

Michigan Journal of International Law

Volume 13 | Issue 3

1992

International Regulation and Control of the Production and Use of Chemicals and Pesticides: Perspectives for a Convention

Hans-Wolfgang Micklitz
Berlin School of Economics

Follow this and additional works at: <https://repository.law.umich.edu/mjil>



Part of the [European Law Commons](#), [Food and Drug Law Commons](#), [International Law Commons](#), and the [Science and Technology Law Commons](#)

Recommended Citation

Hans-Wolfgang Micklitz, *International Regulation and Control of the Production and Use of Chemicals and Pesticides: Perspectives for a Convention*, 13 MICH. J. INT'L L. 653 (1992).

Available at: <https://repository.law.umich.edu/mjil/vol13/iss3/3>

This Article is brought to you for free and open access by the Michigan Journal of International Law at University of Michigan Law School Scholarship Repository. It has been accepted for inclusion in Michigan Journal of International Law by an authorized editor of University of Michigan Law School Scholarship Repository. For more information, please contact mjil.repository@umich.edu.

INTERNATIONAL REGULATION AND CONTROL OF THE PRODUCTION AND USE OF CHEMICALS AND PESTICIDES: PERSPECTIVES FOR A CONVENTION

*Hans-Wolfgang Micklitz**

INTRODUCTION¹

A. *Purpose of the Analysis*

A wide variety of instruments and mechanisms for the regulation and control of chemicals and pesticides is already available internationally. What is missing is an analysis that attempts to systematize the different approaches, to create transparency, to define where they overlap, and to discover prospective deficiencies and shortcomings. In order to accomplish this task, this article covers legally binding rules as well as recommendations and codes — the international soft law. The overall purpose is to outline a framework for future international regulation of chemicals and pesticides and to propose an international convention as a possible solution.²

B. *Points Needing Analysis*

International legal instruments require discussion, not only to de-

* Full Professor, Berlin School of Economics. Formerly Senior Researcher at the Center for European Legal Policy in Bremen, Germany and Jean Monnet Fellow at the European University Institute in Florence, Italy.

1. This article is a revised version of the report presented to the IRPTC/UNEP Ad Hoc Working Group of Experts on the Implementation of the Amended London Guidelines at its first session in Nairobi, October 15-19, 1990. Analysis of International Legal Instruments to the Regulation and Control of the Production and Use of Chemicals, Revised Version, UNEP/PIC.WG.3/Inf.4 (1990). Footnotes and references are restricted to those that are indispensable for the reading and the understanding of the text. The facts on the existing level of regulation are largely based on the following two documents: OECD, ADMINISTRATIVE AND LEGISLATIVE ASPECTS OF CHEMICALS CONTROL: COMPARATIVE ANALYSIS OF SELECTED ISSUES (1985) [hereinafter OECD COMPARATIVE ANALYSIS]; and UNITED NATIONS ENVIRONMENT PROGRAMME SECRETARIAT, COMPARATIVE SURVEY OF NATIONAL NOTIFICATION PROCEDURES AND LEGISLATIVE DEFINITIONS, UNEP/WG.112/4 (1985) [hereinafter UNEP COMPARATIVE SURVEY].

2. Cf. Philip Alston, *International Regulation of Toxic Chemicals*, 7 *ECOLOGY L.Q.* 397 (1978-79) (similarly advocating the international regulation of chemicals); Michael Kloepfer, *Aspekte der internationalen Harmonisierung des Umweltrechts — Zur Rechtsvergleichung und Rechtsvereinheitlichung*, in *CHEMIKALIENRECHT* 9, 281 (1984).

termine the scope of this article but also to establish a framework that facilitates policy formulation in the field of chemicals and pesticides.

The London Guidelines,³ like a number of other national initiatives, cover both chemicals and pesticides. Bringing together chemicals and pesticides in a single report entails a number of difficulties. Chemicals and pesticides follow different regulatory schemes, at least in the legislation of industrialized countries. This might be different in developing countries, but the more the legislation is scrutinized the more apparent it becomes that each product category, whether chemicals, pesticides, food additives, cosmetics, or medicines, is dealt with separately. International regulation must consider these differences and respond to product-specific national rules.

United Nations Environment Programme Governing Council (UNEP GC) Decision 15/30 refers to "other activities related to the production and use of chemicals."⁴ This statement is unclear. International regulation might cover trade in chemicals, but it might also cover production, as is the case with the International Labour Organisation (ILO) Convention Concerning Safety in the Use of Chemicals at Work.⁵ A distinction can be made between process regulation and product regulation:⁶ process regulation aims at the manufacturing process, product regulation at trade. This article mainly focuses on product regulation, but process regulation is considered with respect to the feasibility of banning the production, as opposed to merely the use, of certain extremely dangerous chemicals and pesticides.

The last point needing clarification concerns the types of instruments available for international pesticide and chemical regulation. One possibility is harmonization of the different national approaches in order to define a level of protection and control with worldwide acceptability. The United Nations Food and Agriculture Organization (FAO) International Code of Conduct on the Distribution and Use of Pesticides⁷ is an example of such harmonization. Another pos-

3. UNEP LONDON GUIDELINES FOR THE EXCHANGE OF INFORMATION ON CHEMICALS IN INTERNATIONAL TRADE (Amended 1989). [hereinafter AMENDED LONDON GUIDELINES].

4. Decision 15/30 of the Governing Council of the United Nations Environment Programme, *Environmentally Safe Management of Chemicals, in Particular Those That Are Banned and Severely Restricted in International Trade*, reprinted in 19 ENVTL. POL'Y & L. 125 (1989).

5. International Labour Organisation, *Convention Concerning Safety in the Use of Chemicals at Work*, art. 2(c)(i), 73 OFFICIAL BULL. 71, 73 (1990) [hereinafter ILO Convention].

6. ECKARD REHBINDER & RICHARD STEWART, ENVIRONMENTAL PROTECTION POLICY (Integration Through Law: Europe and the American Federal Experience vol. 2, Mauro Cappelletti et al. eds., 1985).

7. United Nations FAO Conference Resolution 10/85 International Code of Conduct on the Distribution and Use of Pesticides, [Reference Binder 1] Int'l Env't Rep. (BNA) 41:3001 (1985) [hereinafter FAO Code of Conduct].

sibility would be to allow regulatory differences but develop mechanisms to bridge those differences, especially between exporting and importing countries. The London Guidelines⁸ and other efforts⁹ to regulate the export of banned and severely restricted products are in this category. The intention is not to abolish existing differences in the legal status of regulated chemicals and pesticides but to find ways to secure their trade even though they are banned or severely restricted. It is therefore necessary to clearly distinguish between efforts that attempt to harmonize international regulation and efforts that aim to balance differences in the regulatory status of chemicals and pesticides.

C. *Scope of the Analysis*

This article cannot be restricted to international efforts. It must consider the key role of some industrialized countries in chemical and pesticide regulation. Specific emphasis is put on the role of the European Community (EC). With its policy of completing the internal market by 1992,¹⁰ the EC has become the most important international organization in developing regulatory frameworks that unite different national schemes. European initiatives to harmonize chemical and pesticide regulations are important far beyond the borders of the twelve Member States. Due to the enormous importance of the EC market to European Free Trade Association (EFTA) countries, the Europeanization of chemical and pesticide regulation based on Community law is close at hand. International efforts to regulate pesticides and chemicals by the FAO, the General Agreement on Tariffs and Trade (GATT), and the ILO can be analyzed against the background of the numerous regulatory efforts of the European Community and industrialized countries.

The different national, regional, and international laws and regulations will be dealt with by following the development of regulatory instruments and strategies designed to control risks to humans and to the environment. Regulation traditionally starts in industrialized countries with efforts to manage trade in chemicals and pesticides.¹¹ The overall goal is to protect both the user of the product and those workers who may come into contact with it. Therefore, regulations

8. AMENDED LONDON GUIDELINES, *supra* note 3.

9. See *infra* Part I(E).

10. For an analysis, see generally 1992: ONE EUROPEAN MARKET? A CRITICAL ANALYSIS OF THE COMMISSION'S INTERNAL MARKET STRATEGY (Roland Bieber et al. eds., 1988).

11. See Hans-W. Micklitz, *Zur Geschichte des deutschen Pflanzenschutzrechts*, in BREMER KOLLOQUIUM ÜBER PFLANZENSCHUTZ 44 (Eckard Reh binder ed., 1991) (concerning the history of regulation of pesticides).

are adopted to classify products according to risk, to ensure adequate packaging and labeling, and to control advertising. Later, regulatory emphasis shifts from trade regulation to access-to-market regulation. States protect their citizens and the environment against harm from dangerous chemicals and pesticides by controlling market access.

There are different regulatory models, notification procedures, registration procedures, and/or licensing procedures, but they all try to guarantee preventive protection against potential risks. The shift from trade regulation to access-to-market regulation logically increases the degree of protection, but even access-to-market rules cannot guarantee sufficient long-term protection to humans and the environment. A common characteristic of chemicals and pesticides is that their specific risks are unknown when they are brought onto the market and only become clear after years of use and experience. Then the question arises as to how, and even if, these products can be taken off the market. The term of art for regulatory efforts to rid the market of dangerous products is postmarket control.¹²

The analysis of export regulation focuses on existing mechanisms used by international and regional organizations (e.g., UNEP, FAO, the United Nations (U.N.), the Organization for Economic Cooperation and Development (OECD), the GATT, and the EC) and by various States to regulate the exports of chemicals. Information exchange procedures, export notification, and the recently introduced Prior Informed Consent (PIC) procedure define the requirements for trade with banned and severely restricted chemicals.

I. NATIONAL, REGIONAL, AND INTERNATIONAL REGULATION OF PESTICIDES AND CHEMICALS

A. *Regulatory Concepts, Common Goals, and Definitions*

The overall trend in chemical and pesticide regulation is to go beyond the protection of humans against exposure to chemicals and pesticides and to integrate the protection of the environment into the regulatory framework. This extension entails a shift from protection against acute damage or imminent danger to a consideration of potential hazards.¹³ Regulatory actions are no longer limited to cases of actual harm. They now aim at protecting humans and the environment against the risks associated with chemicals. Therefore, the no-

12. See POST MARKET CONTROL OF CONSUMER GOODS (Zentrum für Europäische Rechtspolitik [ZERP] Schriftenreihe, Band 11, Hans-W. Micklitz ed., 1990) (discussing the concept of postmarket controls in comparative perspective).

13. Pesticides legislation aimed first at the protection of humans. In a second step, the legislation was extended to cover protection of the environment.

tions of "risk," "hazard," and "danger" are crucial in all laws and regulations.¹⁴

Protection against risks may be incorporated in a particular law in different ways. The OECD Paper on Administrative and Legislative Aspects of Chemical Control,¹⁵ as well as the UNEP Comparative Survey of National Notification Procedures and Legislative Definitions,¹⁶ distinguishes among:

- (1) the notion of risk being incorporated in the general statement of purpose or goals provisions of a particular law;
- (2) the notion of risk being incorporated in statutory provisions that describe individual duties of care, especially in countries that vest in the manufacturer or importer the primary responsibility for assessing the risks associated with chemicals;
- (3) the notion of risk being incorporated by chemical laws in a number of risk categories representing defined dangerous properties of chemicals; and
- (4) the notion of risk being incorporated in statutory provisions that authorize agencies to take specific regulatory action.¹⁷

Further details can be drawn from the OECD and UNEP papers.¹⁸

The overall trends reported in these two analyses have been strengthened and specified. No common approach, however, can be found in the answers to the questions of whether and to what extent occupational health and safety considerations should be integrated into chemical and pesticide regulation. For some countries, occupational health and safety regulations are crucial for the development of sophisticated chemical regulation (e.g., the United Kingdom).¹⁹ Other countries integrate aspects of occupational health and safety into chemical and pesticide regulation (e.g., Germany's *Gefahrstoffverordnung*).²⁰

The integration of environmental protection into chemical and pesticide regulation constitutes a shift from product-related to media-related regulation. Product-related regulation focuses on the specific risks of the respective products (e.g., chemicals, pesticides); media-re-

14. See ECKARD REHBINDER ET AL., CHEMIKALIENGESETZ-KOMMENTAR UND RECHTSVORSCHRIFTEN ZUM CHEMIKALIENRECHT 37 (1985).

15. OECD COMPARATIVE ANALYSIS, *supra* note 1.

16. UNEP COMPARATIVE SURVEY, *supra* note 1.

17. See OECD COMPARATIVE ANALYSIS, *supra* note 1, at 7, 10.

18. *Id.*; see also UNEP COMPARATIVE SURVEY, *supra* note 1.

