups established under different authorities." 125 Moreover, the draft recommendation proposes that OECD instruct its Environment Committee "to pursue a programme of work designed to facilitate the practical implementation" of the guidelines "with particular attention to the need for further development and improvement in respect of experimental techniques." 126

The guidelines also address themselves to a number of the major obstacles to international cooperation that have been discussed earlier in this Article. For instance, the guidelines recognize the problem of inaccurate and inadequate data assessment, and encourage thorough monitoring at all stages of chemical production, use, and disposal. 127 The draft also seeks to encourage the broadest practicable collection, dissemination, and exchange of data, and recognizes the potential role which might be played by other international bodies such as IRPTC in helping to achieve this goal. 128

121. Id. para. 5.
122. Id. para. 7.
123. Id. Table I, at 15. The suggested requirements include data on physical and chemical properties, toxicity, and distribution in and pathways of the chemical through the environment.
124. The guidelines also urge that a drug's potential for misuse should be considered when assessing it, and that comprehensive labeling of hazardous chemicals be required. Guidelines, supra note 119, at paras. 22-24. A recent study placed even stronger emphasis on the problem of misuse:

[If] one wishes to reduce the burden of drug toxicity in the community, new drugs are not the place to start. Efforts would be better directed to optimizing the use of all hazardous drugs, rather than to restricting the availability of newer agents, which contribute so minimally to the problem.

W. WARDELL & L. LASAGNA, supra note 26, at 103.
125. Guidelines, supra note 119, para. 18.
126. Id. para. 3.
127. See id. paras. 26-27.
128. See id. para. 27. Unfortunately, the draft sidesteps the issue of confidentiality, urging only that "provisions should be made to ensure protection of confidential information." Id. para. 17. Future elaboration on this point would be desirable. It is hoped that any future
The OECD guidelines are the outcome of prolonged negotiations among member governments and represent a major step towards effective international regulation of chemicals. The guidelines are of particular significance in that they are applicable to all chemical substances, regardless of intended use, and they ensure that environmental, as well as health factors will be assessed. The importance of OECD developments in this field is underscored by the fact that the organization's member countries produce and consume a large proportion of the non-Communist world's total chemical output.

The guidelines do not represent an ultimate achievement in international agreements on toxic chemicals. Nevertheless, they are significant as a starting point for further international cooperation in the field of hazardous chemical control. Those who plan future activities for OECD should consider, *inter alia*: the extent to which commonly endorsed methods for assessment can be devised and accepted on an international basis; the possibility of pooling research and assessment facilities within OECD in order to avoid duplication of effort and to maximize the coverage obtained; the development of post-market screening or monitoring procedures; and the minimization of the confidentiality of information in the interests of all concerned.

4. **The European Economic Community (EEC)**

The European Economic Community is a nine-member group of countries which seeks to improve living and working conditions in member nations through the elimination of national trade barriers, wherever practicable. In seeking to promote the removal of national trade barriers, the Treaty of Rome enables EEC to harmonize anti-pollution and other standards for specific products. Thus, in 1967, the EEC Council approved revision of the guidelines will clearly spell out the obligations of manufacturers and national authorities to release as much relevant data as possible. The existing provision is unduly non-committal, and makes no attempt to strike a balance between the legitimate interests of manufacturers in maintaining the confidentiality of strategic information and the interests of international organizations, the scientific community, and the general public in being able to scrutinize the data upon which the decision to introduce a new chemical or continue manufacture of an existing chemical was based. Compare the recommendation by the Review Panel on New Drug Regulation that the U.S. Food and Drug Administration should publicly disclose information provided by drug companies seeking FDA's approval to market a new drug. Existing procedures were said to be "unnecessarily closed to public review and participation and overly dependent on informal unreviewable communications between F.D.A. and its regulatees." N.Y. Times, May 31, 1977, at 24, col. 1.

129. See text accompanying notes 113-114 *supra*.

130. The member countries are Belgium, Denmark, France, the Federal Republic of Germany, Ireland, Italy, Luxembourg, the Netherlands, and the United Kingdom.


132. The Council of Ministers is the chief governing body of the European Economic Community. The role of the EEC Commission is an executive one. In broad terms, the
an initial directive relating to the classification, packaging, and labeling of dangerous substances. The directive was modest in its scope and limited in its environmental significance, concerning itself principally with better informing the public of the nature of dangerous substances, and protecting the work force involved in the production and distribution of such substances. 

In March, 1973, the governments of the member states agreed to notify the Commission of proposed national environmental legislation that affected EEC's environmental program, or was of particular interest to EEC. Member states which proposed the enactment of new legislation agreed to temporarily defer the measures in order to provide the Commission with an opportunity to consider Community-wide legislative action. The agreement provided an exception for national measures which are "urgently necessary for serious reasons of safety or health."

In November, 1973, the Council approved the principles and objectives
of an EEC environmental policy in the form of a "Declaration Concerning the Programme of Action of the European Communities on the Environment."\textsuperscript{138} The program endorsed the principle of internalizing pollution costs through application of the "polluter pays principle,"\textsuperscript{139} and proposed the development of scientific criteria to measure objectively the extent and cost of pollution damage. More specifically, it sought to encourage the improvement and harmonization of quantitative analysis techniques, the promotion of investigations into the long-term toxicity effect of certain substances, and the standardization of toxicity tests.\textsuperscript{140}

In June, 1975, the French government, in accordance with EEC information agreement of March, 1973,\textsuperscript{141} notified the Commission of its intention to adopt legislation controlling the dispersal of chemical substances in the environment. The Commission subsequently invited the French authorities to postpone the application of the proposed measures so that proposals for joint EEC action could be prepared. The outcome was a proposed directive which is currently before the Commission.\textsuperscript{142} The proposed directive seeks to substantially amend the 1967 directive relating to the classification, packaging, and labeling of dangerous substances.\textsuperscript{143} Although the proposal is legally characterized as an amendment, it is, in fact, substantially more significant than a mere "technical amendment" of an existing directive. Thus, it must be examined by the Council\textsuperscript{144} following its consideration by the Economic and Social Committee and the European Parliament.

The major thrust of the proposed directive is to expand the scope of the 1967 directive by requiring that, prior to marketing any new substance, a thorough assessment of the effects on man and the environment be undertaken and submitted to the relevant national authority.\textsuperscript{145} If endorsed by the Council in its present form, the directive will identify those characteristics

\begin{footnotesize}
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\item[139.] \textit{See id. at 6}. \textit{See also Recommendation of the Council Environment Committee at the Ministerial Level of 14 November 1974, reprinted in OECD AND THE ENVIRONMENT, supra note 110, at 50-52.}
\item[140.] \textit{See Council Declaration of 22 November 1973, supra note 138, at 7-11.}
\item[141.] \textit{See text accompanying note 136 supra.}
\item[144.] Treaty Establishing the European Economic Community, \textit{supra} note 131, art. 100.
\item[145.] \textit{See Draft Directive, supra note 142, arts. 5-7. The directive does not apply to medicinal products, narcotics, radioactive substances, munitions, or food additives, all of which have previously been the subject of EEC action. Id. art. 1(2).}
\end{itemize}
\end{footnotesize}
of the substance that must be investigated and reported. Important characteristics to be included in the investigation are the direct, or indirect, risks to man and the environment arising from the various possible uses of the substances. Manufacturers also would be required to provide notification of any new data or other relevant changed circumstances, such as new uses or substantial increases in marketed quantities.

A second significant aspect of the proposed directive is that it contains explicit criteria for identifying and classifying chemicals into certain groups according to their effect on man and the environment. Article 2 of the existing directive classifies substances and preparations as toxic, harmful, or corrosive on the basis of general definitions. However, the present directive fails to establish specific standards for determining whether a substance falls within the general definitions. Therefore, the proposed directive amends Article 2 to specify precise criteria by which a substance is to be classified, and adds a new category of substances deemed to be "dangerous for the environment."

The provisions of the proposed directive are compatible with OECD's draft guidelines for anticipating the effects of chemicals on man and in the environment. The EEC proposal is a step in the right direction, although, regrettably, the proposed amendments to the directive do not affect the existing provision in Article 1(3), that "the classification, packaging and labelling provisions of this Directive do not apply to dangerous substances exported to third countries."

Other initiatives of EEC are also worthy of note. EEC's Joint Research Centre in Ispra, Italy, is currently engaged in establishing an Environmental Chemicals Data and Information Network which is conceptually similar to the more comprehensive IRPTC. The extent of potential overlap between the two programs is unclear at this stage. The Network's major objective is to facilitate access by national authorities to the multiplicity of sources of information on chemical substances which are presently scattered throughout the European Community. In addition to this project, the Commission is presently considering a number of other proposals indirectly relating to the regulation of toxic chemicals.

146. See id. annex VI (parameters for evaluating the environmental risk of certain substances).

147. Id. art. 6(3). As is the case with the OECD guidelines, see note 128 supra, the draft directive does not adequately confront the issue of confidentiality. It simply proposes that complete confidentiality be accorded to "any information concerning marketing or manufacturing." Id. art. 7(3). Such a sweeping provision would be welcomed by manufacturers, but does not appear to be in the best interests of the scientific community or the public.


