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Potentially Hazardous Merchandise: Domestic and International Mechanisms for Consumer Protection

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POTENTIALLY HAZARDOUS MERCHANDISE: DOMESTIC AND INTERNATIONAL MECHANISMS FOR CONSUMER PROTECTION

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I. INTRODUCTION

Health disorders engendered by hazardous, exported foods, pesticides, drugs, and other products recently have attracted

worldwide attention.[1] The exportation of products which have been banned or highly restricted in their country of origin or which become hazardous in the environment of the importing nation is a popular issue for opponents of a perceived monolithic transnational industrial complex, as well as for critics of certain United States corporations.[2] A more widely shared opinion[3] is that the United States has a moral obligation to limit foreseeable harm from the export of potentially hazardous merchandise or at least to supply product hazard information.[4] Critics suggest that

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1. *Export of Hazardous Products: Hearings Before the Subcomm. on International Economic Policy and Trade of the House Comm. on Foreign Affairs,* 96th Cong., 2d Sess. 39 (1980) (testimony of Anwar Fazal, President, International Organization of Consumer Unions) [hereinafter cited as *1980 Hearings on Hazardous Products*]; *An Export Trade in Death,* ADVERTISING AGE, May 15, 1978, at 99; Dowie, et al., *The Corporate Crime of the Century,* MOTHER JONES, Nov. 1979, (special issue focusing on the "dumping" of banned products overseas); Weir, *For Export Only: Poisons, Dangerous Drugs,* ROLLING STONE, Feb. 10, 1977, at 31; *See* Wolterding, *The Poisoning of Central America,* SIERRA, Sept.-Oct. 1981, at 63; Wall St. J., Apr. 8, 1980, at 1, col. 1; Wash. Post, Feb. 25, 1980, at A1, col. 3.

2. *See 1980 Hearings on Hazardous Products, supra* note 1, at 39; *Marketing and Promotion of Infant Formula in Developing Countries: Hearings Before the Subcomm. on International Economic Policy and Trade of the House Comm. on Foreign Affairs,* 96th Cong., 2d Sess. 51 (1980) (statement of Leah Margulies, Director, Infant Formula Program, Interfaith Center on Corporate Responsibility) [hereinafter cited as *1980 Hearings on Infant Formula*].

3. *See, e.g.,* BACKGROUND REPORT ON EXECUTIVE ORDER 12,264 REGARDING THE EXPORT OF BANNED OR SIGNIFICANTLY RESTRICTED SUBSTANCES, 46 Fed. Reg. 7806 (1981) [hereinafter cited as HSEP REPORT]. In February 1978, President Carter created an interagency working group to establish a uniform hazardous substances export policy [hereinafter referred to as HSEP], composed of representatives of the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Food and Drug Administration, Justice, Labor, State, Transportation, and Treasury, as well as the Environmental Protection Agency, Consumer Product Safety Commission, Export-Import Bank, Overseas Private Investment Corporation, ACTION, Agency for International Development, Regulatory Council, Office of Management and Budget, Council on Environmental Quality, Nuclear Regulatory Commission, Office of the United States Trade Representative, and several other Executive offices.

4. Most evaluations of a drug or chemical require sophisticated expertise and advanced technological testing facilities not available in every nation. It has been estimated that toxicological testing for premarket studies of a single new substance costs approximately $100,000 at October 1980 prices. *See* Role of the Information System on Transnational Corporations Regarding the Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceuticals, Report prepared by the Secretariate, 7th Sess., Commission on Transnational Cor-

the United States has abandoned this obligation by resurrecting the doctrine of *caveat emptor*[5] for exclusive application to foreign consumers. The effect of this adverse publicity upon this nation's foreign relations,[6] upon the confidence of foreign buyers in United

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porations, ESCOR (Provisional Agenda Item 11) at 4, U.N. Doc. E/C.10/90 (1981) [hereinafter cited as 1981 Report on Information Exchange]; *United States Export of Banned Products: Hearings Before the Subcomm. on Commerce, Consumer, and Monetary Affairs of the Comm. on Government Operations*, 95th Cong., 2d Sess. 160 (1978) (Barbara Blum, Deputy Administrator, EPA, stating: "The whole EPA in Nigeria is one person. The Minister has one professional and one secretary.") [hereinafter cited as *1978 Hearings on Banned Products*].

At least one Third World nation has taken strong measures to limit the number and type of pharmaceuticals to which its population can be exposed. Bangladesh recently announced a new policy which calls for an immediate ban on more than two hundred "harmful" drugs and for a withdrawal by March 1983 of more than 1500 other "unnecessary" medicines. Although the policy was enacted primarily to safeguard the population from those drugs which were found to be unsafe for their prescribed use and to encourage the production of technologically simple medicines by local companies or charitable organizations, the policy has resulted in a dramatic decrease in the price of pharmaceuticals offered by the transnational companies and a substantial foreign exchange savings. *See* Cunnington, *A country's right to choose*, 10 DEV. F., Sept.-Oct. 1982, 15, 15. One example of the harmful drugs currently marketed in Bangladesh is Orabolin, a steroid used to build muscle in Soviet female athletes. The side effects include liver tumors and fluid retention; in children, the drug initially stimulates growth but later may result in premature stunting. The British Monthly Index of drugs recommends that children not be given Orabolin. Nevertheless, the manufacturer of the drug promotes Orabolin for malnourished children in Bangladesh and its leaflet claims that, despite the contrary findings, "THERE ARE NO CONTRA-INDICATIONS IN CHILDREN." *Id.*