19. See OECD COMPARATIVE ANALYSIS, *supra* note 1, at 5, 7, 11-13, 18-24, 27.

20. Eckard Rehbinder, *Harmonisierung des Chemikalienrechts?: Die Harmonisierungswirkungen der Richtlinie 79/831/EWG in den Mitgliedstaaten der Europäischen Gemeinschaften im Lichte des deutschen Rechts*, in 3 CHEMIKALIENRECHT 79-139 (Gesellschaft für Rechtspolitik 1986). The report is an analysis of the implementation of the Sixth Amendment of the Chemicals Directive.

lated regulation provides for the protection of humans and environment independent of the nature of the respective product. A media-related approach encompasses all kinds of products — chemicals, pesticides, medicines, food additives, cosmetics — and questions the extent to which criteria can be found to protect humans and the environment against potential risks. Even modern chemical laws do not really pursue a media-related approach.²¹ Some rules contain elements of a media-related approach, but exception clauses make clear that product-related regulations overrule media-related controls.²² This differentiation, which is quite common in most of the industrialized countries, leads to the paradoxical consequence that the ultimate use determines the applicable legislation. In other words, pesticides, medicines, food additives, and cosmetics are all “chemicals,” but their different uses make it necessary to decide whether to apply specific product-related laws or the basic chemical regulations. That is why chemical regulation, in practice, focuses on industrial chemicals as a specific category of products, distinguishing them from pesticides and other “chemicals” like medicines or food additives.

Product-related regulation requires a definition of legal scope. There is no common understanding of the terms “chemical” and “pesticide.” In the field of chemicals, specific difficulties arise in differentiating between industrially manufactured chemicals and preparations. European Economic Community (EEC) Directive 67/548 (as amended by the Sixth Amendment) (dangerous substances)²³ and EC Directive 91/414/EEC (pesticides)²⁴ provide some guidance on what is meant by the terms chemical and pesticide. Guidance does not mean that all possible problems are solved. It remains unclear whether preparations containing a chemical regulated by the Sixth Amendment fall under the Sixth Amendment or are excluded from that directive.²⁵ The OECD has developed a glossary of definitions used by industrialized States, mainly OECD members, in their chemi-

21. See Council Directive 79/831 of 18 September 1979 Amending for the Sixth Time Directive 67/548/EEC on the Approximation of the Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances, *pmbl.* & art. 1, 1979 O.J. (L 259) 10-11 [hereinafter Sixth Amendment]. This Council Directive is a typical product of an ambitious approach. Starting from a broad concept of protection which approaches media-related thinking, the Directive's scope is narrower than would be expected from the preamble. See also OECD COMPARATIVE ANALYSIS, *supra* note 1, tbl. 3, at 16.

22. OECD COMPARATIVE ANALYSIS, *supra* note 1, tbl. 3, at 16.

23. Sixth Amendment, *supra* note 21, art. 2(1)(a)-(b), at 11.

24. Council Directive 91/414/EEC of 15 July 1991 Concerning the Placing of Plant Protection Products on the Market, art. 2(1) & (3), 1991 O.J. (L 230) 1, 3.

25. Reh binder, *supra* note 20.

cal legislation.²⁶ The glossary is helpful in understanding regulatory differences, but at the same time it shows that there is not yet a common understanding, even among the industrialized nations.

The same is more or less true for the definition of pesticides. EC Directive 91/414/EEC provides a common framework for the Member States, but its definition differs from the notion in the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).²⁷ From an international perspective, the FAO Code of Conduct on the Distribution and Use of Pesticides supplies a glossary instrumental to the international regulation of pesticides.²⁸

As to the selection of control action, there are still substantial differences in the language and the structure of the laws.²⁹ The relationship between different levels of risks, the basis of their determination, and the selection of control action is subject to different national regulatory approaches. One might summarize the findings of the OECD Analysis and the UNEP Comparative Survey as formulating a "hierarchical system" that links differing degrees of risks to the selection of control action.³⁰ Under this system, levels of control stringency are triggered by corresponding levels of risk. There is an interdependence between the degree of risk and the intensity of regulation.³¹

Modern chemical and pesticide laws do not require a causal link between a substance and its potential hazards.³² Statistical evidence and scientific research indicating that a hazard exists usually suffices to legitimate preventive action. However, the mere potential of a risk does not justify measures as severe as restricting or banning the use or production of a specific chemical or pesticide. More concrete evidence is needed for such actions. One might even conclude from the experience with chemical and pesticide legislation in industrialized countries that market restrictions are adopted only in cases where the causal link between the damage and the substance can no longer be denied. Although it is already a long way from the potential risk to the acute risk, there is a third category that requires an even higher degree of risk than in the case of market restriction: emergency situations.

26. OECD, CHEMICALS CONTROL LEGISLATION AN INTERNATIONAL GLOSSARY OF KEY TERMS (1982).

27. Compare Council Directive 91/414/EEC, *supra* note 24, art. 2(1) & (3), at 3 with the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136(u) (1988).

28. FAO Code of Conduct, *supra* note 7.

29. UNEP COMPARATIVE SURVEY, *supra* note 1, at 23-24; OECD COMPARATIVE ANALYSIS, *supra* note 1, at 14.

30. UNEP COMPARATIVE SURVEY, *supra* note 1, at 23.

31. *Id.*

32. OECD COMPARATIVE ANALYSIS, *supra* note 1, at 14.

Here, the existence of an imminent danger triggers intervention to mitigate the risk.³³

Other countries leave their agencies more discretion in selecting appropriate controls. This is particularly true for the United States where there is a sequence of increasingly stringent prerequisites (in terms of probability of risks and necessary basis for their determination), from requiring testing in order to gather sufficient information to final control action.³⁴ Although the regulatory approach of the European Community and its Member States on the one hand and the United States on the other seems to be different, in actual practice the similarity in interdependence between the degree of risk and selection of control action is striking.

Some inherent limits are, though varying in their legal grounding, recognized in most legal systems. These limiting rules, according to the OECD Report, require agencies:

- a) not to overstep the limits of discretion set out in a law or inherently contained in a delegation of powers;
- b) not to disregard the scope of discretion available under a legal authorization;
- c) to make use of the discretionary powers in a fair and reasonable manner, avoiding arbitrariness, clear errors of judgment and other abuses of discretion.³⁵

Tables in the Report help the reader to visualize the linkage between control action and the degree of danger.³⁶ They show a complicated and sophisticated system that leaves some doubt as to whether the finely tuned differences in hazards and actions are manageable by the agencies.

In adopting specific legislation on chemicals and pesticides, States are assuming the responsibility to protect their citizens and the environment against risks resulting from unsafe chemicals and pesticides. Accepting a statutory responsibility for human safety and the environment entails far-reaching constitutional consequences.³⁷ It is no longer the liberal State guaranteeing individual rights to liberty and freedom. Rather, it is the new welfare State accepting the responsibility to ensure protection, safety, and a healthy environment. Such an extension of responsibilities is not limited to industrialized countries.

33. UNEP COMPARATIVE SURVEY, *supra* note 1, at 23. This is the system that exists in the European Community and its Member States.

34. *Id.*

35. OECD COMPARATIVE ANALYSIS, *supra* note 1, at 27-28.

36. *Id.* tbls. 2 & 4, at 13, 21.

37. See generally Hans-W. Micklitz, *Consumer Rights*, in HUMAN RIGHTS AND THE EUROPEAN COMMUNITY: THE SUBSTANTIVE LAW 53, 72-89 (Andrew Clapham et al. eds., 1991) [hereinafter *Consumer Rights*].

Here, the rights of classical liberalism might be interpreted in light of the new statutory functions as is the case in Germany. New democracies like Spain and Portugal have used their Constitutions to make the protection of humans and the environment a State objective, even a constitutional task.³⁸ However, even where health, safety, and environmental protection are not discussed at the constitutional level, the existence of a statutory responsibility is widely accepted. The U.S. Constitution does not recognize social rights;³⁹ its protection is limited to the classical liberal rights — individual liberty and freedom. Nevertheless, the United States has within the last twenty years developed the furthest-reaching statutes designed to guarantee the protection of humans and the environment against chemicals, pesticides, and other devices.⁴⁰

At the international level, article 12 of the International Covenant on Economic, Social and Cultural Rights includes a right to health,⁴¹ and the 1972 Stockholm Declaration established the agenda for later international efforts to guarantee a healthy environment.⁴² The legal status of these documents remains the subject of a controversial debate, but their mere existence makes it clear that, even in the international arena, rights to safety and a healthy environment are now important considerations. Both could establish the structure for the legitimate development of an international regime for the regulation of chemicals and pesticides. In the long run, trade regulations have to account for health, safety, and environmental concerns.⁴³

B. *Classification, Labeling, Packaging, and Advertising*

In the history of chemical and pesticide regulation, rules on risk classification, on associating specific risks to labeling requirements, and on packaging were the first step in the development of chemical and pesticide regulation.

38. *Id.* at 80-89.

39. 1 EBERHARD GRABITZ, *GRUNDRECHTE IN EUROPA UND USA: STRUKTUREN NATIONALER SYSTEME* (1986).

40. See Giandomenico Majone, *Cross-National Sources of Regulatory Policymaking in Europe and the United States*, J. PUB. POL'Y, Spring 1991, at 79, 90-91, 98.

41. International Covenant on Economic, Social and Cultural Rights, *opened for signature* Dec. 19, 1966, art. 12(1), 993 U.N.T.S. 3, 8, 6 I.L.M. 360, 363-64 (entered into force Jan. 3, 1976). For further details, see *Consumer Rights*, *supra* note 37, at 92-94.

42. See Alston, *supra* note 2, at 410-12, 419 & 432.

43. See Frederic L. Kirgis, Jr., *Effective Pollution Control in Industrialized Countries: International Economic Disincentives, Policy Responses and the GATT*, 70 MICH. L. REV. 859 (1972); see also ENVIRONMENT AND TRADE (Seymour J. Rubin & Thomas R. Graham eds., 1982); Helmut Gröner, *Umweltschutzbedingte Produktnormen als nichttarifäres Handelshemmnis, in UMWELTPOLITIK UND WETTBEWERB* 143 (Helmut Gutzler ed., 1981).

1. Classification

The Sixth Amendment to EEC Directive 67/548/EEC provides fourteen factors for determining hazardous characteristics within the meaning of the directive: explosive, oxidizing, extremely flammable, highly flammable, flammable, very toxic, toxic, harmful, corrosive, irritant, dangerous for the environment, carcinogenic, teratogenic, and mutagenic.⁴⁴ EC Directive 78/631 provides a similar classification scheme for pesticides, ranking them from very toxic, through toxic, to harmful. Classification is based primarily on the acute oral and dermal toxicity to rats in accord with the standard procedures in toxicology.⁴⁵ EC Directive 88/379 extends classification to preparations other than pesticides.⁴⁶ The classification scheme follows the principles laid down in Directive 67/548 on dangerous chemical substances, supplemented by specific provisions on explosiveness, oxidizing tendencies, extreme flammability, high flammability, or flammability.⁴⁷ These three directives provide a common classification scheme of dangerous substances, pesticides, and preparations throughout the European Community. They facilitate orientation on the market and enhance the development of regulatory concepts based on classification.

At the international level, numerous organizations have developed classification schemes, for example, the efforts of the World Health Organization (WHO) and of the International Register for Potentially Toxic Chemicals (IRPTC) in the fields of chemicals and pesticides. However, most of these classification systems are not linked to labeling and packaging requirements. There are two notable differences. The ILO Convention requires specific criteria and systems appropriate for the classification of all chemicals according to the type and degree of their intrinsic hazards.⁴⁸ According to the ILO Convention's Recommendations, classification should be based on characteristics such as: toxic properties, including both acute and chronic health effects in all target organs; chemical or physical characteristics, including flammability, explosiveness, oxidizing properties, and dangerous reactivity; corrosive and irritant properties; carcinogenic effects; allergenic and

44. Sixth Amendment, *supra* note 21, art. 2(2), at 11-12.

45. Council Directive 78/631 of 26 June 1978 on the Approximation of the Laws of the Member States Relating to the Classification, Packaging and Labelling of Dangerous Preparations (pesticides), art. 3, 1978 O.J. (L 206) 13, 14-15.

46. Council Directive 88/379 of 7 June 1988 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Classification, Packaging and Labelling of Dangerous Preparations, art. 3, 1988 O.J. (L 187) 14, 15-22.

47. *Id.*

48. ILO Convention, *supra* note 5, art. 6, at 73.

sensitizing effects; teratogenic and mutagenic effects; and effects on the reproductive system.⁴⁹ From a lawyer's point of view, the prerequisites are similar to EEC Directive 67/548.

The FAO Code refers to the WHO recommended classification of pesticides by hazards as the starting point for labeling and packaging requirements.⁵⁰ Classification in the WHO-recommended scheme differs from the EC Directive 78/631⁵¹ in that the WHO scheme distinguishes four categories of hazards: extremely hazardous, highly hazardous, moderately hazardous, and slightly hazardous.

2. Labeling and Packaging

At the EC level, the marketing of classified chemicals, pesticides, and preparations is tied to labeling and packaging requirements. Although the labeling and packaging requirements differ according to the category of products concerned, the basic concept derives from Directive 67/548.