149. Id. art. 2(2)(i).

150. See text accompanying notes 118-129 supra.

151. Draft Directive, supra note 142, art. 1(3).

152. See text accompanying notes 95-109 supra.

153. These include: (1) a draft directive concerning the marketing and circulation of phytopharmaceutical products used for protecting crops against diseases, insects, and weeds,
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D. Conclusion

1. The Need for Broader Regulation

The foregoing analysis of existing bilateral and multilateral agreements suggests four major factors that have hindered the development of a comprehensive international approach to the evaluation and regulation of toxic chemicals. First, the international institutional response to the problems of potentially toxic chemicals has been excessively fragmented. The majority of the bilateral and multilateral programs tend to restrict themselves to a narrow range of chemicals, and then seek to examine only a limited aspect of the effects of those chemicals. Most commonly, a program will focus on a specific category of chemicals such as food and food additives, pharmaceuticals, veterinary products, cosmetics and toiletries, radioactive substances, or certain household products, and will analyze the effects on human health while excluding any consideration of environmental effects. Only pesticides have been internationally evaluated for their effects on both humans and the environment. Thus, the intended use of a particular chemical substance determines which potentially adverse effects should be guarded against and with which organization the responsibility for research and evaluation lies. Such artificial categorization tends to overlook the extensive synergistic effects of many chemical substances, and encourages institutional overlap in some areas of concern and total neglect in other areas. This situation is the outcome of thirty years of reaction to particular problems which have, at one time or another, caught the international imagination. However, the four major programs considered above have recognized the need to adopt a comprehensive approach to the assessment of

Commission of the European Community, Europe Press Notice No. 2941, Sept. 1, 1976, at 5 (new series); (2) a draft directive seeking to harmonize member states' legislation concerning materials and objects designed to come into contact with food products, Commission of the European Community, Europe Press Notice No. 2089, Nov. 8, 1976, at 11 (new series); and (3) a draft directive to control toxic and dangerous wastes through the development of a system of safeguards and controls. Commission of the European Community, Europe Press Notice No. 2133, Jan. 15, 1977, at 9 (new series). The proposal was approved in principle by the European Parliament in January, 1977.

154. See text accompanying notes 66-69 supra.

155. The international situation is, in many respects, no more than a composite reflection of the stages of development of toxic chemical controls that have been reached at the various national levels. A recent study of the U.S. approach to control of carcinogenic substances concluded that there are six principal defects in the federal regulatory framework:

A. The lack of both scientific and regulatory information; B. The lack of resources for research and enforcement; C. The hesitancy of agencies to act when carcinogenic hazards are indicated; D. The lack of a comprehensive, coordinated approach; E. The uncertainty of statutory and judicial guidance; and F. The discretion of agencies to consider non-health factors in the decisionmaking process.

all potentially toxic chemicals in relation to their effects upon both humans and the environment.\textsuperscript{156}

2. \textit{The Need for Adequate Data}

The second major barrier to the development of international cooperation is the inadequacy of the existing data relating to the toxicity of chemicals in use. As discussed in Section I,\textsuperscript{157} a variety of factors contribute to this inadequacy, but there is little doubt that the lack of exchange of existing data only exacerbates the problem. A lack of exchange of existing data leads to duplication in testing, which is a waste of resources, and reduces the level of sophistication in testing by denying scientists an opportunity to study and improve upon tests already performed. The international programs analyzed above will make a major contribution towards achieving universal access to existing scientific and regulatory data, will provide a considerable stimulus for the accumulation of new data, and hopefully will improve the quality and sophistication of the data.

3. \textit{The Need for Coordination}

A third problem has been the lack of a single catalyst organization to provide some cohesion and to promote and coordinate the development of a unified international approach to chemical regulation. As IRPTC gets underway in Geneva, IARC is proposing to expand its research and data-gathering activities concerning carcinogenesis, and EEC is establishing an Environmental Chemicals Data and Information Network. It remains to be seen whether IRPTC, which is the most broadly based program of all, will be able to rise above the temptation to act as a mere clearinghouse for information, and serve instead as a catalyst and coordinator for all the international programs. Its success in this role will depend on the vision of its administrators, its level of funding and support within the United Nations Environment Programme, the degree of support it receives from the major chemical producing nations, and the extent to which other international agencies are prepared to work in unison with it. However, the increased exchange of data will not reach its full potential for influencing chemical regulation until the fourth factor hindering international regulation, the lack of internationally accepted standards, is overcome.

\textsuperscript{156} The importance of developing comprehensive programs was emphasized in a recent report on fluorocarbons which concluded that collection of environmental data, the designs of research programmes, and the analysis of institutional approaches to international co-ordination and regulation should be undertaken whenever possible with a view toward meeting a range of needs rather than focusing exclusively and narrowly on a single potential contaminant.

\textsuperscript{157} See text accompanying notes 12-22 supra.
4. The Need for Internationally Accepted Standards

The absence of some form of internationally accepted standards for the evaluation and use of potentially toxic chemicals has been the most significant obstacle to effective international regulation. The United Nations Conference on the Human Environment called for worldwide harmonization of product standards wherever appropriate, although, in deference to the interests of the developing countries, it specifically acknowledged that such standards "should not be expected to be applied universally by all countries with respect to given industrial processes or products." The adoption of uniform international chemical standards would greatly simplify the existing situation and would facilitate an increased global flow of chemicals. It would be especially advantageous to those countries that do not presently have the facilities to satisfactorily evaluate chemical products, and would enable countries to pool their financial and technical resources to a greater extent than at present. In practice, however, the achievement of across-the-board uniformity in international chemical standard setting remains strictly a long-term ideal which may never be fully realized.

Nevertheless, it is important that a number of organizations are working towards the harmonization of chemicals standards in particular fields. In carcinogenesis testing, scientists have expressed the need for standardization of analytical methods to enable them to compare data presented by different laboratories in different countries, and IARC has proposed the development of internationally agreed upon testing protocols. IARC already prepared authoritative evaluations of the carcinogenic risks involved in the use of specific chemicals, although these evaluations only take the form of recommendations.

a. The experience of the Codex Alimentarius Commission

A more elaborate procedure for the development of international standards has been achieved by the Codex Alimentarius Commission, which sets international standards and codes of practice relating to maximum limits for pesticide residues and specifications for the identity and purity of food additives. The experience of the Commission in the pursuit of its objectives is indicative of some of the problems which would be involved in any broader scheme to harmonize international chemical standards.

Since its establishment in 1962, the Commission has achieved a membership of 114 countries. It has proposed 130 international food standards,

158. The Stockholm Declaration, supra note 55, recommendation 103(e).
159. IARC REPORT, supra note 6, at 47.
160. SOME CARBAMATES, THIOCARBAMATES AND CARBAZIDES, supra note 88, at 24. IARC is currently preparing a "Manual of Selected Analytical Methods for Environmental Carcinogens."
161. See text accompanying note 88 supra.
162. See generally CODEX ALIMENTARIUS COMMISSION, supra note 62.
almost 900 international maximum pesticide residue limits, and 14 international codes of practice.\textsuperscript{163} Member countries may subscribe to these standards, limits, or codes by any of three methods—full acceptance, target acceptance within a certain time limit, or acceptance with specified deviations. The recommendations made by the Commission to governments are the product of several years of technical discussions and negotiations,\textsuperscript{164} but they are not necessarily assured of widespread acceptance. By 1976, only forty-seven countries had indicated their full or qualified acceptance of several of the food standards, and only twenty-five countries had done so for several pesticide residue limits.\textsuperscript{165} Because Codex standards are adopted unilaterally, they become binding only after acceptance by a participating state.\textsuperscript{166} Most of the acceptances have come from developing countries.\textsuperscript{167} Despite the relatively low rate of formal acceptances, the process used for the development of standards has often served to focus attention on the problems and to stimulate affirmative national action.\textsuperscript{168}

\textbf{b. The barriers to acceptance of international chemical standards}

It is difficult to see how the creation of international standards for chemicals could be performed any more rapidly or with much greater success than has been achieved by the Codex. Any attempt to establish standards without the incorporation of considerable flexibility and the provision of adequate time for consideration by governments will provoke controversy and opposition and become counter-productive. Harmonization of chemical standards is further complicated by the unique nature of many chemical substances and compounds and their varying conditions of manufacture, use, and disposal. Even the formulation of universally applicable test protocols and procedures presents major difficulties.

Furthermore, the importance of international trade in chemicals and the vital role of chemicals in assisting and promoting industrial and agricultural output provides governments with a strong incentive to either explicitly or implicitly refuse to adopt meaningful standards which might restrict their freedom of action. Even when international standards are adopted, it is often difficult to supervise compliance, and even more difficult to undertake enforcement measures. To this extent, the realization of international standards depends on the preparedness of governments to carry out the obliga-

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\textsuperscript{163} G. Kermode, \textit{supra} note 64, at 3.

\textsuperscript{164} See \textit{Codex Alimentarius Commission}, \textit{supra} note 62, at 31-40 (describing the relevant procedures).