Packaging must satisfy the following requirements:

- (a) it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed;
- (b) the materials constituting the packaging and fastening must not be susceptible to adverse attack by the contents, or liable to form harmful or dangerous compounds with the contents;
- (c) packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;
- (d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be repeatedly refastened without the contents escaping.⁵²

Member States are allowed to go beyond that mandatory level and to prescribe additional requirements: that packages shall initially be closed with a seal so that when the package is opened for the first time, the seal is irreparably damaged; that containers with a capacity not exceeding three liters that contain dangerous substances intended for domestic use shall have child-resistant fastenings; and that containers with a capacity not exceeding one liter that contain very toxic, toxic, or corrosive liquids intended for domestic use shall carry a tactile warning of danger. The options for packaging rules on child-resistant

49. ILO, *Recommendation Concerning Safety in the Use of Chemicals at Work*, 73 OFFICIAL BULL. 84, art. 6, at 85 (1990) [hereinafter *ILO Recommendation*].

50. FAO Code of Conduct, *supra* note 7, art. 10(2)(3).

51. Council Directive 78/631, *supra* note 45, art. 3, at 14-15.

52. Sixth Amendment, *supra* note 21, art. 15, at 16.

fastenings and tactile warnings have been subject to controversial debate throughout the Community. Here, the Member States' packaging rules differ considerably.⁵³

The packaging rules are supplemented by labeling rules. According to Directive 67/548, Member States have to ensure that dangerous substances cannot be placed on the market unless the labeling on their packages satisfies the following requirements:

Every package shall show clearly and indelibly the following:

- the name of the substance,
- the origin of the substance,
- the danger symbol, when laid down, and indication of danger involved in the use of the substance,
- standard phrases indicating the special risks arising from such dangers,
- standard phrases indicating the safety advice relating to the use of the substance.⁵⁴

These factors are spelled out in the directive in some detail. Harmonization is nearly total. While some derogations are allowed, the Member States are obliged to inform the Commission of them. The directives on pesticides and on dangerous preparations, 78/631⁵⁵ and 88/379⁵⁶ respectively, supplement the above mentioned prerequisites by providing further product-related labeling requirements. It is hard to distinguish the different packaging and labeling rules on dangerous substances, pesticides, and preparations. Even the Community seems to be somewhat confused. In its latest directive on dangerous preparations, 88/379, it indicated that the rules should be reviewed to discover where they differ and where loopholes need to be closed.⁵⁷ From an international perspective, it is important that the labeling and packaging rules in the Community have been totally harmonized. Products classified, labeled, and packaged according to these three directives⁵⁸ can be marketed throughout the Community. There is, however, one exception. When products do not fall within the scope of the three directives, considerable differences between national provisions remain.

At the international level, packaging and labeling rules on pesticides and chemicals are mentioned in the GATT Agreement on Tech-

53. Reh binder, *supra* note 20.

54. Sixth Amendment, *supra* note 21, art. 16(2), at 16.

55. Council Directive 78/631, *supra* note 45, arts. 6 & 7, at 16-17.

56. Council Directive 88/379, *supra* note 46, arts. 7 & 8, at 23-25.

57. *Id.* pmbl., at 15.

58. Council Directive 88/379, *supra* note 46; Sixth Amendment, *supra* note 21; Council Directive 78/631, *supra* note 45.

nical Barriers to Trade.⁵⁹ In its preamble, the Agreement urges the parties to ensure that both technical regulations and standards (including requirements for packaging, marking, and labeling) and methods for certifying conformity with technical regulations and standards do not create unnecessary obstacles to international trade. The Agreement, however, does not lay down minimum requirements in any form as to the labeling and packaging of chemicals and pesticides as such. It tries to eliminate possible technical barriers to trade resulting from deviating labeling and packaging standards.

Quite specific rules on the labeling of chemicals and pesticides can be found in the Convention on Safety in the Use of Chemicals at Work.⁶⁰ The primary addressee of the "labeling and marking requirements" in the Convention is the employee, but the Convention applies to all branches of economic activity in which chemicals are used in enterprises, including production, handling, storage, transport, and disposal.⁶¹

Article 7 of the Convention requires signatory States to ensure that hazardous chemicals are labeled so as to provide essential information regarding their identity, their classification, the hazards they present, and the safety precautions to be observed. The requirements of what should be understood by readers of the label are found in the ILO Recommendations.⁶² Specifically, labeling requirements should cover, in conformity with existing national or international systems:

- (a) the information to be given on the label including as appropriate:
 - (i) trade names;
 - (ii) identity of the chemical;
 - (iii) name, address and telephone number of the supplier;
 - (iv) hazard symbols;
 - (v) nature of the special risks associated with the use of the chemical;
 - (vi) safety precautions;
 - (vii) identification of the batch;
 - (viii) the statement that a chemical safety data sheet giving additional information is available from the employer;
 - (ix) the classification assigned under a system established by the competent authority;
- (b) the legibility, durability and size of the label;
- (c) the uniformity of labels and symbols, including colours.⁶³

59. GATT, AGREEMENT ON TECHNICAL BARRIERS TO TRADE pmb. (1979) (currently under revision in the Uruguay Round).

60. ILO Convention, *supra* note 5, art. 7, at 74; see also ILO Recommendation, *supra* note 49, art. 8, at 86.

61. ILO Convention, *supra* note 5, arts. 2 & 7, at 73-74.

62. *Id.* art. 7, at 74; ILO Recommendation, *supra* note 49, art. 8, at 86.

63. ILO Recommendation, *supra* note 49, art. 8(2), at 86.

Criteria for the preparation of chemical safety data and information sheets shall be established by the competent authorities, and then the sheets shall be provided to employers.⁶⁴ There is no link, however, between the classification of a substance and its labeling and packaging with a view to marketing. Information on the dangerous aspects of chemicals and pesticides could be improved indirectly here, but the Convention is not aimed at regulating the trade in or the production of chemicals and pesticides.

The FAO Code of Conduct institutes industrial and governmental responsibilities for labeling and packaging for chemical safety, especially pesticides.⁶⁵ Pesticide containers should be clearly labeled in accordance with applicable international guidelines such as the FAO Guidelines on Good Labeling Practices.⁶⁶ Article 10 of the FAO Code then requires industry:

- to use labels that include recommendations consistent with those of the recognized research and advisory agencies in the country of sale;
- to include appropriate symbols and pictographs whenever possible in addition to written instructions, warnings and precautions;
- to use labels that in international trade clearly show appropriate WHO hazard classification of the contents or, if this is inappropriate or inconsistent with the national regulations, use the relevant classification;
- to include in the appropriate language or languages, a warning against the reuse of containers and instructions for the safe disposal or decontamination of empty containers;
- to identify each lot or batch of product in numbers or letters that can be read, transcribed or communicated by anyone, without the need for codes or other means or deciphering;
- to use labels that are marked with the date, month and year of formulation of the lot or batch and with the relevant information on the storage stability of the product.⁶⁷

Article 10(3) refers to the packaging, storage, and disposal of pesticides which should be in conformity with the principles laid down in the FAO Guidelines for the Packaging and Storage of Pesticides,⁶⁸ the FAO Guidelines on the Disposal of Surplus Pesticides and Pesticides Containers,⁶⁹ and the WHO Specifications for Pesticides used in Pub-

64. ILO Convention, *supra* note 5, art. 8, at 74.

65. FAO Code of Conduct, *supra* note 7, art. 10.

66. FAO, GUIDELINES ON GOOD LABELLING PRACTICE OF PESTICIDES, FAO Doc. COA6/85/9 (1985); FAO, PICTOGRAMS FOR PESTICIDE LABELS.

67. FAO Code of Conduct, *supra* note 7, art. 10(2).

68. FAO, GUIDELINES FOR THE PACKAGING AND STORAGE OF PESTICIDES (1985).

69. FAO, GUIDELINES ON THE DISPOSAL OF SURPLUS PESTICIDES AND PESTICIDES CONTAINERS (1985).

lic Health.⁷⁰ Finally, governments are invited to take the necessary regulatory measures to prohibit the repacking, decanting, or dispensing of any pesticide into food or beverage containers and to enforce rigidly punitive measures that effectively deter such practices.⁷¹

The FAO labeling and packaging rules for pesticides, although not mandatory, are approaching the status of the national and regional rules. They provide a minimum standard in labeling and packaging, a minimum standard that has not yet been achieved in the field of chemical substances and preparations.

3. Advertising

Even modern chemical laws do not provide for mandatory advertising rules. This omission is due to the fact that chemical laws, in principle, are restricted to industrially manufactured chemicals; they exclude preparations dedicated to end-users. This is not the case when chemicals like preparations or pesticides are sold in a manufactured form to end-users. Here, advertising rules might be important to the user. This is particularly true for pesticides, where there have been reports of unfair practices, mainly from Third World countries.⁷² Industrialized countries have not developed specific rules for pesticide advertising. Pesticide advertising is usually subject to rules and regulations concerning unfair marketing practices. The point of reference is not a specific category or product but the market transaction. Equivalent rules do not yet exist on the international level, but the International Chamber of Commerce and the United Nations have attempted to establish fair practices codes.

These efforts can be seen in the FAO Code of Conduct. Article 11 provides extensive rules for the regulation of pesticide advertising.⁷³ The primary target of article 11 is industry itself, but international organizations and public sector groups are invited to call attention to departures from this article.⁷⁴ Under this code, governments are encouraged to work with manufacturers to take advantage of the manufacturers' marketing skills and infrastructures to provide public service

70. WORLD HEALTH ORGANIZATION, SPECIFICATIONS FOR PESTICIDES USED IN PUBLIC HEALTH (1985).

71. FAO Code of Conduct, *supra* note 7, art. 10(4).

72. See DAVID BULL, A GROWING PROBLEM: PESTICIDES AND THE THIRD WORLD POOR 92-123 (1982) (illustrations of pesticide advertisements); FOO GAIK SIM, THE PESTICIDE POISONING REPORT 3 (1985); DAVID WEIR & MARK SHAPIRO, CIRCLE OF POISON, PESTICIDES AND PEOPLE IN A HUNGRY WORLD 40-43 (1981).

73. FAO Code of Conduct, *supra* note 7, art. 11.

74. *Id.*; see also GRETTA GOLDENMAN & SAROVINI RENGAM, PROBLEM PESTICIDES, PESTICIDE PROBLEMS (2d ed. 1988).

advertising regarding the safe and effective use of pesticides.⁷⁵ Such advertising could focus on proper equipment use and maintenance, special precautions for children and pregnant women, the danger of reusing containers, and the importance of following label directions. Although these general rules apply to all kinds of transactions, they are shaped by the needs of the trade between pesticide-producing States and Third World importing States.

C. *Premarket Control of Chemicals and Pesticides*

The Sixth Amendment applies only to newly marketed products.⁷⁶ The U.S. Toxic Substances Control Act (TSCA), to the contrary, explicitly controls both old and new chemicals.⁷⁷ Pesticide control regulations suffer from the same defect. These regulations require statutory review of all new products but do not provide similar scrutiny for products already on the market.⁷⁸

1. Spectrum of Preventive Control Measures

There are three types of preventive control:⁷⁹ prior approval procedures, notification procedures, and regulatory mechanisms in which the primary responsibility rests with the manufacturer. The last category assumes there are no other statutory regulations of chemicals and pesticides and that the manufacturer alone can decide what will be manufactured and how it will be sold.

Most of the industrialized countries have introduced either prior approval procedures or notification procedures, but there are still a considerable number of developing countries without premarket control of chemicals and pesticides.⁸⁰ Notification procedures can be un-

75. FAO Code of Conduct, *supra* note 7, art. 11(3).

76. Sixth Amendment, *supra* note 21, pmb., at 10.

77. See Toxic Substances Control Act, 15 U.S.C. §§ 2603(b)(1)(C), 2604(a) (1988) [hereinafter TSCA].

78. For a comparative analysis of the EC Sixth Amendment and the U.S. TSCA, see George B. Wilkinson, *The Sixth Amendment: Toxic Substance Control in the EEC*, 12 LAW & POL'Y INT'L BUS. 461, 486-97 (1980); see also Robert A. Wyman, Jr., *Control of Toxic Substances: The Attempt to Harmonize the Notification Requirements of the U.S. Toxic Substances Control Act and the European Community Sixth Amendment*, 20 VA. J. INT'L L. 417 (1980). Although somewhat outdated these two articles provide a valuable analysis of both regulatory schemes. See generally *International Regulation of Toxic Substances* (panel discussion), 73 PROC. AM. SOC'Y INT'L L. 76 (1979) [hereinafter *International Regulation of Toxic Substances*]. For a more recent perspective, see RONALD BRICKMAN ET AL., *CONTROLLING CHEMICALS* (1985).

79. See REHBINDER, *supra* note 14, at 5.

80. *Review of Environmental Activities Related to the Production and Use of Chemicals*, UNEP Informal Consultative Meeting on the Implementation of the Amended London Guidelines, UNEP/PIC. CONS. 1/4 (1990); for a comparative analysis, see also REVUE JURIDIQUE DE L'ENVIRONNEMENT, LES PESTICIDES EN DROIT COMPARÉ (1987).

derstood as a mechanism of shared responsibility. The manufacturer has to notify a competent authority of its intention to manufacture or market a new chemical. The authority then takes the necessary steps to ensure that the chemicals are adequately tested, classified, labeled, and packaged. The procedure is different in countries where chemicals and pesticides are subject to a prior approval procedure. In those States, the competent authorities must actually approve a chemical or pesticide before it can be manufactured and marketed.

2. Chemicals

Japan uses a substance-related licensing procedure.⁸¹ It consists both of a screening mechanism designed to assess the risks associated with a particular substance and of a subsequent procedure of formal control. It determines whether the substance belongs to the category of "specified chemical substances." That category consists of substances that are persistent, tend to accumulate in living organisms, and have toxic properties.⁸² The majority of chemical licensing schemes in other States have a much more limited scope and purpose. Germany, Denmark, Norway, Sweden, and Switzerland each have introduced a licensing procedure to control the manufacture, sale, and/or use of particularly hazardous substances. New Zealand only regulates the sale of these substances. These procedures do not create general, substance-related chemical controls.⁸³

The licensing procedures in the Netherlands and the United Kingdom have a broader purpose. Those procedures would allow the introduction of substance-related control. Under the Dutch chemical regulation, a competent agency is authorized to deny a permit where necessary to protect humans and the environment.⁸⁴ It has been disputed whether the Sixth Amendment provides the opportunity to introduce such a licensing scheme. With respect to manufacture and use, Member States are not bound by the directive as long as their procedures are not seen as disguised attempts to control the marketing of substances already notified under the directive and thus freely available for sale in the EC. A licensing procedure that protects against specific risks of manufacture or use seems permissible.⁸⁵

81. OECD COMPARATIVE ANALYSIS, *supra* note 1, at 15; UNEP COMPARATIVE SURVEY, *supra* note 1, at 18.

82. OECD COMPARATIVE ANALYSIS, *supra* note 1, at 15; UNEP COMPARATIVE SURVEY, *supra* note 1, at 18.

83. UNEP COMPARATIVE SURVEY, *supra* note 1, at 17.

84. *Id.* (the Netherlands draft subsequently became law); see also Reh binder, *supra* note 20.

85. UNEP COMPARATIVE SURVEY, *supra* note 1, at 17.

Chemical licensing procedures are not common in the industrialized countries. The broadest attempt to introduce premarket control of chemicals is based on the idea that notification suffices to protect humans and the environment. This is particularly true for the Member States of the EC, and also for the EFTA countries and the United States. The EC Member States have implemented the Sixth Amendment differently. This could significantly impact European integration.⁸⁶ From an international perspective, however, it is much more important to stress the relative harmony among most industrialized countries with respect to the necessary limitation of premarket notification procedures.

The history of the international harmonization of chemical regulation illuminates the incentives for the development of an international model of chemicals control. Since the early 1970s, a number of industrialized countries have discussed the necessity of adopting chemical regulations. France set the European legislative machinery into motion by notifying the Community of its intentions to adopt chemical legislation.⁸⁷ Across the Atlantic, the United States was already in the process of preparing specific chemical-related legislation.⁸⁸ These initiatives were pooled by the OECD. The OECD and the European Community, both international organizations grouping highly industrialized countries, initiated an intensive period of cooperation to guarantee a harmonized approach to regulation among their members to prevent the emergence of new, technical trade barriers. These OECD and EC initiatives were quite successful. There is no evidence that the remaining disparities between EC and U.S. chemical control regulations have led to international trade problems.

Despite the similarities among the legislative efforts of industrialized countries to control chemicals, those similarities do not override a number of important differences.⁸⁹ In the United States, manufacturers have to notify the competent agencies before manufacturing a new chemical.⁹⁰ Under the Sixth Amendment, notification is only necessary before marketing a new chemical.⁹¹ This difference is important in deciding the extent to which Member States are allowed to introduce licensing procedures related to the manufacture and use of specific highly dangerous chemical substances. The difference between

86. See Reh binder, *supra* note 20.

87. Wilkinson, *supra* note 78, at 471.

88. *Id.* at 473, 486.

89. See *id.* at 486; Wyman, *supra* note 78, at 442-43.

90. TSCA, 15 U.S.C. § 2604(a) (1988).

91. Sixth Amendment, *supra* note 21, art. 6(1), at 13.

premanufacturing and premarketing notification is even more important for determining under which conditions chemicals that have not been notified to the authorities might be exported to countries outside either the European Community or the United States. Premanufacturing notification excludes such an opportunity. Premarketing notification allows manufacturers to produce chemicals without notifying the competent authorities if they are able to demonstrate that these chemicals have been produced for export only.

Other difficulties in the negotiations between the OECD and the EC resulted from the differences in the notice procedures of the United States and the EC.⁹² Section 5 of the TSCA requires premanufacturing notice and testing for new substances and substances that are subject to significant "new uses."⁹³ The Sixth Amendment requires elaborate notification documents, including testing results.⁹⁴ Unlike TSCA section 5, which confers no competence on the Environmental Protection Agency (EPA) to compel manufacturers to conduct testing, the Sixth Amendment establishes a mandatory testing scheme for all new chemicals.⁹⁵ In the European Community, responsibility rests upon the manufacturer to judge the possible risk of the notified chemical; in the United States, responsibility lies with the EPA to review the notice and request additional information necessary for risk assessment.⁹⁶ The differences between mandatory testing combined with the manufacturers' responsibility to assess the results as opposed to mere paper notice in conjunction with a statutory risk assessment had led to a situation where testing disparities became a crucial area of concern in the dialogue between the OECD and the EC.

The Sixth Amendment advocated a unique mandatory test screening, valid for all types of chemicals. The U.S. approach focused on the possible toxicity of the product.⁹⁷ The differences in the test philosophy reflect the differences in risk assessment. The EC has a quantity-triggering mechanism that subjects chemicals to a basic test supplemented by additional testing if more than a certain quantity is produced. The U.S. risk assessment procedure was less rigid and less predictable because it focused on the toxicity of the chemical sub-

92. Wilkinson, *supra* note 78, at 489; Wyman, *supra* note 78, at 442-57.

93. TSCA, 15 U.S.C. § 2604(a) (1988).

94. Sixth Amendment, *supra* note 21, art. 6(1), at 13.

95. Compare TSCA, 15 U.S.C. § 2603(a) (1988) with Sixth Amendment, *supra* note 21, art. 6, at 13; see also Wilkinson, *supra* note 78, at 489.

96. Compare Sixth Amendment, *supra* note 21, art. 6(1), at 13 with TSCA 15 U.S.C. §§ 2603(a), 2604(b) (1988); see also Wilkinson, *supra* note 78, at 495-97.

97. Wilkinson, *supra* note 78, at 491-92.

stances alone.⁹⁸

Here the OECD stepped in and tried to develop a common testing framework. Two recommendations, the Guidelines for Testing of Chemicals⁹⁹ and the Good Laboratory Practice in the Testing of Chemicals,¹⁰⁰ both adopted in 1982, have been of considerable importance in bringing together the different approaches. The Guidelines for Testing of Chemicals establishes a minimum set of tests, making European mandatory testing compatible with U.S. optional testing in the case of presumed toxicity.

The EPA used the OECD as an international forum to push the development of minimum testing requirements, although it had no competence under TSCA to adopt such minimum mandatory standards for testing.¹⁰¹ U.S. manufacturers, contemplating the need to defend themselves in future lawsuits under the TSCA, wanted a clear administrative record for TSCA regulations. Therefore, the EPA acted cautiously in its negotiations with the EC and kept careful records of all meetings.¹⁰² European manufacturers, on the other hand, had to accept common Guidelines on Good Laboratory Practice in the Testing of Chemicals. In their national legislation most of the EC Member States refer, in one form or another, to the OECD Guidelines.¹⁰³ The Guidelines are not directly integrated into the laws and are not mandatory in strictly legal terms, but they play a major role in present practice.

No equivalent premarket control legislation exists on the international floor. The Ad Hoc Meeting of Senior Government Official Experts in Environmental Law, Montevideo 1982, adopted a program for the development and periodic review of environmental law.¹⁰⁴ It concluded that international trade in potentially harmful chemicals calls for action, but this mandate has not yet been realized.

3. Pesticides

By authority of either special pesticide laws or general chemical

98. *Id.*

99. OECD, GUIDELINES FOR TESTING OF CHEMICALS (1982).

100. OECD, GOOD LABORATORY PRACTICE IN THE TESTING OF CHEMICALS (1982).

101. For a detailed presentation of the OECD policy, see remarks of M.C. Bracken in *International Regulation of Toxic Substances* (panel discussion), *supra* note 78, at 88; see also BRICKMAN, *supra* note 78, at 298 (discussing the EPA's role in OECD negotiations).

102. Wilkinson, *supra* note 78, at 489-90.

103. Reh binder, *supra* note 20.

104. Montevideo Programme for the Development and Periodic Review of Environmental Law, Ad Hoc Meeting of Senior Government Officials Expert in Environmental Law, Montevideo, 6 November 1981; UNEP Governing Council, Decision 10/21 (May 31, 1982).

laws, most industrialized countries require that a pesticide be registered prior to market entry.¹⁰⁵ The registration procedure is essentially a substance-related licensing procedure. Many countries, including Denmark, France, Germany, and Switzerland, call it a "prior approval procedure," thereby underscoring that pesticides can be marketed only if the competent authority has positively approved their safety.¹⁰⁶ The same type of prior approval procedure is commonly used for medicines.¹⁰⁷ Therefore, one who intends to manufacture and market a new pesticide must perform a series of tests and present the results to the appropriate competent agencies. The manufacturer must also initiate, if necessary, additional testing and decide whether, under what conditions, and for what purpose the pesticide might be put on the market.¹⁰⁸

The normal prerequisites for pesticide approval are sufficient effectiveness, suitability, and safety for humans, animals, and the environment (Denmark, France, Germany, the Netherlands, Japan, Sweden, Switzerland, and the United States).¹⁰⁹ The integration of environmental protection into the licensing procedure is relatively new, and the main objective is still to protect humans rather than the environment. Countries tend to use a two-pronged approach, ranking the protection of the environment behind human health and safety. Sometimes there are additional prerequisites related to the producer or to methods of production. In the United Kingdom, the same kind of assessment is made under a voluntary joint industry-government certification scheme, the Pesticide Safety Precautions Scheme.¹¹⁰ This voluntary arrangement preceded the 1968 introduction of prior approval procedures in the former Federal Republic of Germany. In 1986, however, the United Kingdom joined the majority of the industrialized countries and inserted a prior approval procedure in its pesticide legislation.

At the European level, premarket control of pesticides has never reached the same degree of public and political attention as premarket

105. UNEP COMPARATIVE SURVEY, *supra* note 1, at 18. For a comparative analysis, see KLAUS BOSSELMANN, RECHT DER GEFÄHRSTOFFE: RECHTSVERGLEICHENDER ÜBERBLICK (1987); Charlotte Uram, *International Regulation of the Sale and Use of Pesticides*, 10 Nw. J. INT'L L. & BUS. 460, 463, 467 (1990); see also *supra* note 78 and accompanying text.

106. UNEP COMPARATIVE SURVEY, *supra* note 1, at 18.

107. For a recent analysis of medicine regulation in the European context, see D. HART & N. REICH, INTEGRATION UND RECHT DES ARZNEIMITTELMARKETS IN DER EG (ZERP Schriftenreihe, Band 13, 1990); for an analysis of the situation in a third world country, see G. MATUSCH, DRUG SAFETY IN KENYA (ZERP-Discussion Paper, Band 6, 1991).

108. See UNEP COMPARATIVE SURVEY, *supra* note 1, at 18-19.

109. *Id.* at 18.

110. *Id.*

control of chemicals. In 1976 the Commission of the European Community presented a proposal for the establishment of a European prior approval procedure.¹¹¹ The draft was meant to supplement Directive 78/631¹¹² on the classification, labeling, and packaging of pesticides, but it was not supported by the Council. The White Paper on the Completion of the Internal Market by 1992 gave a new impetus to the harmonization of premarket control in the European Community.¹¹³

In 1991 the Commission adopted a new, completely revised system.¹¹⁴ It provides for a two-tier control that distinguishes between the registration of active substances and the prior approval of preparations.¹¹⁵ Prior approval of preparations (pesticides) should be left to the Member States. The Member States, however, can approve only those preparations whose active substances appear in annex I.¹¹⁶ Article 5 states that an active substance shall be included in annex I for an initial period not exceeding ten years only if

- (a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;
- (b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any unacceptable [sic] influence on the environment as provided for in Article 4(1)(b)(iv) and (v).¹¹⁷

The directive does not currently contain a list of active substances. It should be compiled later by the Standing Committee on Plant Health. Prior approval of preparations by the Member States requires both a listing of the active substances at the Community level and all of the following:

- (b) it is established, in the light of current scientific and technical knowledge [sic] and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with Article 3(3), and having regard to all normal conditions under which it may be used, and to the consequences of its use:
 - (i) it is sufficiently effective;
 - (ii) it has no unacceptable effect on plants or plant products;

111. Commission Proposal for a Council Directive Concerning the Placing of EEC-accepted Plant Protection Products on the Market, art. 3, 1976 O.J. (C 212) 3, 5.