\textsuperscript{165} G. Kermode, \textit{supra} note 64, at 4.


\textsuperscript{167} G. Kermode, \textit{supra} note 64, at 4.

\textsuperscript{168} For example, a recent encouraging development was the enactment of a Nigerian food law that adopted recommended Codex standards for particular food products not covered by national standards. G. Kermode, \textit{supra} note 64, at 5.
tions which they have assumed. Undoubtedly, in some areas of mutual international concern, the incentives to achieve harmonization of standards will be sufficiently strong to enable the conclusion of effective agreements. The incentives will increase as an awareness of the stakes involved in toxic chemical regulation grows and as an appreciation of the tangible rewards that may be reaped from international cooperation emerges. Nevertheless, the road to widespread harmonization of international chemical standards will be long.

c. A code of ethics for international trade in chemicals

In the meantime, the adoption of an international code of ethics, governing the international trade in chemicals, should be considered. Such a code, cast in general terms and requiring a responsible attitude in matters affecting health and the environment, could provide at least a minimum degree of protection in situations where no specific legislative or treaty requirements have yet been devised. For instance, the code could require that every government provide to the government of an importing country a comprehensive statement outlining all available technical data and the domestic legal and scientific status of any chemical substance exported from within its jurisdiction. However, it may be difficult to obtain agreement among nations that such a code is the proper interim step, or if so, what specific provisions should be included. Even if a consensus among enough nations can be obtained to make the code feasible, problems arise as to what action should or can be taken if a violation occurs. In view of these difficulties, such a code should be viewed only as a short-term measure, rather than a substitute for the ultimate goal of harmonizing international chemical standards.

III
TRADE AND ECONOMIC IMPLICATIONS OF INTERNATIONAL CHEMICAL REGULATION

Measures seeking to regulate the international flow of chemical substances may have a profound global economic impact. On the one hand, the chemical industry is a major factor in the economies of most developed nations, and the extent of a country's chemical exporting activity is often a key determinant of its balance of payments situation. On the other hand, many of the developing countries are hopeful that their severe food shortages will be ameliorated by the Green Revolution, which emphasizes the efficient and widespread use of fertilizers, insecticides, herbicides, and a variety of other chemical products. These developments, along with rising

170. See text accompanying note 173 infra.
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expectations, lower mortality rates, and high population growth rates, have increased the reliance of the Third World countries upon imported chemicals. Further, an ever-increasing range and quantity of pharmaceutical products are being developed for human consumption around the world.

In view of the worldwide economic ramifications of international chemical regulation, this section will examine: (1) the extent and significance of international chemical flows; (2) the international implications of disparate national health and environmental standards; and (3) the policy implications of unilateral attempts to encourage compliance with health and environmental standards.

A. The Extent and Significance of International Chemical Flows

Twelve percent of the total export trade of the Western industrialized countries is accounted for by the chemical industry. In some countries this proportion is higher and continues to expand. In West Germany, for example, chemical exports reached a peak of 14.5% in 1974 before declining to 12.4% in 1975. The most recent figures available, for the first half of 1976, indicate a resurgence within the industry resulting in a rate of expansion in excess of that applying to world trade generally. World consumption and production of chemicals achieved a 9.5% per annum growth in volume in the decade up to 1972. In that year, the less developed countries of the world imported $7.75 billion worth of chemicals from the OECD member nations in Western Europe and North America, and the member nations of Japan and Australia. One American firm alone is reported to have sold nearly a half-billion dollars worth of agricultural chemicals worldwide in 1974, while a number of European companies rely on the export market to take up to fifty percent of their annual output.

The magnitude of international trade in chemicals is thus enormous,

171. See text accompanying note 177 infra.
172. While part of the growing extra consumption of human drugs is accounted for by areas which were under-supplied previously, much of it is explained by "iatrogenesis"—the "disease of medical progress." See generally I. Illich, MEDICAL NEMESIS: THE EXPROPRIATION OF HEALTH (1975). Symptomatic of the clinical, social, and cultural iatrogenesis, which Illich discerns in Western countries, is the ever increasing reliance on drugs and the accompanying loss of the individual's capacity to cope unaided with his or her reality.
173. OECD, CHEMICAL ASSESSMENT, supra note 9, ¶ 8. The largest exporters, in descending order, are West Germany, the United States, France, the United Kingdom, and the Netherlands. Id.
175. Id. at 33. But cf. OECD, CHEMICAL ASSESSMENT, supra note 9, ¶ 14 (predicting a lower growth rate in the period to 1980).
176. OECD, CHEMICAL ASSESSMENT, supra note 9, ¶ 7.
177. Id. ¶ 7, at 9 fig. 2. Broken down, the figures indicate that Western Europe accounted for $4.9 billion, North America for $1.7 billion, and Japan and Australia for $1.2 billion. Id.
179. European Chemicals: A Boom in Prospect, supra note 174, at 32.
and any attempts to modify the direction, scope, or nature of the trade will significantly affect the economies of both developed and developing nations.

**B. The International Implications of Disparate National Health and Environmental Standards**

Disparate national health and environmental standards are due, in large part, to policy decisions in each country which emphasize different priorities and set varying degrees of risk acceptance for chemical regulation. These disparities in policy approaches often take the form of differing pollutant emission or product quality standards and differences in the enforcement of standards, which in turn contribute to the differences in costs arising out of comparative technological efficiencies, the availability of substitute inputs, and variations in national economic structures. In a field such as the chemical industry, where large scale capital investment is required and high export levels are usually achieved, the impact of harsher national standards could have a strongly detrimental impact on a country's balance of payments situation. Capital investment may be redirected and export earnings accrue to manufacturers located in countries with lower environmental standards. As will be seen below, these potentially negative balance of payments implications can be partly avoided through international joint action or by unilateral adjustment of the terms of trade. This Article will now examine: (1) the extent to which chemical development, production, and use are the subject of disparate national standards; and (2) the devices by which governments seek to minimize detrimental domestic effects of disparate standards.

1. Disparate National Standards

   a. Standards relating to research, development, and pre-market testing

   The extent to which pre-market testing of toxic chemicals is required varies from country to country according to the proposed uses and exposure patterns, the amount to be produced, the nature of the population likely to be exposed, the potential biological and environmental persistence of the chemical, and a number of other factors. The stringency of the applicable legislative requirements will be a significant determinant of the level of research and development costs incurred in pre-market testing. At the international level, increased export prices could be expected to reduce demand, and thus profits, for most products. A recent study of the likely consequences of the testing requirements incorporated into the U.S. Toxic Substances Control Act, conducted on behalf of an industry group, concluded that a reduction in the chemical trade balance as high as twenty-

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five percent could result. This estimate has been criticized by economists on the grounds that the research and development costs are incurred in any event in relation to domestic production, and need not necessarily be passed on to foreign purchasers. Rather than prejudice their ability to compete in foreign markets, manufacturers may choose to absorb most of the additional costs.

Higher domestic research and development costs may, however, prompt a preference for foreign laboratories and markets. Manufacturers based in countries where the costs of research and development are high as a result of government regulation, may obtain substantial savings by relocating some of their testing facilities in countries with lower standards. Relocation decisions might also be significantly influenced by differing tax provisions relating to research and development, and legal factors such as patent protection.

A recent study of the pharmaceutical industry concluded that stringent regulatory conditions prevailing in the United States since 1962 have proved to be a significant inducement for firms to establish foreign research and manufacturing facilities. A survey of the fifteen largest U.S. pharmaceutical firms indicated that they conducted almost no initial testing abroad prior to 1966. By 1974, the firms were testing one-half of their new chemicals abroad, and the majority of new discoveries were being first marketed overseas. The adoption of stricter regulatory conditions relating to non-pharmaceutical, potentially toxic chemicals could lead to a similar response by non-pharmaceutical chemical manufacturers.

The impact upon the consumer of different standards of pre-market

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181. Toxic Substances Control Act: Hearings on S. 776 Before the Subcomm. on the Environment of the Senate Comm. on Commerce, 94th Cong., 1st Sess. 98, 107 (1976) (statement of George Dominguez, representative of Manufacturing Chemists Association (MCA)) [hereinafter cited as Toxic Substances Control Act Hearings]. The MCA also estimated that, as a result of the passage of the Toxic Substances Control Act, U.S. research and development expenditures would have to increase by 30% in order to maintain the existing rate of product innovation. Id. at 104.