112. Council Directive 78/631, *supra* note 45.

113. Completing the Internal Market: White Paper from the Commission to the European Council, COM(85)310 final.

114. Council Directive 91/414, *supra* note 24.

115. *Id.* arts. 3, 4, at 4-5.

116. *Id.* art. 4(1)(a), at 4.

117. *Id.* art. 5(1), at 6.

- (iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;
- (iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;
- (v) it has no unacceptable influence on the environment, having particular regard to the following considerations:
 - its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater,
 - its impact on non-target species;
- (c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants can be determined by appropriate methods, harmonized according to the procedure in Article 21, or, if not, agreed by the authorities responsible for the authorization;
- (d) its residues, resulting from authorized uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use;
- (e) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use and storage of the product.¹¹⁸

Once a pesticide is registered by a Member State, all the other States would have to allow it to be marketed. A harmonized Community procedure for national registration is lacking. Again, a future definition of this procedure is left to the Standing Committee of Plant Health.

The draft of the above directive was much criticized by Member States with higher levels of protection, as well as by environmental activists.¹¹⁹ It was said to promote the free flow of pesticides and to ignore the necessity of effective environmental protection.¹²⁰ The prerequisites for authorizing preparations and for listing active substances require that there be no "unacceptable influence on the environment."¹²¹ These standards have been accused of falling behind the existing standards of industrialized countries where mere effects on the environment, not only "harmful" or "unacceptable" effects, have to be considered in the risk assessment.¹²² Another point of criticism was the lack of clear criteria for the listing of the active substances and the prior approval of preparations. That task was again left to a Commit-

118. *Id.* art. 4(1)(a)-(e), at 4-5.

119. 4 PAN EUROPE NEWSLETTER, Dec. 1989, at 21-27.

120. *Id.*

121. Council Directive 91/414, *supra* note 24, arts. 4(1)(b)(v) & 5(1)(a), at 4-5, 6.

122. Eckard Reh binder, *Einführung*, in BREMER KOLLOQUIUM ÜBER PFLANZENSCHUTZ, *supra* note 11, at 3.

tee without any parliamentary or public control. Annexes II and III of the current directive attempt to remedy this problem.¹²³ If a Member State has authorized a plant protection product, other Member States cannot prevent the production, storage, and movement of that product. However, Council Directive 91/414 allows Member States to prevent the marketing and use of products that they have not authorized. Pesticides already banned in some Member States cannot return to the markets of those States.¹²⁴ The extensive involvement of FAO in developing common registration standards might contribute to harmonizing the registration procedure in the European Community.

Under the heading "Reducing Health Hazards," article 5 of the FAO Code of Conduct on the Distribution and Use of Pesticides requires governments that have not yet done so to "implement a pesticide registration and control scheme."¹²⁵ Article 6 states:

Governments should take action to introduce the necessary legislation for the regulation, including registration, of pesticides, and make provisions for its effective enforcement, including the establishment of appropriate educational advisory, extension and health-care services. The Guidelines for the registration and control of pesticides should be followed as far as possible, taking full account of local needs, social and economic conditions, levels of literacy, climatic conditions and the availability of pesticide application equipment.¹²⁶

The FAO Code formulates the background conditions of premarket control rather than the procedure itself. The latter is spelled out in the FAO Guidelines on the Registration and Control of Pesticides.¹²⁷ The Code itself grants autonomy to States to decide on the criteria for admitting pesticides to their markets. Reference is made to differences in climate, differences in economic resources, and, implicitly, differences in the possibility of securing the safety of those who apply the pesticides.¹²⁸

The Guidelines for the Registration and Control of Pesticides is designed to be a model registration procedure. This scheme turned out to be too sophisticated for countries lacking the necessary infra-

123. Council Directive 91/414, *supra* note 24, annexes II-III, at 15-32.

124. *Id.* art. 3, at 4.

125. FAO Code of Conduct, *supra* note 7, art. 5.

126. *Id.* art. 6.

127. FAO, GUIDELINES FOR THE REGISTRATION AND CONTROL OF PESTICIDES (INCLUDING A MODEL SCHEME FOR THE ESTABLISHMENT OF NATIONAL ORGANIZATIONS) (1985); FAO, ADDENDA TO THE GUIDELINES FOR THE REGISTRATION AND CONTROL OF PESTICIDES (1988).

128. The Code has been blamed for not adequately addressing the problem of industry double standards. GOLDENMAN & RENGAM, *supra* note 74, at 20-22.

structure. Therefore, FAO is preparing Guidelines on the Initial Introduction of a Simple National Pesticide Registration and Control Scheme. Testing requirements are stated in the Guidelines on Environmental Criteria for the Registration of Pesticides,¹²⁹ presently under revision. The Guidelines on Good Laboratory Practices define minimum testing standards.¹³⁰ There are ten other guidelines already published, under revision, or under consideration leading to the conclusion that the FAO fulfills the same role in the development of common testing rules for international trade in pesticides as the OECD does in the international regulation of chemicals. Industrialized countries have pooled their interests in chemical regulation within the OECD, a forum to which Third World countries have no access. FAO is open to all States. Developing countries may bring their influence to bear, but FAO is primarily an organization dealing with food and agriculture and not with health, safety, or environmental protection. In the 1970s, however, it seriously began to consider these objectives. This might explain why the FAO is seen as the appropriate forum for international coordination and cooperation.

D. *Postmarket Control of "Old" Substances and "Old" Pesticides*

Postmarket control mechanisms cover two different areas of concern. First, regulatory mechanisms have to be found for the handling of risks from chemicals and pesticides brought into circulation before premarket control legislation was adopted. Second, measures are needed to withdraw from the market, or even to ban the production of, products that legally entered circulation under previous premarket control mechanisms but that later turned out to be dangerous. Currently, when there is no common denominator on premarket control mechanisms of pesticides and chemicals in sight, it might sound strange to emphasize postmarket control mechanisms at the international level. Public attention, however, is increasingly focused on chemicals and pesticides that are legally manufactured and marketed all over the world, but that nevertheless constitute risks. The lesson to be learned is that premarket controls cannot guarantee that long-term hazards will not emerge.

1. Concept of Postmarket Control

Postmarket control of old chemicals and old pesticides uses a

129. FAO, GUIDELINES ON ENVIRONMENTAL CRITERIA FOR THE REGISTRATION OF PESTICIDES (1985).

130. FAO Code of Conduct, *supra* note 7, at 37 n.4 (explicitly referring to the OECD Guidelines prepared for the testing of chemicals but then expanded to pesticides).

three-step procedure. A competent regulatory authority must first make safety an acceptable reason for engaging in postmarket control. It then has to investigate the dangers arising from the questioned chemicals and pesticides. Finally, it must decide what action to take. Although regulations in distinguishing more and more sophisticated degrees of danger often create more problems than they pretend to solve, there seems to be a commonly accepted difference in premarket and postmarket control of chemicals and pesticides. Premarket control relates to potential hazards; postmarket control relates to suspected and known risks.¹³¹ Defining the risk is the starting point for investigating the danger. Regulatory bodies can only take postmarket control action if they get the necessary information on risks to humans and the environment. Once the information is available, the authorities enter the decision-making process. Modern chemical and pesticide laws provide several regulatory instruments to fight possible dangers.¹³²

Although postmarket control in industrialized countries is a relatively new regulatory field, some common trends are already clear. There is a tendency to confer responsibility for postmarket control mechanisms on the statutorily competent authorities that are already responsible for premarket control. These authorities have thereby gained substantial power. They benefit from the uncertainties in defining risks, from comprehensive mandates in investigating dangers, and from discretion in taking the appropriate measures.¹³³

This tendency might be somewhat counterbalanced by splitting competencies. Industrialized countries tend to establish separate authorities for each category of products — one agency for chemicals, another for pesticides. When competence for multiple products is brought under the same umbrella organization, separate divisions on chemicals and pesticides are usually set up, as in the case of the EPA.

There is an important difference in the regulatory philosophies of European and U.S. authorities. It has been noted that

although U.S. and European governments have addressed the problem of chemical control at roughly the same times and have assumed similar responsibilities, they have developed markedly different procedures for reaching regulatory decisions. Two distinct patterns emerge. American regulatory processes stand apart in the complexity of their procedures, the heavy reliance on formal analysis of risks and benefits, the openness of administrative decision making, and the active supervision of executive agencies by Congress and the courts. European processes, despite

131. OECD COMPARATIVE ANALYSIS, *supra* note 1, at 9-14.

132. *Id.* tbl. 4, at 21.

133. Majone, *supra* note 40, at 97-98.

some notable differences among them, share simpler administrative procedures, greater informality in the analysis of evidence, less complete public access to decision makers, and relatively little oversight by parliament or the courts. Yet one of our most intriguing conclusions is that these contrasting methods of decision making have led to remarkably similar policy choices, particularly in the selection of specific chemicals as targets of regulation.¹³⁴

Access to information plays a key role in postmarket control. The 1980s demonstrated the growing power of national and international nongovernmental organizations to bring the risks of chemicals and pesticides to the public's attention and to push regulatory agencies into action. Effective postmarket control requires the early public dissemination of information on even potential risks of chemicals and pesticides. Access to information, however, has to be weighed against the legitimate intellectual property interests of manufacturers in protecting data on chemicals and pesticides. The industrialized countries have not yet arrived at a common solution. The TSCA obliges chemical manufacturers to make publicly available all data about their products related to health, safety, and environmental protection. The Sixth Amendment chose a much more restrictive approach. Data are not made available to the public because manufacturers may require confidentiality.¹³⁵ The OECD has tried to harmonize differences between the United States and the European Community. Two guidelines on the confidentiality of data protection have been developed. The extent to which European and U.S. manufacturers have harmonized their differences has never been investigated. As far as is currently known, problems have not arisen, but mainly European manufacturers have feared the liberal U.S. approach to data protection. Even EC policy has changed, as indicated by the newly adopted Directive on Freedom of Access to Information.¹³⁶

Whatever solutions are found among the industrialized countries to balance the conflicting interests of the public in having early access to information about potential hazards of chemicals and pesticides and of manufacturers to protect these data, there is much pressure on international and nongovernmental organizations, watchdogs of the international trade in chemicals and pesticides, to establish their own

134. BRICKMAN, *supra* note 78, at 23.

135. Wilkinson, *supra* note 78, at 483. For a more comprehensive treatment, see Wyman, *supra* note 78, at 451-52.

136. Council Directive 90/313 of 7 June 1990 on the Freedom of Access to Information on the Environment, 1990 O.J. (L 158) 56; GERD WINTER, ÖFFENTLICHKEIT VON UMWELT-INFORMATIONEN: EUROPÄISCHE UND NORDAMERIKANISCHE RECHTE UND ERFAHRUNGEN (1990).

data collection systems.¹³⁷ These systems, however, can never reach the same level and quality as the systems erected in the multinational enterprises or in the competent authorities of the main chemical- and pesticide-producing countries. International information systems that do not distinguish between confidential and nonconfidential data on potential risks of chemicals and pesticides and that guarantee access to information run the risk of stocking only the "second best" data.

2. Information Collection and Information Exchange

At the national level, highly sophisticated regulatory systems have been developed in the EC, the EFTA countries, and the United States. Despite considerable differences in detail, there seems to be an inverse relationship between the quality of premarket control and that of postmarket control. In other words, in countries with a well-developed system of premarket control of pesticides, as in Germany, postmarket control is less developed. Quite the opposite is true for technical consumer goods. These goods are usually not subject to any kind of statutory premarket control, but highly sophisticated systems exist to withdraw unsafe technical consumer goods from the market.¹³⁸ Well developed data collection is based on accident surveillance systems; on the notification duties of manufacturers, suppliers, and importers; and on mechanisms to guarantee that informal information from individuals or organizations is dealt with appropriately. The overall intention of these mechanisms is to guarantee that competent authorities are brought into a position where they can assess the reported risks with respect to the legal requirements.

At the EC level, a sophisticated system of information collection and information exchange is operating only in the area of technical consumer goods. Here, the so-called Rapid Exchange System, Council Regulation 84/133, requires the reporting of formal and informal regulatory actions of Member State authorities to the Commission, which guarantees the exchange of information with all the other Member States.¹³⁹ The Draft Directive on Product Safety 90/C 156/07 even tries to establish a mechanism under which the Commission itself

137. Y. Domzalski, *Les Interpolés des Associations de Consommateurs*, BEUC/113/84 (1984).

138. See CHRISTIAN JOERGES ET AL., *DIE SICHERHEIT VON KONSUMERGÜTERN UND DIE ENTWICKLUNG DER EUROPÄISCHEN GEMEINSCHAFTEN* (ZERP Schriftenreihe, Band 2, 1988) for a comprehensive analysis of consumer product safety legislation in the European Community.