182. Id. at 101.


184. Wardell & Lasagna, supra note 46, at 157 fig. 2.

185. Id.

186. H. GRABOWSKI, supra note 183, at 49. The impact of stringent U.S. regulatory controls has been criticized as disabling the U.S. pharmaceutical industry "to grow in their home market through new product introductions and to obtain an adequate return on their [research and development investment, forcing] firms to give priority to foreign pharmaceutical markets, with eventual commensurate reallocation of their research and development resources, or to diversity into other business areas." Clymer, supra note 43, at 137. In conjunction with this trend, there is usually a considerable time lag before the introduction into the U.S. market of new pharmaceutical products available abroad. One study of new drugs marketed in the United States between 1965 and 1969 indicated that the products had been introduced, on the average, 1 year earlier in France, 1.6 years earlier in Germany, and 2.1 years earlier in Great Britain. W. WARDELL & L. LASAGNA, supra note 26, at 51-52.
testing is not as easily determined as is the effect upon the manufacturer. In considering the overall economic effects of more stringent standards, it has been claimed that greater consumer confidence in the safety of drugs will lead to increased demand, thereby partially offsetting the decrease in demand caused by higher prices.\textsuperscript{187} The major issue, however, is the extent to which the benefits of delaying the introduction of new chemical substances outweigh the resulting therapeutic losses.\textsuperscript{188}

Whatever the outcome of the quest to devise economically and socially optimal pre-market screening requirements for particular countries, the fact remains that different national regulatory standards have a major impact on the location of research, development, and manufacturing activities.

\textit{b. Standards relating to conditions of production}

The chemical processing industries have a very great potential for direct and indirect pollution of the environment and damage to human health.\textsuperscript{189} As a result of this high potential for pollution, measures taken within the chemical processing industries in an attempt to protect the environment can involve enormous costs.\textsuperscript{190} Additional substantial outlays

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\item\textsuperscript{187} \textit{Toxic Substances Control Act Hearings}, supra note 181, at 102. However, at least as far as prescription drugs are concerned, consumers often lack safety information. Further, they often lack the ability to choose whether to use a particular drug, as this decision generally is made by the prescribing physician. See Padway, \textit{Federal Regulation of Ritalin in the Treatment of Hyperactivity}, \textit{7 ECOLOGY L.Q.} 457 (1978) (suggesting requirements for the distribution of a federally approved "drug label" to the parents of those children receiving Ritalin for the treatment of hyperactivity).
\item\textsuperscript{188} Comprehensive pre-market testing requirements often involve lengthy marketing delays. For example, over the last fifteen years, the time necessary to conduct the required toxicological studies on pesticide compounds is estimated to have increased from a minimum of thirty days to four years or more in some cases. The associated costs have risen, due to more stringent testing and inflation, from $10,000 to as much as $700,000. OECD, \textit{Chemical Assessment}, supra note 9, \textsuperscript{80} See also id. \textsuperscript{82} Another study has indicated that substantial benefits have been foregone by U.S. consumers as a result of new drug introduction delays. S. Pelzman, \textit{supra} note 41, at 83.
\item\textsuperscript{189} Evan, \textit{Socio-Economic and Labour Aspects of Pollution Control in the Chemical Industries}, \textit{110 INT'L LAB. REV.} 219 (1974). This potential is a function of the following characteristics of the industries: (1) the diverse nature of the raw materials used, and the highly imperfect state of knowledge relating to their direct and synergistic effects on the environment; (2) the production of large quantities of liquid and gaseous effluents, and the subsequent need to dispose of both the hazardous and non-hazardous waste; (3) the use of large energy inputs and the consequent problems of air and water pollution; (4) the need to handle large quantities of potentially hazardous materials under a variety of conditions; and (5) the generation of significant hazards in the working environment during the manufacture and distribution of chemicals and chemically based products.
\item\textsuperscript{190} This is well illustrated by recent U.S. experience. For the past 30 years, the chemical industry has been among the most profitable and rapidly growing in America. \textit{Environmental Quality}, supra note 1, at 160. With the advent of wide-ranging anti-pollution legislation, the required pollution control expenditure by the industry is exceeded only by that of the electrical power and petroleum industries. \textit{Id.} at 166-67. It has been estimated that chemical plants in the United States are presently spending about 11\% of their total plant and equipment expenditures
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may be necessitated by advanced occupational health and safety requirements. There has been a growing awareness of the occupational hazards faced by workers in the chemical industries. Legislative health and safety measures may require the replacement of toxic chemicals with less harmful substances, or even the complete abandonment of a particular process. Where the production of toxic chemicals cannot be completely eliminated, a variety of preventive measures may be taken to enhance the degree of safety surrounding the production process. These could include: increased mechanization; the development of remote control processes; the use of continuous instead of batch processes to reduce the risk of leakages in enclosed production systems and to minimize manual operations; the sealing of equipment and pipelines; increased regular maintenance of equipment; safety conscious design of plants and equipment; and periodic medical examinations of workers to detect any adverse effects due to industrial pollutants.\footnote{Roshchin, Protection of the Working Environment, 110 INT'L LAB. REV. 235 (1974).}

The high costs of compliance with pollution abatement and industrial health and safety requirements are especially significant for smaller firms, which may not have the technical or financial resources to overcome these problems.\footnote{ENVIRONMENTAL QUALITY, supra note 1, at 161.} Even in circumstances of high demand and substitution inelasticity, where additional costs can to a large degree be passed on to the consumer, reduced percentage returns on investment may prompt consideration of plant closure or relocation in a country where the relevant standards are less stringent and costs are not as high.\footnote{On possible strategies for slowing or preventing such relocation, see text accompanying notes 244-258 infra.} Further disincentives to location in countries with highly developed health and environmental standards are the costs of adopting new methods of production in the face of the delays inherent in decisionmaking by a cumbersome, often fragmented, bureaucratic regulatory structure and the uncertainties surrounding the application of changing technological, environmental, and medical standards. These drawbacks can be ameliorated in part by efficient administrative procedures, but the fact remains that, from the manufacturer's viewpoint, "a heavy burden will have to be borne by the chemical industries in terms of investments, operations, research, slower innovation, lost growth and employment opportunities, and increased risk."\footnote{Evan, supra note 189, at 227.}

The significance of these factors encouraging relocation of production facilities becomes apparent in view of the major disparities that exist between countries in relation to regulatory requirements for the protection of pollution control, including $9 billion over the next 10 years for water pollution treatment alone. Id. at 161. A similar situation exists in the other industrialized countries such as Germany, Japan, and the Netherlands. Evan, supra note 189, at 224.
health and the environment, and will be considered later, in the context of industrial relocation.195

c. Standards regulating or prohibiting the use of specific substances196

Whenever one country imposes restrictions on the use of a particular chemical substance or compound, problems are created with respect to imports and exports of offending products.197 If a country's trading partners refrain from regulating the products in question, or adopt different standards, then appropriate import safeguards must be implemented. Where exports are concerned, manufacturers may or may not be permitted to continue the production of domestically offensive goods for export purposes. If they are not, they must either export the modified product or forego the foreign market. Even if unmodified exports are permitted, the manufacturer will have to bear the additional costs of developing and maintaining two different production lines for similar products.

The consequences of disparate national standards for domestic use may be particularly severe for less-developed countries. The costs of compliance with stringent export standards are less easily absorbed by the often technologically unsophisticated and less versatile industries established in developing nations.198 The burden is increased when exports are destined for several markets with different standards. The imposition of more rigorous environmental standards on products exchanged in international trade could also give rise to a form of "neo-protectionism." "The real danger is if the environmental standards enforced by the developed countries are unrealistic and unilateral and are arbitrarily invoked by them to keep some of the exports of the developing countries out of their own markets."199 It is necessary to consider the means by which the domestic impact of divergent national standards may be exacerbated or avoided.

2. Devices by which Governments Seek to Minimize the Domestic Impact of Disparate Standards

There is already in existence a considerable body of literature outlining the export and import control devices that may be employed by governments seeking to minimize the domestic impact of disparate national environ-

195. See text accompanying notes 244-258 infra.
mental and health standards. A brief examination of the approach adopted in the United States will illustrate the problems and approaches of a large number of countries.

In 1972, the amendments to the Federal Water Pollution Control Act included recognition of the problem of unevenly incurred costs associated with disparate national standards. Congress directed the Secretary of Commerce to undertake an extensive study to determine, inter alia: (1) the impact of pollution abatement and control programs upon production costs and market prices of domestic manufacturers; (2) the extent to which similar programs would be initiated in foreign countries and the resulting costs; (3) the probable competitive advantage of a foreign manufacturer who is not subject to such pollution control programs or who receives government subsidies for such programs; and (4) the means by which any such advantages may be determined and offset. The resulting reports by the U.S. Commerce Department indicated only that the cost of environmental requirements "will have significant economic consequences" and substantially affect the U.S. trade position. The reports concluded that greater specificity was not possible in circumstances characterized by the absence of detailed and reliable data and, in the case of foreign estimates, reluctance by governments and manufacturers to disclose information which was unlikely to be used in their best interests.

a. Import restrictions

The Trade Act of 1974 contains provisions that increase the power of the federal government to compensate for or reverse the adverse impact upon U.S. trade arising from the different levels of environmental control costs incurred by producers in foreign countries. The Act employs two


203. Id. at 3.


major strategies. First, the President may grant "import relief" where increased quantities of imports are "a substantial cause of serious injury or threat thereof, to the domestic industry producing an article like or directly competitive with the imported article." The relief may take the form of an increase in duty on the imported article, a tariff-rate quota, a quantitative restriction on the import of the article, or the negotiation of an orderly marketing agreement with the foreign exporter. Unlike this first strategy, which seeks to offset the impact of "legal" trade practices that injure U.S. manufacturers, the second strategy seeks to combat the use of "unfair" or "illegal" trade practices by a foreign country through retaliatory action devised at the discretion of the President. The President may take "all appropriate and feasible steps within his power" to eliminate the "unfair" practice, and specifically may suspend, withdraw, or refuse to implement trade agreement concessions with the offending country, or may impose new duties or other import restrictions.