139. Council Decision 84/113 of 2 March 1984 Introducing a Community System for the Rapid Exchange of Information on Dangers Arising from the Use of Consumer Products, 1984 O.J. (L 70) 16, as amended 1989 O.J. (L17) 51, and 1990 O.J. (L 173) 49. For a critical review, see Josef Falke, *What Should be the Content of an E.E.C. General Directive on the Safety of Technical Consumer Goods*, BEUC LEGAL NEWS, Nov.-Dec. 1986, at 16.

is able to take action at the Community level in emergency situations.¹⁴⁰

There is no EC equivalent for controlling chemicals and pesticides. There is no mechanism obliging Member States to exchange information with the Commission or with the other Member States on possible risks from unsafe chemicals or pesticides. Presently, the consultative committees, composed of representatives of Member States and the Commission and constituted under the respective directives, guarantee that an informal exchange of information can take place. However, these committees are working behind closed doors; neither public interest groups nor manufacturers have been officially granted access. Also, the committees themselves are under no duty to report on their activities.¹⁴¹

The situation is different when Member States want to prohibit or restrict the marketing of chemicals or pesticides that comply with accepted European standards. Here, the directives provide a safeguard procedure under which Member States must notify the Commission of their intentions. The Commission, in turn, then initiates a procedure to find a common position at the European level.¹⁴² However, there is no legal obligation to come to a joint solution. The Community has no power to take action if one Member State legitimately prohibits the import of certain unsafe chemicals or pesticides for health, safety, and environmental protection reasons. This mechanism, established under the Sixth Amendment, is used in Directive 91/414 on pesticides.¹⁴³

Information collection and exchange about possible risks from dangerous pesticides and chemicals and about regulatory actions taken by States to mitigate these risks constitute two of the predominant areas of concern for international organizations.¹⁴⁴ U.N. organizations concentrate their toxic chemical efforts on the collection, evaluation, and dissemination of information on chemical risks. The environmental health criteria program, for example, compiles and analyzes the available information on the health effects of a limited

140. Commission Amended Proposal 90/C 156/07 of 11 June 1990 for a Council Directive Concerning General Product Safety, arts. 8-11, 1990 O.J. (C 156) 8, 12-13; see also Josef Falke, *Elements of a Horizontal Product Safety Policy for the European Community*, 12 J. CONSUMER POL'Y 207 (1989); Stephen Weatherill, *A General Duty to Supply Only Safe Goods in the Community, Some Remarks from a British Perspective*, 13 J. CONSUMER POL'Y 79 (1990).

141. H. Bentlage, *An Advisory Board for Consumer Product Safety: The German Experience — European Perspectives*, in *STUDIE IM AUFTRAG DER EUROPÄISCHEN GEMEINSCHAFTEN (ZERP Vertrags-Nummer 6674/89/15, 1990)*.

142. The safeguard procedure is not specific to a particular directive. It is a widely spread mechanism to cope with differing regulatory actions of Member States to fight unsafe products.

143. Council Directive 91/414, *supra* note 24, art. 11, at 9.

144. See BRICKMAN, *supra* note 78, at 291.

number of selected pollutants. These evaluations are published in a series of reports, some of which even conclude with regulatory recommendations. WHO has established a similar program on work place hazards.¹⁴⁵

Several U.N. programs focus more on dissemination of information than on evaluation. The International Register of Potentially Toxic Chemicals is charged with developing an international data bank on toxic chemicals, particularly common agrochemicals. ILO publishes bibliographies and an encyclopedia of occupational health and safety, both of which contain information on chemical hazards. The International Programme on Chemical Safety (IPCS), an effort cosponsored by WHO, ILO, and UNEP, has been established to register national institutions and support agencies in a coordinated program of new research on specific hazards.

In contrast to the EC, or even the OECD, programs, the efforts of the U.N. organizations in the area of toxic substance control seem rather fragmented, even duplicative. They try to achieve, however, what is undoubtedly their principal purpose and value: to render service to those countries that lack an indigenous capability to compile such information and to evaluate the world literature on chemical hazards. In fulfilling these functions, the U.N. agencies help extend the benefits of scientific information and increased sophistication in controlling risks to the less advantaged regions of the world.¹⁴⁶

After information on toxic chemical risks has been collected, mechanisms have to be established to promote collective regulatory action. This is where international organizations have become involved and have demonstrated their willingness to play a key role. The emergence of information collection and exchange in the field of regulatory action restricting or banning chemicals and pesticides is closely related to the discussion of international efforts to regulate the export and import of severely restricted and banned chemicals and pesticides.¹⁴⁷

The OECD is playing a leading role in the management of risks from old chemicals and pesticides that were originally produced and marketed long before mechanisms of premarket control were developed. The OECD, supported by the main chemical-producing countries, is trying to develop a program for dealing with old chemicals and

145. For a comparative overview, see OECD, REPORT OF THE EXPERT GROUP ON INFORMATION EXCHANGE RELATED TO EXPORT OF HAZARDOUS CHEMICALS (1982).

146. BRICKMAN, *supra* note 78, at 291.

147. See *supra* Part II(E).

pesticides.¹⁴⁸ Currently, there is no common methodology for selecting old substances. Different criteria, resulting from the divergent experiences of the key authorities of the various States, are under discussion. For instance, the German Federal Environmental Agency, composed of representatives from the chemical industry, government agencies, and science, advocates a multistep procedure. From the original list of 4,554 substances, only sixty remain to be further examined. The parallel to the late 1970s, when the introduction of premarket control mechanisms on chemicals was discussed in Europe and in the United States, is striking. Once more, it may be necessary to find a common denominator in order to evaluate over 100,000 chemical substances and to decide which require the highest degree of public attention.¹⁴⁹ A recent EC initiative that translates the OECD program into EC legislation seems to be a first step in that direction.¹⁵⁰

3. Rules to Ban or Restrict the Production, Marketing, and Use of Unsafe Chemicals and Pesticides

Deciding to ban or restrict unsafe chemicals and pesticides entails a complicated procedure of balancing interests. This procedure takes place at the national level. Each State defines the instruments and chooses the regulatory form under which the action is taken. In Germany and Japan, partial bans or restrictions of chemicals are accomplished by regulation. Most States delegate the authority to ban or restrict the marketing and use of unsafe chemicals and pesticides to the agency in charge of premarket control.¹⁵¹

There are considerable differences in the instruments on which action can be based. The OECD Report gives an overview using a set of tables that link the trigger mechanism to the selection of control action.¹⁵² It should be noted, however, that most of the industrialized countries provide not only for the possibility of restricting or banning the marketing of unsafe chemicals but also for intervening in the production process itself and prohibiting the manufacture of dangerous

148. James E. Brydon et al., *OECD's Work on Investigation of High Production Volume Chemicals*, 13 Int'l Env't Rep. (BNA) 263 (June 13, 1990).

149. *Id.* at 263-64.

150. Commission Proposal 90/C 276/01 of 5 October 1990 for a Council Regulation (EEC) on the Evaluation and the Control of the Environmental Risks of Existing Substances, 1990 O.J. (C 276) 1; Hans-W. Micklitz, *Organisational Structures of Product Safety Regulation*, in *LA SÉCURITÉ DES BIENS DE CONSOMMATION, INTÉGRATION EUROPÉENNE ET CONSOMMATION SUISSE* (B. Stauder ed.) (describing and analyzing premarket and postmarket regulation in the field of product safety) [hereinafter *Organisational Structures*].

151. UNEP COMPARATIVE SURVEY, *supra* note 1, at 15.

152. See OECD COMPARATIVE ANALYSIS, *supra* note 1, tbls. 2, 3, 4, 5, at 13, 16, 21-22.

chemicals.¹⁵³

EC Member States remain responsible for restricting or banning the manufacture, use, and marketing of unsafe chemicals and pesticides. There is not yet an agreement, even with a view toward the Internal Market, regarding postmarket control at the European level. The directives to ban and restrict unsafe chemicals, Directive 76/769,¹⁵⁴ and to regulate unsafe pesticides, Directive 79/117,¹⁵⁵ provide a regulatory framework that may be regarded as a starting point for European postmarket control management. A ban or restriction, however, entails setting the complicated and lengthy agreement procedure of the Community into motion. The Council, the legislative organ, rather than the Commission, the executive organ, must make the necessary decision. Agreements are often reached at the lowest common denominator and resulting measures are adopted only after considerable delay. It is not surprising that there is little harmony within the Community regarding which particular chemicals and pesticides are to be restricted or banned.¹⁵⁶ The example of pentachlorophenol illustrates the difficulties; the former Federal Republic of Germany decided to ban pentachlorophenol after informing the Commission and waiting more than one year for a joint approach.¹⁵⁷

At the international level, banning or restricting the production, use, and marketing of unsafe chemicals and pesticides requires an agreement in the competent international organization(s) to either issue a recommendation or develop a binding convention. There are only a few examples thus far where a worldwide agreement is being considered to regulate unsafe chemicals and pesticides. Reference can be made to the OECD recommendation to ban PCB¹⁵⁸ and the most recent Montreal Protocol to reduce the production of chemicals that deplete the ozone layer.¹⁵⁹

International organizations have to develop more flexible systems to compensate for their lack of regulatory competence. One well-

153. UNEP COMPARATIVE SURVEY, *supra* note 1, at 15.

154. Council Directive 76/769 of 27 July 1976 on the Approximation of the Laws, Regulations and Administrative Procedures of the Member States Relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations, 1976 O.J. (L 262) 201.

155. Council Directive 79/117 of 21 December 1978 Prohibiting the Placing on the Market and Use of Plant Protection Products Containing Certain Active Substances, 1979 O.J. (L 33) 36.

156. *Organisational Structures*, *supra* note 150.

157. Pentachlorophenolverbotsverordnung, 1989 Bundesgesetzblatt I 2235.

158. See OECD Council Decision, Protection of the Environment by Control of Polychlorinated Biphenyls (Feb. 13, 1987). For further details, see OECD, THE OECD CHEMICALS PROGRAMME (1988); Alston, *supra* note 2, at 423.

159. Montreal Protocol on Substances that Deplete the Ozone Layer, S. TREATY DOC. No. 10, 100th Cong., 1st Sess. (1987).

known but highly controversial mechanism to initiate the worldwide banning and restricting of unsafe chemicals and pesticides is the adoption of the U.N. Consolidated List, now in its third edition.¹⁶⁰ This list compiles information about regulatory actions on chemicals and pesticides in order to show, mainly to developing countries, the type of actions taken by the industrialized countries to combat unsafe chemicals and pesticides. The Consolidated List is not legally binding, but it may have a moral impact in that the products on the list are stigmatized and consequently more difficult to market worldwide. The list may affect regulatory action in developing countries. It also may become instrumental for nongovernmental organizations in their fight against trade in pesticides and chemicals that pose a well known risk to humans and the environment. An example is the Dirty Dozen Campaign of the Pesticides Action Network (PAN).

E. Regulation of the Export and Import of Banned and Severely Restricted Chemicals and Pesticides

There are a number of national and international rules on the export and import of banned and severely restricted chemicals and pesticides that merit consideration. From a national perspective, efforts by the United States, mainly during the late 1970s and early 1980s, to regulate the export of pesticides and chemicals must be mentioned.¹⁶¹ From a regional perspective, reference should be made to Council Regulation 1734/88 concerning the export and import of certain dangerous chemicals.¹⁶² However, national and regional efforts lag behind the overwhelming interest of international organizations in advocating harmonized regulation on the export and import of banned

160. For further analysis, see HANS-W. MICKLITZ, EXPORT OF DANGEROUS PHARMACEUTICALS TO THIRD WORLD COUNTRIES (ZERP-Discussion Papers, 1987).

161. For the leading article on this subject, see Francine Schulberg, *United States Export of Products Banned for Domestic Use*, 20 HARV. INT'L L.J. 331 (1979). For an international perspective, see Lothar Gündling, *Prior Notification and Consultation*, in TRANSFERRING HAZARDOUS TECHNOLOGIES AND SUBSTANCES: THE INTERNATIONAL CHALLENGE 63 (Günther Handl & Robert Lutz eds., 1989); Eckard Reh binder, *Export von Schädlingsbekämpfungsmassnahmen: Gemeinsame Verantwortung von Export- und Importstaat?*, in JAHRBUCH DES UMWELT- UND TECHNIKRECHTS 337 (UTR Band 5, 1988); Marc Pallem aerts, *Diplomacy and Double Standards: The Regulation of International Trade in Pesticides* (1985) (unpublished Masters thesis, Harvard Law School).