206. 19 U.S.C. § 2251(b)(1) (Supp V 1975). Although the President makes the final determination as to the appropriateness and form of relief prior to any action, the International Trade Commission must report to the President on the injury or threatened injury from a particular import, and recommend whether relief is warranted. A Roadmap to the Trade Act, supra note 205, at 151. The "substantial cause" language of this section broadens the circumstances under which import relief may be granted. Prior to the adoption of § 2251, import relief could be granted only where the increased imports were "the major factor in causing, or threatening to cause, such injury." Pub. L. No. 87-794, § 301(b)(3), 76 Stat. 883 (1962) (emphasis added).

207. A tariff-rate quota imposes a tariff only on those items that exceed a specified and allowable quantity for that good. A Roadmap to the Trade Act, supra note 205, at 153 n.204.


209. To invoke retaliatory action under the Trade Act, the President must determine that the foreign country:

(1) maintains unjustifiable or unreasonable tariff or other import restrictions which impair the value of trade commitments made to the United States or which burden, restrict, or discriminate against United States commerce,

(2) engages in discriminatory or other acts or policies which are unjustifiable or unreasonable and which burden or restrict United States commerce,

(3) provides subsidies (or other incentives having the effect of subsidies) on its exports of one or more products to the United States or to other foreign markets which have the effect of substantially reducing sales of the competitive United States product or products in the United States or in those other foreign markets, or

(4) imposes unjustifiable or unreasonable restrictions on access to supplies of food, raw materials, or manufactured or semimanufactured products which burden or restrict United States commerce.

Id. § 2411(a)(1)-(4). Unfair trade practices might include discriminatory tariffs or quotas relating only to U.S. goods, or the subsidization of pollution abatement costs in order to enhance the competitiveness of exports.

210. Id. § 2241(a)(A), (B). The President's discretion to implement a retaliatory strategy is limited somewhat by the following subsection, which provides that the President shall not take such action unless:

(1) the Secretary of the Treasury has found that such country or instrumentality provides subsidies (or other incentives having the effect of subsidies) on such exports;

(2) the International Trade Commission has found that such exports to the United States have the effect of substantially reducing sales of the competitive United States product or products in the United States; and

(3) the President finds that the Antidumping Act, 1921, and [19 U.S.C.] section 1303 . . . are inadequate to deter such practices.

Id. § 2411(c)(1)-(3).
b. Exemption of exports from domestic standards

A second means of minimizing the adverse impact of lower environmental control costs on the domestic economy is to require imports to comply with domestic standards for the product while exempting exports from those stringent requirements. For example, in the United States, domestic standards for food, drugs, and pesticides apply equally to imported goods. In contrast, exports are generally not required to comply with domestic standards. Pesticide exports are permitted as long as they are in compliance with the specifications of the foreign purchasers, and limited data are supplied to the Environmental Protection Agency upon request. The only safeguard required is State Department notification to the importing nation of final suspension and/or cancellation of the registration of a pesticide. Until such action is final, foreign purchasers are not required to be notified that a product is suspected to be hazardous. Export regulations for products regulated by the Food and Drug Administration are not entirely consistent from product to product. In general, however, food, drug, and cosmetic exports are permitted if they conform to the specifications of the user and the laws of the purchasing country and are labeled as exports.

c. A balanced approach

The Toxic Substances Control Act of 1976 seeks to achieve a balance between the interests of domestic producers, the interests of exporters, and the interests of foreign buyers wishing to import chemicals that are known, or suspected to be toxic. In general, with the exception of the provisions requiring the reporting and retention of information, the Act does not apply to chemicals that are produced for export purposes and are clearly so identified. However, the EPA Administrator may find, or require testing to determine whether a chemical to be exported will present an unreasonable risk of injury to health or the environment within the United States. Where the Administrator does find an unreasonable risk, all of the provisions of the Act shall apply to that chemical.

211. Although the stated policy is to apply domestic standards, in practice it is often difficult to ensure that the imports comply in all respects with those standards. See generally FDA International Report, supra note 48. The FDA devoted 195 man-years to its domestic import surveillance program in fiscal year 1976. Id. at 21.


213. Id. § 1360(b).

214. For a general analysis of the export provisions for the various products regulated by FDA, see FDA International Report, supra note 48, app. B.

215. Id.


217. Id. § 2607.

218. Id. § 2611(a)(1).

219. Id. § 2611(a)(2).

220. Id.
not empowered to make such a finding with respect to the health or environment in a foreign country. However, the Act seeks to protect foreign interests by requiring the Administrator to notify the government of an importing country that all testing data pursuant to the domestic provisions of the Act will be made available to it.\(^2\)\(^2\)\(^1\) In addition, notice of any domestic administrative or judicial rule, order, action, or relief, currently pending or previously issued under the authority of the Act, must also be furnished.\(^2\)\(^2\)\(^2\)

The importation of chemicals into the United States is permitted only in accordance with the domestic requirements of the Act.\(^2\)\(^2\)\(^3\) Thus, foreign chemicals must comply in all respects with domestic standards.

It can be seen from the foregoing survey of U.S. law that there are a number of devices, primarily import restrictions and the exemption of exports from domestic standards, by which a government may seek to offset foreign trade disadvantages that might otherwise result from domestic health and environmental protection measures. It is also apparent that these various devices and justifications could be used to mask broader discriminatory or protectionist motives.\(^2\)\(^2\)\(^4\) Such protectionism may be detrimental to the interests of the developed and less-developed countries alike. Imported chemicals play a significant role in the quest of the less-developed countries for increased industrial development and improved agricultural techniques. Similarly, chemical exports are a major source of income for many of the industrialized countries which are grappling with growing balance of payments deficits and unacceptably high levels of unemployment and inflation. Both groups are therefore anxious to ensure that no one country is able to take undue advantage of disparate national standards to promote its own welfare at the expense of others.

In seeking to minimize such advantages, two strategies are available. The first strategy—the adoption of uniform international standards for the regulation of toxic chemicals—was discussed above.\(^2\)\(^2\)\(^5\) However, standardization is a slow and cumbersome process. The fact that such standardization must be viewed as a long-term solution makes the second strategy even more attractive. Under this second approach, examined below, an individual country acts unilaterally to encourage other countries to comply with its domestic health and environmental standards relating to potentially toxic chemicals.

\(^{221}\) Id. \$ 2611(b)(1).
\(^{222}\) Id. \$ 2611(b)(2).
\(^{223}\) Id. \$ 2612(a)(1).


\(^{225}\) See text accompanying notes 160-168 supra.
C. Policy Implications of Unilateral Attempts to Encourage Compliance with Health and Environmental Standards

There are a number of ways in which national authorities might seek to encourage foreign compliance with domestic health and environmental standards relating to the production and export of chemical substances.\textsuperscript{226} In general terms, such objectives can be promoted by action in the areas of trade, foreign aid, and the transfer of technology. To a large extent, the issues revolve around the relationship of the industrialized countries to their poorer and less developed trading partners. Some commentators assert that the dictates of international morality, not to mention environmental self-interest, oblige the industrialized countries to seek to prevent a repetition in the less-developed countries (LDCs) of the uncontrolled exploitation of the environment which has accompanied large scale industrialization.\textsuperscript{227} Others reject such an approach as being "paternalistic" and argue that the LDCs must determine their own priorities.\textsuperscript{228} They point to the dilemma faced by nations with millions of undernourished or malnourished people, where a choice must be made between the production of less food or the use of environmentally damaging pesticides to protect crops and increase yields. The policy implications of these approaches with respect to particular unilateral actions that might be taken in the field of international chemical regulation are analyzed below.

\textsuperscript{226} This Article does not attempt to consider the international implications of air and water pollution problems that might result from the activities of the chemical industry. These aspects have been dealt with at length elsewhere. The most useful general guide to the literature is GRIEVES, INTERNATIONAL LAW, ORGANIZATION, AND THE ENVIRONMENT: A BIBLIOGRAPHY AND RESEARCH GUIDE (1974). See also United Nations Conference on the Human Environment: Bibliography, U.N. Doc. A/Conf. 48/13/Rev.1 (1972); Nanda, The Establishment of International Standards for Transnational Environmental Injury, 60 IOWA L. REV. 385 (1975); S. McCaffrey, Private Remedies for Transfrontier Environmental Disturbances (International Union for the Conservation of Nature and Natural Resources Environmental Policy and Law Paper No. 8, 1975); Schneider, State Responsibility for Environmental Protection and Preservation, 2 YALE STUD. WORLD PUB. ORD. 32 (1975); Hoffman, State Responsibility in International Law and Transboundary Pollution Injuries, 25 INT'L & COMP. L. Q. 509 (1976).

\textsuperscript{227} See, e.g., Strong, International Law and International Morality, 10 L. SOC'Y GAZETTE 83 (1976).

\textsuperscript{228} Pollution has been characterized as a "rich man's disease" which the poor countries would be delighted to contract because of the industrial development with which it is usually associated. Long, Identifying Environmental Options in Development, 69 DEV. DIG. 34, 35 (1971).

Developing countries have of late been warned of the price that has to be paid in the form of environmental pollution for industrial development. All developing countries are aware of the risks, but they would be quite prepared to accept from the developed countries even 100 percent of their gross national pollution if thereby they could diversify their economies through industrialization.

1. **Requirements that Imports Meet Domestic Product Standards**

The right and responsibility of national authorities to ensure that imported products do not present a threat to domestic health or environment are beyond dispute. The most efficient and appropriate means to achieve this objective is to require that imports comply with the standards for domestically produced goods. The difficulty lies in determining whether the imposition of a particular domestic standard was undertaken for legitimate environmental purposes, or to protect a domestic industry from foreign competition.

Custom procedures, and national certification and licensing requirements, being extremely discretionary, may constitute a substantial nontariff trade barrier. ... [R]egulations may be structured intentionally to be protectionist in nature, or may act as trade barriers designed to mitigate the impact of domestic costs, especially if designed to facilitate compliance by domestic producers.

In any event, potentially adverse effects may be mitigated if adequate notice is given to suppliers and an attempt is made to cushion any impact that would otherwise be particularly disruptive. Where international product standards do exist, they should act as a further safeguard against the unilateral imposition of arbitrary, unrealistic, or discriminatory standards.

2. **Requirements that Imports be Manufactured in Accordance with Specific Environmental and Health Standards**

It has been argued that the fundamental importance of global environmental responsibility could justify a country in discriminating against any imported goods that it considers to have been produced in circumstances

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229. The GATT specifically permits the imposition of measures "necessary to protect human, animal or plant life or health." GATT, supra note 224, art. XX. However, the exception is subject to the limitation that such measures are not to be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. Id. See also Kirgis, supra note 200, at 901.


232. It has been suggested that the international product standards developed for food and pesticide residues by the Codex Alimentarius Commission might serve this function through the GATT. Groetzinger, The New GATT Code and the International Harmonization of Product Standards, 8 CORNELL INT'L L. J. 168 (1975). The Stockholm Declaration warned that environmental standards should not be "directed towards gaining trade advantages." The Stockholm Declaration, supra note 55, recommendation 103(e). The Declaration further recommended that arrangements be made to "monitor, assess, and regularly report the emergence of tariff and non-tariff barriers to trade as a result of environmental policies." Id. recommendation 105.
grossly detrimental to health or the environment.\textsuperscript{233} This proposition applies to goods that are not \textit{per se} hazardous to health or the environment in the importing country. The argument is based on the view that an importing country should not implicitly support the willful and perhaps unnecessary degradation of a foreign environment. One proponent of this view has suggested the implementation of the following provision as part of the Draft Convention on Environment Cooperation Among Nations:\textsuperscript{224}

A State Party to the present Convention may prohibit the entry into its territory of goods, [if such] goods or the production or distribution thereof have caused pollution in the country of origin or other countries, provided:

\begin{itemize}
  \item[a)] that such pollution in whole or in part was due to insufficient measures of pollution control,
  \item[b)] that sufficient measures have been undertaken with respect to the production of similar goods, if any, in the State issuing the prohibition, or at least measures implying a greater degree of pollution control, and
  \item[c)] that the difference in respect of pollution control will influence the competitive position of imported goods in relation to goods of domestic production, or, as the case may be, goods from a third country applying sufficient or more severe measures of pollution control.\textsuperscript{235}
\end{itemize}

In this context, a distinction must be made between activities that have purely domestic environmental implications for the exporting nation, and those that might have regional or even global consequences. It is clear that a legitimate area of official international concern exists where effects are felt beyond national boundaries.\textsuperscript{236} Thus, if a major chemical producing plant refused to abate its discharge of toxic effluents into international waters, a ban on the import of its products would be warranted.\textsuperscript{237} Similarly, it can be

\textsuperscript{233} See Founex Report, \textit{supra} note 199, at 30.

\textsuperscript{234} World Peace Through Law Center, Draft Convention on Environment Cooperation Among Nations (undated).

\textsuperscript{235} \textit{Id.} art. XLIV. \textit{Cf. id.} art. VIII (signatory state need not meet the Convention's anti-pollution requirements if the pollution is confined to its own territory).

\textsuperscript{236} It is a strongly established principle of international law that a state may not use or permit the use of its territory in such a manner as to cause substantial damage in another state. Lac Lanoux Arbitration (France v. Spain), 12 R. Int'l Arb. Awards 281 (1963) (in the original French), 53 Am. J. Int'l L. 156 (1959) (condensed English translation); Trail Smelter Arbitration (United States v. Canada) 3 R. Int'l Arb. Awards 1905 (1949), 35 AM. J. INT'L L. 684 (1941); Corfu Channel Case (United Kingdom v. Albania), [1949] I.C.J. 4. See generally Bleicher, \textit{An Overview of International Environmental Regulation}, 2 ECOLOGY L. Q. 1, 9-30 (1972).

\textsuperscript{237} Thus, the United States has acted to protect internationally shared resources. The importation of whale products is banned under the Marine Mammal Protection Act. 16 U.S.C. § 1371 (Supp. V 1975). The importation of certain fisheries products may be banned under the Fisherman's Protection Act from foreign countries whose nationals are conducting fishing operations in a manner inconsistent with international fishery conservation programs. 22 U.S.C. § 1978 (Supp. V 1975). In both these instances, the jurisdictional issues are relatively clear cut because the locus of the offending activity is not within national territory. See also note 243 infra, concerning the Ribicoff Amendment to the Tax Reform Act of 1976.
argued that where the intensity of environmental degradation occurring within a country amounts to a denial of basic human rights, a legitimate cause for international concern is presented which justifies unilateral or multilateral action against goods manufactured under such conditions. This argument for international action is analogous to situations where wholly domestic acts of genocide, apartheid, and torture have been recognized as practices violative of international human rights; thereby constituting legitimate causes for international concern.

In circumstances where direct international concern is not so clearly justified, the imposition of such sanctions should be undertaken only with the utmost caution. If caution is not observed, the dangers inherent in this form of international action are manifold, and include the following: (1) the decision to prohibit the import of a product might not take account of those unique environmental characteristics of the exporting nation which might justify a less stringent environmental standard; (2) difficulties could arise in determining whether sanctions were justified in the particular circumstances; (3) sanctions would be particularly attractive to countries seeking to develop protective barriers for their own goods under the guise of altruistic concern for environmental or human rights; and (4) such an approach would provide an irresistible opportunity for the neo-imperialistic or paternalistic imposition of the wealthier countries' preferences. As the Founex Report concluded:

When the concern spreads from the quality of a product to the environment in which such a product was produced, the alarm bells should ring all over the world, for it would be the beginning of the worst form of protectionism.240

238. The first principle of the Stockholm Declaration of the United Nations Conference on Human Environment declares that:

Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations . . . .

The Stockholm Declaration, supra note 55, principle 1. In the Nuclear Test Cases, Australia and New Zealand asserted that French nuclear testing in the Pacific amounted to a violation of international human rights. A majority of the International Court of Justice declined to rule on the merits of the case on the basis that it had become moot as a result of France's termination of nuclear testing. Nuclear Test Cases (Australia v. France) (New Zealand v. France), [1974] I.C.J. 253, 457.

239. See generally Humphrey, The International Law of Human Rights in the Middle Twentieth Century, in The Present State of International Law and Other Essays 75 (M. Bos ed. 1973). Only one commentator so far has undertaken an examination of the concept of human rights in relation to protection of the environment. W. Gormley, Human Rights and Environment: The Need for International Co-operation (1976). The book is largely devoted to consideration of a proposal within the Council of Europe to guarantee the human right of individuals to "a pure, healthful, and decent environment." The proposal envisages that legal obligations resulting from the creation of such a right could, in some circumstances, be directly enforced by individuals, groups, and non-governmental organizations. Id. at 74.

240. Founex Report, supra note 199, at 31. The report also warned that "humanitarian concern for environment can far too easily become a selfish argument for greater protection-
Where the practice giving rise to international concern involves a threat to the health of workers who may be engaged in chemical production under hazardous conditions, adequate international remedies already exist. The International Labor Organization has, over a period of almost sixty years, developed a network of international standards and conventions relating to occupational health and safety.\textsuperscript{241} The enforcement mechanisms of these conventions provide the appropriate means for countries to express their concern over hazardous foreign employment conditions.\textsuperscript{242}

One other weapon that should also be considered as a possible means of influencing the environmental policies of other countries is the unofficial imposition of a consumer boycott of specific products, or of all imports from an offending country.\textsuperscript{243} The effectiveness of such an approach will vary according to the perceived significance of the offensive conduct and the elasticity of demand for the product.