162. Council Regulation 1734/88 of 16 June 1988 Concerning Export From and Import Into the Community of Certain Dangerous Chemicals, 1988 O.J. (L 155) 2. The Commission has proposed an amended version of this regulation. The amended version would incorporate a prior informed consent procedure. Commission Proposal 91/C 17/20 of 20 December 1990 for a Council Regulation Concerning Export and Import of Certain Dangerous Chemicals, 1991 O.J. (C 17) 16; see also Marc Pallem aerts, *Export Notification: The EC Approach in the International Context*, EUR. ENV'T REV., Feb. 1987, at 25 (discussing the draft proposal for the above-cited regulation).

and severely restricted chemicals and pesticides. Among the most notable efforts are:

- OECD Recommendation C (84) 37 Information Exchange Related to Export of Banned or Severely Restricted Chemicals (1984);
- OECD Guiding Principles on Information Exchange Related to Export of Banned or Severely Restricted Chemicals (1984);
- UNEP Amended London Guidelines for the Exchange of Information on Chemicals in International Trade (1989);
- FAO International Code of Conduct on the Distribution and Use of Pesticides (1989);
- UNEP Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989).

1. Concept, Definition, and Role of International Organizations

The export and import of banned and severely restricted chemicals and pesticides has become an international issue. The first initiative to develop international rules, notably undertaken by the OECD, derived from the U.S. policy of the late 1970s and early 1980s to regulate exports and imports from a human rights perspective.¹⁶³ However, national efforts to control exports and imports have slackened and have been replaced by attempts by different international organizations to find a harmonized procedure. The different regulatory approaches of the industrialized nations toward exports of banned and severely restricted chemicals and pesticides are seen as a technical barrier to trade requiring an international process of harmonization. The interest in and impact of such an international understanding, however, is limited.

The original plan to harmonize export/import rules worldwide involved merely bridging the gaps between the differences in the various national efforts to protect their citizens and the environment against risks resulting from pesticides and chemicals. Nevertheless, the differences that continue even among industrialized nations lead to a situation in which one industrialized country bans or restricts certain pesticides or chemicals while another allows their continued production and marketing.¹⁶⁴

The main impetus for an international rule, however, is not the differences among industrialized nations. Developing countries, the primary recipients of exports of banned and severely restricted chemicals and pesticides, complained in the late 1970s that there was no

163. See generally M.G. Kaladharan Nayar, *Human Rights: The United Nations and United States Foreign Policy*, 19 HARV. INT'L L.J. 813, 824-31 (1978); Dana J. Jacob, Comment, *Hazardous Exports from a Human Rights Perspective*, 14 SW. U. L. REV. 81 (1983).

164. See Schulberg, *supra* note 161, at 331-33.

national legislation to protect them from such exports. Therefore, the overall perspective in the early 1980s was not to harmonize the international rules on the production, use, and marketing of chemicals and pesticides. Rather, the goal of the 1970s and 1980s was to find international rules bridging the gap between the differences among the extensive chemicals and pesticides regulations of the industrialized exporting countries and the lack of comparable rules in the importing developing countries. One might even conclude that the original intention was not to regulate the trade of banned and severely restricted chemicals and pesticides but to find rules under which trade in these incriminated product categories could be legitimated.

In this period, the OECD played a key role in international efforts to resolve export/import issues. In 1984, the OECD adopted its Recommendation on the Information Exchange Related to Export of Banned or Severely Restricted Chemicals¹⁶⁵ and the Guiding Principles.¹⁶⁶ For a number of years, a consensus among the OECD States determined the nature of the discussion in broader forums like UNEP and FAO. The regulatory model, based on a clear distinction between information exchange on the one hand and export notification on the other, has been overcome only in the last few years. Under pressure from developing countries supported by nongovernmental organizations, the OECD regulatory models were further developed and supplemented by the PIC procedure.¹⁶⁷

The PIC procedure represents an important shift in the regulation of hazardous, not just banned and severely restricted, chemicals and pesticides. These rules may be the starting point for the development of international rules on the production, use, and marketing of chemicals and pesticides. This is true for two reasons. First, the PIC procedure establishes a mechanism that guarantees that all actions taken by countries to restrict or ban chemicals or pesticides can be integrated. Second, the rules on classification, labeling, and technical assistance integrated within the UNEP Amended London Guidelines not only support the scope of the more narrow rules on banned and severely restricted chemicals and pesticides, but may be understood as an effort to establish international minimum standards applicable to all chemicals and pesticides. The Basle Convention providing for PIC¹⁶⁸ has

165. OECD, RECOMMENDATION ON THE INFORMATION EXCHANGE RELATED TO EXPORT OF BANNED OR SEVERELY RESTRICTED CHEMICALS (1984).

166. OECD, GUIDING PRINCIPLES ON INFORMATION EXCHANGE RELATED TO EXPORT OF BANNED OR SEVERELY RESTRICTED CHEMICALS (1984).

167. AMENDED LONDON GUIDELINES, *supra* note 3; FAO Code of Conduct, *supra* note 7.

168. UNEP, *Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal*, ENVTL. POL'Y & L., Apr. 1989, at 68. For the EC's commitment in imple-

considerably facilitated the adoption of the Amended London Guidelines.

This view of the further development of international rules for the export of banned and severely restricted pesticides and chemicals is considerably strengthened by the fact that GATT has put the issue in the Uruguay Round. GATT established notification and information exchange mechanisms in the early 1980s, an effort initiated by the strong engagement of the OECD, FAO, and UNEP. GATT felt that something should be done and entered the field.¹⁶⁹ The discussions and negotiations on the rules, however, took place within the OECD, FAO, and UNEP. With the establishment of the Working Group on Trade of Domestically Prohibited Goods and Other Hazardous Substances, the international scenario has changed dramatically. GATT's involvement makes it clear that rules are needed at the international level to integrate the original GATT idea of free trade with the necessity of protection of health, safety, and the environment. GATT's commitment could well constitute the beginning of the development of an international regulatory order for product safety and environmental protection.

2. Information Exchange, Export Notification, and Prior Informed Consent Procedure

The OECD Recommendation on Information Exchange and the Guiding Principles, both adopted in 1984, have introduced a two-tier procedure.¹⁷⁰ This procedure remains valid and is used worldwide. The procedure is based on the distinction between the exchange of information on regulatory action and the notification of an export once it occurs. Information exchange simply means that States that have taken action to ban or severely restrict a chemical or pesticide are to notify the other members of the relevant international organizations. Such information exchange should guarantee that the other members are kept abreast of the actions taken within the network. The establishment of an information exchange mechanism involves defining the types of action that require notification:

menting the Convention, see Commission Proposal 90/C 289/05 of 10 October 1990 for a Council Regulation (EEC) on the Supervision and Control of Shipments of Waste Within, Into and Out Of the European Community, 1990 O.J. (C 289) 9.

169. Eckard Reh binder, *Environmental Protection and the Law of International Trade*, in *THE FUTURE OF THE INTERNATIONAL LAW OF THE ENVIRONMENT* 357 (R.J. Dupuy ed., 1985) (with particular reference to the export of hazardous chemicals and transfrontier disposal of wastes).

170. RECOMMENDATION ON INFORMATION EXCHANGE, *supra* note 165; GUIDING PRINCIPLES ON INFORMATION EXCHANGE, *supra* note 166.

- only final action as promoted by the industrialized countries or already provisional and intermediary actions;
- a definition of what is to be understood by hazardous chemicals, only banned or severely restricted, or at the same time unregistered or voluntarily withdrawn, chemicals and pesticides;
- last, but not least, it requires the complicated determination of the category "severely restricted."¹⁷¹

The OECD Guiding Principles have taken a narrow approach, covering only final actions and limiting the scope to banned and severely restricted products, excluding both informal activities of manufacturers and never-registered products. This approach determines the scope of each and every international mechanism currently under discussion. Information exchange about final regulatory actions on limited product categories constituted the industrialized States' original offer to guarantee the developing States some minimum protection. Mere information exchange between designated authorities seemed quite moderate, but information exchange becomes substantially more important once an organization compiles and files the information in a separate document like the Consolidated List.¹⁷²

Export notification must be clearly distinguished from mere information exchange about regulatory actions. With export notification, the exporter notifies the exporting authorities and/or the importing authorities that the exporter intends to export chemicals or pesticides. The OECD Guiding Principles originally blocked the efforts of developing countries to use export notification to impede international trade in chemicals and pesticides. PIC means that the exporter must notify the planned destination of an intention to export and then wait for the importing country's consent before shipping the products. Numerous variations have been discussed within the last few years, ranging from stop shipment notification to a more flexible approach where only annual notification would be necessary.

There are also various opinions on the appropriate level of government involvement. Developing countries pushed for a model where exporters would be required to notify statutory authorities in both the exporting and importing States and where each statutory authority transmits the notification to the other. In contrast, manufacturers promoted the idea of organizing export notification between the exporter and the importer and not engaging the statutory authorities of either State.

The prevailing export notification mechanism, as set out by the

171. GUIDING PRINCIPLES ON INFORMATION EXCHANGE, *supra* note 166, at 1094.

172. See Gündling, *supra* note 161; Pallemarts, *supra* note 161.

OECD Guiding Principles, leaves room for interpretation. The language provides that, if the export of a chemical banned or severely restricted in the State of export occurs, the State of export should ensure that the necessary steps are taken to provide the designated national authority of the State of import with relevant information.¹⁷³ In the words of the OECD and the original London Guidelines, the purpose of export notification is "to remind the State of the import of the original notification regarding control action (information exchange) and to alert it to the fact that an export will occur or is occurring."¹⁷⁴ There are some minor differences between the OECD Guiding Principles, the original UNEP Guidelines, and article 9 of the 1985 version of the FAO Code of Conduct, but whatever these differences are, no stop-shipment notification, not even notification prior to export, is mandatory. The roles of exporters and importers and of exporting and importing authorities are not clearly defined.

Despite this uncertainty, the information exchange and export notification originally promoted by the OECD Guiding Principles have become part of the national regulatory systems of most industrialized nations. Provisions of U.S. chemical and pesticide laws and regulations cover information exchange and notification procedures as provided under the OECD Guiding Principles.¹⁷⁵ EC Regulation 1734/88 codifies the OECD, UNEP, and FAO international consensus.¹⁷⁶ The EC regulation wisely avoids a number of conflicts over its scope by listing twenty-one chemicals and pesticides that fall within the ambit of the exchange and notification mechanism.¹⁷⁷

The PIC procedure in the Amended London Guidelines and in the FAO Code of Conduct constitutes a considerable step toward a more sophisticated scheme for the regulation of trade in banned and severely restricted pesticides. The adoption of the PIC procedure is properly seen as the response of the developing countries to the OECD States' efforts to impose the agreement on information exchange and export notification on them. A conflict resulted from the adoption of the PIC procedures. The industrialized nations defended the OECD

173. GUIDING PRINCIPLES ON INFORMATION EXCHANGE, *supra* note 166.

174. AMENDED LONDON GUIDELINES, *supra* note 3, art. 8(b).

175. See generally Raymond Hill, *Problems and Policy for Pesticide Exports to Less Developed Countries*, 28 NAT. RESOURCES J. 699 (1988) (reviewing U.S. and international policies regulating pesticide exports); Robert E. Lutz, *The Export of Danger: A View from the Developed World*, 20 N.Y.U. J. INT'L L. & POL. 629, 642-69 (1988) (analyzing the extent to which the United States and other technology producing countries regulate hazardous exports).

176. Council Regulation 1734/88, *supra* note 162, currently under revision to implement PIC procedures. Commission Proposal 91/C 17/20, *supra* note 162, pmb. & art. 1, at 16-17.

177. Council Regulation 1734/88, *supra* note 162, art. 2(1)-(2) & Annexes I-II, at 17-18 & 21.

system as sufficient to deal with banned and severely restricted pesticides while the developing countries advocated a mechanism to guarantee that importing countries are informed of the export of banned and severely restricted chemicals prior to export. This conflict led to the development of the red-flag approach.

The red-flag approach is a PIC procedure that centers on the idea that exporting and importing States can negotiate an alert list. Importing countries must decide whether to accept, accept with restrictions, or reject imports of listed chemicals and pesticides. The red-flag approach can be described as a "control-action-related PIC procedure," control-action-related because PIC is bound to the control action and not to the concrete export.

Crucial to the operation of the red-flag approach is determining which products under what conditions should be on the alert list. The answer is pragmatic. Chemicals that ten or more countries have banned or severely restricted will be automatically placed on the list. Those that five or more but less than ten countries have banned or severely restricted will be subject to an "informal consultative process," to determine whether they meet the London Guidelines and FAO Code definitions of banned or severely restricted for health or environmental reasons.¹⁷⁸ Chemicals meeting the definitions will be placed on the list. This system applies to chemicals subjected to control actions before the implementation of the PIC scheme and will lead to the establishment of an initial red-flag list.

A different system will apply to chemicals that are banned or severely restricted after the circulation of the initial list. These chemicals will automatically become subject to PIC requirements when even a single government takes a control action "meeting the definitions of the London Guidelines" and notifies the PIC body of that action.¹⁷⁹ However, there is "an informal consultative process" to "assist UNEP and FAO in determining whether the control action meets the definition,"¹⁸⁰ a process that places discretion with UNEP, FAO secretariats, consulted competent national authorities, and experts. For the first time, a worldwide mechanism has been established to constantly review chemicals and pesticides as to whether they should be put on the red-flag list.