\textsuperscript{241} Evan, \textit{supra} note 189, at 233. The General Conference of the International Labor Organization adopted an Occupational Cancer Convention in 1974, which includes, \textit{inter alia}, requirements that ratifying states: endeavor to replace carcinogenic substances to which workers may be exposed; periodically determine the carcinogenic substances to which occupational exposure shall be prohibited or made subject to authorization or control; and prescribe measures which should be taken for the protection of workers. Convention Concerning Prevention and Control of Occupational Hazards Caused by Carcinogenic Substances and Agents, I.L. Convention No. 139 recommendation 147 (1974) (adopted June 24, 1974) (to appear in the United Nations Treaty Series). The ratification of such conventions is invariably a time-consuming process. By June 1, 1977, only eight countries had ratified the Convention. International Labor Office, Chart of Ratifications (July 1977 Supp.).

\textsuperscript{242} Evan, \textit{supra} note 189, at 234.

\textsuperscript{243} One consumer boycott of Japanese and Russian goods has been organized by environmental groups in the United States and elsewhere, as a reaction to the threat of extinction posed by the whaling activities of those countries. Scarff, \textit{The International Management of Whales, Dolphins, and Porpoises: An Interdisciplinary Assessment}, \textit{6 ECOLOGY L. Q.} 323, 369 (1977). Although not passed with environmentally motivated boycotts in mind, the Ribicoff Amendment to the Tax Reform Act of 1976, Pub. L. 94-455, §§ 1061-1064, 1066-1067, 90 Stat. 1650 (1976) (codified at 26 U.S.C.A. §§ 908, 952(a), 995(b)(1), 999 (West Supp. 1977)), is worthy of note in this context. The Amendment incorporates an anti-boycott provision which denies certain tax benefits to U.S. taxpayers who, in certain ways, participate in or cooperate with an international boycott carried on by a foreign country that requires the U.S. taxpayer to participate in the boycott as a condition of doing business in that country. 26 U.S.C.A. § 999(c)(2) (West Supp. 1977). The law does not apply to situations in which consumers are simply urged to voluntarily boycott the goods of a particular country. \textit{See id.} § 999(b)(3). Further, the law does permit a taxpayer to agree to meet the requirements \textit{imposed by a foreign country} with respect to an international boycott if a U.S. law, regulation, or executive order sanctions participation in, or cooperation with, that international boycott. \textit{Id.} § 999(b)(4). The objective of the Amendment is to discourage the participation of U.S. companies in boycotts imposed by Arab states against trade with Israel. \textit{See generally} Steiner, \textit{International Boycotts and Domestic Order: American Involvement in the Arab-Israeli Conflict}, \textit{54 TEx. L. REV.} 1355, 1380-84 (1976).
3. Measures to Reverse or Reduce the Relocation of Polluting or Hazardous Industries

Countries with more stringent environmental standards could reduce the need for unilateral action to encourage foreign compliance with those standards if they produced more goods domestically. A significant step towards the achievement of this result is the reversal of the present trend among manufacturers toward relocation in countries with less stringent environmental standards. It has already been noted that the relocation of a polluting or hazardous industry in a more hospitable regulatory surrounding may be an attractive alternative to an entrepreneur faced with rapidly rising costs in an environmentally conscious country.244 In general, relocation in a less-developed country (LDC) offers the prospect of lower labor costs and more plentiful supplies, proximity to raw materials, possible tax advantages, cheap land, and the opportunity to increase profits through artificially high transfer pricing and other lucrative, less-than-"arms length" dealings with parent corporations. The construction of new facilities also enables anti-pollution equipment to be incorporated more effectively and less expensively at the initial planning stage, rather than through modification of existing facilities.245

It generally will be difficult, if not impossible, to prevent a determined entrepreneur from relocating. The proliferation of multinational corporations with their complex and mobile network of financial, manufacturing, and distribution arrangements emphasizes this reality.246 Nevertheless, a variety of indirect measures may be utilized to deter relocation. These may be positive, in the form of subsidies, low interest rate loans to pay for extra costs attributable to higher environmental standards, or other monetary and fiscal incentives. They may also be negative, in the form of withdrawal of government business or fiscal incentives from the offending firm, the blocking of foreign exchange transfers to finance the new development, or the threat of harsher import standards. The effective use of these measures to counter the prospect of a mass industrial exodus from the industrialized nations may be responsible for the fact that predictions of large-scale relocation do not yet seem to have been borne out.247 Other deterring factors

246. Walter, Environmental Control and Patterns of International Trade and Investment: An Emerging Policy Issue, BANCA NAZIONALE LAVORO Q. REV. (Italy), March, 1972, at 94.
which may be relevant include: the relative political and economic instability of many LDCs; the fact that demanding standards already exist, or may be enacted, in some of these countries; and the fact that the environmental awareness of organizations such as the World Bank248 and the U.S. Agency for International Development249 might lead them to withhold development assistance from an industry proposing to relocate without incorporation of appropriate environmental controls.

There are two other important factors that should be taken into account in seeking to deter the relocation of polluting or hazardous industries. There has been considerable debate on the merits of transferring these industries to LDCs, where less stringent regulatory standards are imposed upon their operations.250 The prospect of widespread industrial relocation has particularly disturbed employee groups in the industrialized countries.251 But this debate often overlooks the point that different standards of environmental protection in developing countries may be justified by a variety of factors, including different pollution assimilative capacities of the environment in its present state and different degrees of existing industrialization and population density.

In addition, any acceleration in the transfer of industries to an LDC will generally be of considerable benefit to the LDC's development strategy252 and will be in line with a variety of United Nations resolutions seeking to encourage a more equitable distribution of the world's industrial base.253


249. See text accompanying notes 273-274 infra.

250. See generally Castro, Environment and Development: The Case of Developing Countries, 26 INT'L ORG. 410 (1972); Woodhouse, Re-visioning the Future of the Third World: An Ecological Perspective on Development, 25 WORLD POL. 1 (1972); Kulig, Environmental Policies for the Developing Countries and Their Development Strategy, in Founex Report, supra note 199, at 95.

251. See, e.g., Commission of the European Communities, Europe Press Notice No. 2099, Nov. 24, 1976, at 11 (new series). The Union of Industries of the European Economic Community (UNICE) urged the Commission of the European Communities that EEC environment policies "must not encourage the gradual implantation of certain industries in countries which apply less stringent requirements . . . and which already enjoy special facilities in many other fields." Id.

252. In general terms, the contribution of any enterprise to an LDC's economic and social development will depend upon factors such as: (1) the extent to which the enterprise utilizes an appropriate capital/labor ratio; (2) the extent to which it meets the basic needs of the local populace rather than catering to the demands of the luxury sector; (3) the fiscal terms on which it operates; and (4) the proportion of its profits that remain within the LDC. See generally E. Hagen, The Economics of Development (1968). But cf. Bauer, Western Guilt and Third World Poverty, COMMENTARY, Jan., 1976, at 31 ("Contact with the West has been the principal agent of material progress [in the Third World]. Indeed the very idea of material progress is Western . . . ").

253. The Programme of Action on the Establishment of a New International Economic Order, adopted by the U.N. General Assembly, resolves that:

All efforts should be made by the international community to take measures to encourage the industrialization of the developing countries, and to this end:
The real need is to encourage LDCs not to adopt a short-sighted approach to the protection of their own environment. The transfer of industries can be beneficial to the recipients only as long as it is accompanied by appropriate environmental safeguards. In this respect, the industrialized nations can be of assistance to the LDCs by encouraging thorough and objective environmental impact assessments to ensure that the LDCs are fully aware of the environmental consequences of their new acquisitions. Wealthy nations can help to achieve this goal by urging domestically based multinational corporations to undertake such assessments, and by providing expert environmental planning assistance if requested by the LDCs. Finally, genuine, altruistic concern for the environment of a foreign country can be effectively and convincingly demonstrated by offering financial assistance to ensure that environmental safeguards are incorporated into any development planning.

The major argument that can be used against this approach is that the LDCs are apt to find the need to industrialize too great and should, for their own good, be prevented from enticing industries that could ultimately have a significantly adverse environmental impact. This argument smacks of paternalism and overlooks the commitment of many LDCs to the preservation of a healthy environment. In the final analysis, it must be the responsibility of the national government to determine what social and economic objectives and priorities will be sought, and what level of risk will be acceptable. However, this approach does not preclude the legitimate expression of concern by a foreign government at the development of

(a) The developed countries should respond favourably, within the framework of their official aid as well as international institutions, to the requests of developing countries for the financing of industrial projects;
(b) The developing countries should encourage investors to finance industrial production projects, particularly export-oriented production, in developing countries, in agreement with the latter and in the context of their laws and regulations;


255. See The Stockholm Declaration, supra note 55, principle 12.

256. This would be the logical extension of proposals such as those which advocate the banning of exports of "industrial equipment and vehicles not equipped with the latest air pollution control equipment required [in the U.S.]." Coan, Hillis, & McCloskey, Strategies for International Environmental Action: The Case for an Environmentally Oriented Foreign Policy, 14 NAT. RESOURCES J. 87, 90 (1974).


258. "States have ... the sovereign right to exploit their own resources pursuant to their own environmental policies." Id. principle 21. See also the United Nations General Assembly Declaration on Permanent Sovereignty over Natural Resources, G.A. Res. 1803, 17 GAOR, 1st Annexes (Agenda Item No. 39) I, at 59, U.N. Doc. CA/L. 412/Rev.2 (1962).
potentially hazardous or polluting facilities, provided such views are predicated upon concern for the international ramifications of the development.

4. Requirements that All Exports Must Satisfy Domestic Standards

It has been suggested that "the overseas sale of environmentally hazardous substances might be prohibited if their use is banned" in the United States.\textsuperscript{259} Arguments can be put forth to justify a policy prohibiting the export of chemical substances that do not meet domestic standards. It can be argued that a country has a moral obligation to ensure that the protection that it accords to its own environment and residents is also provided to foreign consumers. The fact that many LDCs have neither the facilities nor the resources to exhaustively evaluate imported chemical substances further justifies this policy.\textsuperscript{260} At present, many countries, including the United States, permit the export of pesticides and other chemical substances that have been banned from domestic use.\textsuperscript{261} This dichotomy will often accelerate the spread of harmful products to foreign makers. Typically, domestic producers rush to export their existing supplies before export restrictions are imposed, or foreign purchasers prohibit or limit importation of the hazardous substance. While this course of action has engendered considerable controversy,\textsuperscript{262} there have been few attempts to analyze the issues involved with a view to clarifying future policy options.

The domestic ban on a toxic chemical may reflect either a decision based on the unique environmental conditions prevailing in an individual nation, or a judgment that its use involves risks that are politically unacceptable to the domestic society.\textsuperscript{263} In either case, the judgment is a subjective one, based upon distinctively domestic considerations that may or may not be applicable elsewhere. There is thus good reason to conclude that a flexible, case-by-case approach should be the order of the day in judging whether the export of a domestically banned chemical is proper.

The international experience with the pesticide DDT illustrates the point that although prohibition is favored in one country, there may be countervailing factors elsewhere that justify continued use. Widespread DDT use has provoked severe environmental problems, and its increasing

\textsuperscript{259} Coan, Hillis, & McCloskey, \textit{supra} note 256, at 90.

\textsuperscript{260} For example, Argentina claims that the developing countries are "often not able to afford the necessary resources so as to keep up-to-date with the more sophisticated methods of analysis" for evaluating pesticides. \textsc{Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Report of the Eighth Session of the Codex Committee on Pesticide Residues} para. 178 (1976).

\textsuperscript{261} See text accompanying notes 213-218 \textit{supra}.

\textsuperscript{262} FDA \textit{International Report}, \textit{supra} note 48, at 36-37.

concentration in the fatty tissues of humans and animals is a cause of growing concern. Responding to these and other concerns that were presented during seven months of cancellation hearings in 1971 and 1972, the EPA Administrator banned the use of DDT within the United States for virtually all crop production and nonhealth purposes. While the ban on DDT use has been judged appropriate in light of environmental concerns in the United States, it is not clear that its use should be prohibited in other environments. From the perspective of the LDCs, certain evidence reveals that DDT is highly beneficial in terms of increased agricultural productivity, is cheaper than other pesticides, and is effective protection against malaria and other tropical diseases. It has been estimated that DDT has saved five million lives in underdeveloped areas and prevented 100 million illnesses since its introduction in 1942. On balance, one eminent commentator has concluded that despite the growing global danger arising from existing patterns of DDT use, there seem to be compelling reasons for the most populous countries in the world to continue to rely on massive quantities of DDT in the years ahead.

As the DDT example illustrates, the development of flexible norms and procedures governing the export of potentially toxic chemicals is essential. A former EPA Administrator has claimed that chemical pollution is not a problem that can be solved unilaterally. Nevertheless, there are a number of measures that an exporting country can adopt in an effort to minimize the environmental and health risks presented by exported chemical substances. First, it can require that all known data and other information relating to a potentially toxic chemical be provided to the purchaser and the government of the country for which the substance is intended for use. In particular, the information upon which domestic regulation or prohibition was based should be included. Second, where the government of the importing country requests assistance in the evaluation of a particular chemical substance, such assistance should be provided. If necessary, this assistance should be made available at the expense of the manufacturer or

264. Falk, The Global Environment and International Law: Challenge and Response, 23 KANSAS L. REV. 385, 395 (1975). See also Clement, The Pesticides Controversy, 2 ENV'TL AFF. 445, 464-65 (1972). A recent study of available evidence concludes, however, that "no proof is yet available that DDT is an immediate threat to human health," despite the fact that chemical workers and others have been exposed to relatively high concentrations for over 20 years. One problem in assessing DDT's effects is that its ubiquity leaves no uncontaminated control population against which to measure its carcinogenic effects. Henahan, supra note 7, at 29.
266. See Henahan, supra note 7, at 31.
267. Id.
268. Falk, supra note 264, at 397.
270. For examples of some possible measures, see Guidelines, supra note 119.
exporter. Third, there is no reason why domestic classification, packaging, and labeling requirements should not be applied equally to all exported substances.\textsuperscript{271} The inappropriate usage of chemicals that results from inadequate or incomplete information is a major problem in LDCs, as it is elsewhere. Adherence to domestic packaging and labeling requirements will help to minimize the improper use of chemicals. As a last resort, an exporting country that becomes aware of serious adverse consequences resulting from the improper and unjustified use of a toxic chemical should take action either to secure a less hazardous use of the substance, or in extreme circumstances, to prohibit its export to the offending country.\textsuperscript{272}

5. The Use of Foreign Aid

Through the use of an ecologically aware foreign policy, an individual country can promote a responsible and balanced approach to the use of known and potentially toxic substances. Assistance with development projects involving the construction of chemical manufacturing plants can be conditioned on the observance of sound environmental policies, and the incorporation of adequate safeguards at all stages of production and distribution. In the United States, development assistance activities are approved, administered, and supervised by the Agency for International Development. Despite initially strong resistance, the Agency has recently agreed to observe the provisions of the National Environmental Policy Act,\textsuperscript{273} which require the preparation of an environmental impact statement for all "major Federal actions significantly affecting the quality of the human environment."\textsuperscript{274} President Carter’s 1977 environmental message to Congress also called upon the Agency to encourage environmentally sound policies in the LDCs.\textsuperscript{275} Since 1970, the World Bank has also undertaken "to review and evaluate every investment project from the standpoint of its potential effects on the environment."\textsuperscript{276} The Bank’s evaluation is not, however, subject to any outside scrutiny.

\textsuperscript{271} But cf. Draft Directive, supra note 142, art. 1(3) ("The classification, packaging and labelling provisions of the directive do not apply to dangerous substances exported to third world countries.").

\textsuperscript{272} Advocacy of this course of action, even if limited to extreme circumstances, seems at first glance somewhat inconsistent with the general approach adopted in this Article. However, every country is ultimately entitled to determine, within the limits of international morality, what it will provide and to whom. The use of this prerogative is entirely legitimate, providing it is exercised with the utmost caution and for very good reasons. In any event, it may well be that sufficient justification will only exist in circumstances where the action can be more appropriately characterized as humanitarian, rather than environmental, such as when a chemical is being used in connection with torture, or in blatant disregard of its toxicity to humans.

\textsuperscript{273} Appelbaum, supra note 10, at 344.


\textsuperscript{275} President to Vow Strong Support to Protect Nation’s Environment, N.Y. Times, May 23, 1977, at 1, col. 1.

\textsuperscript{276} World Bank, Environment and Development 8 (1975); Economic Development Projects, supra note 248.
In addition to the traditional forms of foreign aid, developed countries also might provide assistance to LDCs to cover extra costs that may flow from efforts to maintain or improve environmental quality. In circumstances involving a threat to international environmental well-being, a government could consider the use of negative inducements (such as a suspension of foreign aid) to countries that refuse to cooperate in the control of toxic chemicals, although such action might better be undertaken pursuant to a resolution of the United Nations.

6. Summary

The above analysis indicates that a variety of strategies are open to countries wishing to promote environmental responsibility in the international flow of chemicals through unilateral action. It must be recognized, however, that unilateral actions alone may not contribute significantly to the achievement of a more equitable social and environmental world order. The likelihood of success through unilateral action is undercut by the highly competitive and geographically dispersed nature of chemical production and marketing activities. The emphasis must be on a cooperative global approach supplemented by demonstrations of national concern.

CONCLUSION

This Article has explored the obstacles to, and prospects for, development of a uniform international approach to the testing and control of toxic chemicals. The existing international situation is characterized by a lack of quantitative and qualitative data on chemical toxicity, and by the development of an excessively fragmented regulatory response.

This Article has examined the proposals to control toxic chemical development and use that are being considered by a number of international organizations. The Article has also demonstrated the significance of international chemical flows in terms of world trade and considered the implications of proposals to relocate toxic chemical producing industries.

Whatever the outcome of present proposals for reform, a pressing need remains to develop a comprehensive international response to the major threat posed by toxic chemicals. It is to be hoped that the occurrence of a major chemical-related disaster will not be a necessary condition precedent to adoption of appropriate safety measures.


278. See text accompanying note 9 supra.