The PIC procedure also confers a key role on IRPTC. IRPTC must disseminate the control action to all participating countries and

178. AMENDED LONDON GUIDELINES, *supra* note 3, at annex I(1)(b)(ii).

179. *Id.* annex II(1)(c).

180. *Id.* annex II(2)-(4).

verify whether they will accept exports of the controlled substance.¹⁸¹ The introduction of the PIC procedure has redefined the responsibilities of importing and exporting countries. The OECD model vests in the importing country primary responsibility for deciding what to do with the information received. The PIC procedure, however, explicitly starts from the concept of shared responsibility between exporting and importing countries. The Amended London Guidelines clearly state that "[i]t should be the function of designate national authorities with regard to export of banned or severely restricted chemicals 'to implement appropriate procedures, within their authority, designed to ensure that exports do not occur contrary to the PIC decisions or participating importing countries.'"¹⁸² Although the exact meaning of the reference is far from clear,¹⁸³ exporting countries have accepted their responsibility to contribute to the implementation of the Amended London Guidelines.

3. Classification, Packaging, Labeling, and Technical Assistance

The PIC procedure does not provide explicit classification, packaging, and labeling rules. Rather, it emphasizes fundamental principles. States should recognize exported chemicals are subject to no less stringent requirements of classification, packaging, and labeling than comparable products designated for domestic use. A similar rule has been introduced in EC regulation 1734/88.¹⁸⁴ However, the Amended London Guidelines go one step further by asking States, when they elaborate and implement existing or future harmonized procedures for the classification, packaging, and labeling of chemicals in international trade, to consider the special circumstances surrounding the management of chemicals in developing countries.¹⁸⁵

The request to consider the special chemical management problems of developing countries shows that the implementation of the PIC procedure, the information exchange, and the notification system is only possible if resources are made available by industrialized States to build the necessary infrastructure in developing countries. This request has led national development aid institutions and interna-

181. *Id.* annex II.

182. *Id.* art. 12(c)(iv).

183. *Paper Presentation*, Ad Hoc Working Group of Experts on the Implementation of the Amended London Guidelines, 1st Sess., UNEP/PIC. WG. 3/Inf. (1990) (The topic of this session: Proposals on Draft Model National Legislation on Management of Chemicals for the Implementation of the Amended London Guidelines).

184. Council Regulation 1734/88, *supra* note 162, art. 5, at 3. The proposed amendment is found at Commission Proposal 91/C 17/20, *supra* note 162, art. 6, at 19-20.

185. AMENDED LONDON GUIDELINES, *supra* note 3, art. 14(b).

tional organizations to evaluate the incoming data on banned or severely restricted pesticides with the goal of establishing the prerequisites for import control.¹⁸⁶

4. Regulation of Banned and Severely Restricted Products Within UNEP, FAO, and the GATT

The existing GATT rules articulate a clear message: any form of restriction of the export of hazardous chemicals runs counter to the GATT ideal of free trade.¹⁸⁷ As a result, there is no mechanism to allow GATT Contracting Parties to restrict exports for foreign policy reasons. However, article XX of the GATT allows an importing country to impose restrictions if the importing country is convinced the goods endanger health and the environment.¹⁸⁸ Article XX presents the problem of distinguishing legitimate interests from protectionist considerations. The GATT Agreement on Technical Barriers to Trade tries to balance these conflicting interests by asking signatory States to notify GATT if they wish to restrict the import of certain products for health, safety, and environmental reasons.¹⁸⁹ Unfortunately, GATT has no rules to deal with the problem of deviating health, safety, and environmental protection standards. This shortcoming might well be the source of GATT's interest in developing its own rules.¹⁹⁰

II. DETERMINING FACTORS IN THE INTERNATIONALIZATION OF CHEMICAL AND PESTICIDE REGULATION

For international regulation of chemicals and pesticides to develop further, it is necessary to determine the factors that influence the process of internationalization. This conclusion, therefore, should be read as a preface to the ongoing debate regarding the feasibility of an international convention on the production and use of chemicals and pesti-

186. Bangkok, Thailand Workshop on Pesticides Regulatory Principles and Procedures for the Asian and the Pacific Region, *Implementation of the International Code of Conduct on the Distribution and Use of Pesticides* (Technical Assistance Project Financed Through a Trust Fund Provided by the Government of Japan, 1988).

187. General Agreement on Tariffs and Trade, *opened for signature* Oct. 30, 1947, art. XI, 61 Stat. A3, 55 U.N.T.S. 187, 224-28; Michael Rom, *Export Controls in GATT*, 18 J. WORLD TRADE L. 125 (1984).

188. GATT, *supra* note 187, art. XX, at 262-65.

189. See generally Patrizio Merciai, *Safeguard Measures in GATT*, 15 J. WORLD TRADE L. 41 (1981).

190. For further details, see John Sankey, *Domestically Prohibited Goods and Hazardous Substances — A New GATT Working Group is Established*, J. WORLD TRADE, Dec. 1989, at 99. For a broader view, especially with respect to the relationship between U.S. and EC chemical regulation and GATT, see remarks of Edmund B. Frost, in *International Regulation of Toxic Substances* (panel discussion), *supra* note 77, at 102; remarks of Robert E. Herzstein, in *id.* at 92.

cides, a convention on which UNEP intends to elaborate in the next few years. This intention has not yet been explicitly voiced, however, because UNEP fears strong and immediate objections from the industrialized States.¹⁹¹

A. *Economic and Political Incentives*

The most important impetus for the development of international regulatory mechanisms is the industrialized States' fear that divergent national standards may lead to new trade barriers.¹⁹² In fact, the desire to prevent trade barriers induced the OECD and EEC to come to a joint solution on the regulatory framework for the control of chemicals. Similar motivations exist in the area of pesticides. The FAO Code of Conduct on the Distribution and Use of Pesticides seeks to develop a worldwide regulatory framework to guarantee the free flow of pesticides.

States have strong incentives to prevent the technical barriers to trade that result from divergent national control legislation. This does not mean that health, safety, and environmental policy objectives should be set aside. They may be pursued alongside the trade policy objectives. The fear of technical barriers to trade improves the prospects of international regulation of chemicals and pesticides considerably, but, at the same time, it limits the goals that can be achieved. Health, safety, and environmental protection as such are never the objectives of regulation. Social protection is subordinate to the overriding goal of the free flow of chemicals and pesticides.

The difference in philosophies becomes clear when one considers the question of international rules for the protection of health and safety in the workplace. When such regulation was discussed within the OECD and the European Community, the two organizations failed to integrate the protection of health and safety at work and international chemical regulation in a single framework. Ten years later, the negative effects of differing State standards on the protection of health and safety at work are indisputable. It is within the context of the steadily growing importance of differing standards for health and safety at work that the ILO convention must be seen.

Defensive strategies against unfair imports can easily be combined

191. *The Draft Model National Legislation on the Management of Chemicals for the Implementation of the Amended London Guidelines*, Ad Hoc Working Group of Experts on the Implementation of the Amended London Guidelines, 1st Sess., UNEP/PIC. WG. 3/3 (1990). One might understand this document as a preparatory document for an international convention.

192. This assumption is underscored by the most recent initiative of the OECD organizing the workshop held September 17-20, 1991 called Economic Effects of PIC.

with health, safety, and environmental objectives. In 1974, the United States introduced rules in its Trade Act providing sanctions against importing countries that benefit from lower production costs because of workplace health and safety standards far below those of the United States.¹⁹³ Finland has just adopted a regulation imposing a charge per ton on oil delivered to its ports by tankers without double bottoms.¹⁹⁴

Despite the decisive role of economic incentives, one should not underestimate the importance political incentives. A striking example of the power of political incentives is the development of rules on the regulation of banned and severely restricted pesticides and chemicals, most notably the adoption of the PIC procedure. Extensive pressure from different actors has led to a regulatory mechanism that presents GATT with the challenge of bringing the GATT's free trade philosophy closer to the safety and environmental protection concerns of UNEP.

B. *The Relationship Between Unilateral and International Actions to Control Pesticides and Chemicals*

Unilateral action to control chemicals and pesticides has been necessary to legitimate international action. For example, had the United States not taken the initiative in the late 1970s, organizations like the OECD, UNEP, and FAO would have had no incentive to internationalize the export/import issue. Another example is the development of international rules to control chemicals. Here, the close cooperation of the United States and Europe through the OECD and the European Community underscores the necessity of developing genuine international rules that are adapted not only to the needs of the industrialized States but also to those of the developing States.

UNEP will play a key role in the development of international rules on the control of chemicals. Historically, the development of rules on banned and severely restricted chemicals illustrates how the rule-making machinery could work. Here the OECD had defined the parameters of the international debate. It took a number of years and extensive pressure to transform the OECD Guiding Principles, which served the needs of industrialized countries, into a regulatory concept

193. Ian C. Ballon, *The Implications of Making the Denial of Internationally Recognized Worker Rights Actionable Under Section 301 of the Trade Act of 1974*, 28 VA. J. INT'L L. 73, 88-127 (1987); Harlan Mandel, Note, *In Pursuit of the Missing Link: International Workers Rights and International Trade?*, 27 COLUM. J. TRANSNAT'L L. 443 (1989); see generally R.R. KERTON, *DOUBLE STANDARDS: CONSUMER AND WORKER PROTECTION IN AN UNEQUAL WORLD* (1990); James M. Zimmermann, *Extraterritorial Application of Federal Labor Laws: Congress's Flawed Extension of the ADEA*, 21 CORNELL INT'L L.J. 103 (1988).

194. *Tankers: Double Trouble*, ECONOMIST, Apr. 21-27, 1990, at 31.

that fits into a world where developing countries play an ever increasing role. The compromise between the United States and the EC Member States could serve as a model for the drafting of an international convention. Any UNEP effort, however, must consider its effects on international trade, for a solution will only be found in coordination with GATT. GATT may require a broader approach, integrating not only chemicals but also pesticides, in order to forge an international consensus on the control of pesticides and chemicals.

C. *National Involvement in the Control of Chemicals and Pesticides and International Perspectives for Action*

The relatively rapid compromise between the United States and the European Community on the regulation of chemicals was facilitated by the fact that new regulatory models and new administrative procedures had to be constructed to cope with chemicals. It is far easier to come to an international solution on the control of dangerous substances if there is no need to overcome national administrative structures and traditions. The same is true for the regulation of banned and severely restricted chemicals and pesticides. The PIC procedure is a novelty; it is a genuine international instrument. There are no national traditions to be changed. An international convention on chemicals could benefit from the relatively young legal infrastructure. The convention could step into the vacuum in the field of consumer and environmental protection, leaving space for the introduction of regulatory concepts that go beyond the premarket control mechanisms that the industrialized States established.

The development of international regulation of pesticides and medicines shows that it is very difficult, almost impossible, to forge a common control mechanism. Although the FAO Code provides a registration procedure, a number of industrialized countries have introduced prior approval procedures that go far beyond the FAO compromise. The philosophy of the FAO Code sets the tone for the future regulation of chemicals. International rules never should be more than a common platform for States. The States must remain free to leave the platform and establish stricter standards to protect humans and the environment.

D. *Trends in the Control of Chemicals and Pesticides*

An analysis of national, regional, and international rules reveals an overall trend toward establishing premarket control procedures. Premarket control is widely accepted in the field of pesticides, and a consensus has almost been reached in the regulation of chemicals as

well. The best prospect for international regulation is an approach that relies on notification procedures and on concepts of shared responsibility between manufacturers and government agencies.

However, concentration on the premarket control of chemicals and pesticides suffers from a major deficiency. It focuses too closely on the control of newly introduced chemicals and pesticides, thereby neglecting the dangers of chemicals and pesticides that have been or still are circulating without having been effectively controlled before marketing. Such a focus is also inadequate in cases where risks become evident only after chemicals or pesticides have been subject to some form of premarket control. The most advanced industrialized countries are discovering the necessity of establishing effective postmarket control mechanisms.

Deviating market restrictions, however, close markets and run counter to the idea of free trade without technical barriers. Harmonizing access to the world market by introducing common premarket control mechanisms is one side of the coin, harmonizing postmarket control is the other. The international regulation of banned and severely restricted chemicals and pesticides, mainly in the form of the PIC procedure, constitutes an important move towards the development of international postmarket control management, but so far it is based on final regulatory action. What is needed is a mechanism that guarantees the collection and dissemination of risks in order to decide, at an international level, which products should be subject to market restrictions.

The PIC procedure is a remarkable innovation in that it provides for the review of products not yet on the red-flag list. However, the necessary controls should be accomplished by a joint FAO/UNEP program in cooperation with the OECD to determine the most dangerous chemicals and pesticides on the market and to formulate common criteria for testing and decision making. Nonetheless, even such a joint international approach will need unilateral action to keep moving.