5. *See* W. Prosser, THE LAW OF TORTS § 95 (4th ed. 1971). Recent decisions by United States courts and agencies indicate an awareness that access to full product quality information is critical in limiting personal, property, and economic harm to consumers. *See* B.F. Goodrich Co. v. Department of Transp., 541 F.2d 1178 (6th Cir. 1976), *cert. denied*, 430 U.S. 930 (1977) (supporting the National Highway Traffic Safety Administration's uniform tire quality grading system). The Federal Trade Commission staff has urged a "full disclosure" approach to consumer goods in the past. *See* Ferguson, *Consumer Ignorance as a Source of Monopoly Power: FTC Staff Report on Self-Regulation, Standardization, and Product Differentiation II*, ANTITRUST L. & ECON. REV., Spring 1972, at 55, 68. Under the assumption that "there is no inherent legal right for the seller of a product to withhold information about his product that, if known, would affect the consumer's decision to buy that product versus some other seller's product," producers should supply information concerning performance and other characteristics directly to consumers. *Id.*

6. *See, e.g., 1980 Hearings on Hazardous Products, supra* note 1, at 18 app.,

States goods and companies, and upon the United States balance of trade has not gone unnoticed.[7]

Choosing the degree and mode of regulating these exports is a complex process. Vast differences exist between the economic, cultural, political, and physical environments of the United States and that of many importing nations. Regulations based upon an analysis of the effect of a product upon the population of the United States may fail to reflect conditions in the importing nation.[8] Regulations which are limited to the home marketplace may be interpreted as disregarding foreign consumer welfare.[9] On the other hand, if the regulations are too sweeping, they may be viewed as infringing upon each sovereign nation's right to determine what is best for its citizens. To compound the difficulty of designing an administratively practicable regulatory structure, proposed export controls typically interface with existing regulations restricting the reimportation of contaminated goods, limiting the transport of hazardous residues via air or water,[10] and reg-

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19 app. (letters from the Embassy of Nigeria and the Indonesian Consumers Organization); HSEP Report, *supra* note 3, at 7806; World Health Organization, International Code of Marketing of Breast-Milk Substitutes (1981) [hereinafter cited as World Health Organization Code]. The well publicized role of the United States as the sole dissenter to the World Health Organization Code exacerbates tension between the United States and many Third World nations. *See infra* text accompanying notes 16, 183-92.

7. *Id. See* HSEP Report, *supra* note 3, at 7806.

8. *1978 Hearings on Banned Products, supra* note 4, at 93. Dr. Donald Kennedy, Commissioner, Food and Drug Administration stated:

> In our view, the relative safety and efficacy of a drug or medical device is a composit judgment which must be made by each country based upon many factors, such as the status of the health care system in that country, patient compliance with dosage regimens, alternative therapies that may be available, and other health-related and social characteristics of that nation's population. A number of diseases prevalent through the world —especially in the tropics where most of the developing nations are found—are rare or nonexistent in this country. A drug that is useful against such a disease may never receive adequate testing in this country to warrant its approval here.

9. *Id. See* articles cited *supra* note 1.

10. This Note will not focus on the environmental impact resulting from the natural global dispersion patterns of locally applied hazardous substances. At least one case, however, demonstrates the shortcomings of current United States export policy in this regard. In March 1978 the Food and Drug Administration (FDA) issued a final rule prohibiting the nonessential use of certain chlorofluorocarbons (CFCs) as aerosal propellants in containers of foods, drugs, and cosmetics. HSEP Report, *supra* note 3, at 7807. Simultaneously, the Envi-

ulating manufacturing processes for hazardous substances;[11] as well as with antitrust and first amendment concerns.[12] Last, the present United States administration has emphasized the need to avoid overly burdensome regulations which might disadvantage United States firms in the international marketplace.[13]

This Note will examine the domestic and international efforts to predict and mitigate the adverse effects of potentially hazardous merchandise.[14] A comparison will be made between a strict

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ronmental Protection Agency (EPA) prohibited domestic production, processing and use of CFCs, but did not ban export of unprocessed CFCs. *Id.* These actions were taken following a determination that the substance could deplete stratospheric ozone, thereby causing, among other adverse effects, climatic changes and increased rates of skin cancer. *Id.* When manufacturers of hair spray requested information regarding export of products containing CFC propellants, the FDA advised that the shipments were lawful, provided that the items were not prohibited by the country to which they were shipped. *Id.*

11. As the United States and other developed nations impose tighter domestic controls, the pressure on industry to relocate in areas with somewhat lax environmental and worker protection laws increases. According to the industry's 1974 estimates, United States chemical firms spend 44% less on pollution controls abroad than in the United States. *1980 Hearings on Hazardous Products, supra* note 1, at 7. A number of recent expansions abroad by United States asbestos manufacturers have occured because minimal safety standards were established by the Occupational Safety and Health Administration [hereinafter referred to as OSHA] in 1971. *Id.* at 8-9. Also reported are incidents of mercury poisoning in and around a Nicaraguan plant partially owned and managed by a United States firm. *Id.* at 141. *See also* 124 CONG. REC. 19,762 (1978) (remarks of Rep. Obey).

12. *See infra* note 265.

13. Exec. Order No. 12,290, 46 Fed. Reg. 12,943 (1981), *reprinted in* 50 U.S.C. App. § 2403nt (Supp. 1981) [hereinafter cited as Exec. Order No. 12,290]; *see also President's Statement on Signing S. 2796 into Law,* 14 WEEKLY COMP. PRES. DOC. 2001 (Nov. 10, 1978) (authorizing continuing existence of Consumer Product Safety Commission).

14. These products were within the scope of Exec. Order No. 12,264, 46 Fed. Reg. 4659 (1981) [hereinafter cited as Exec. Order No. 12,264], which briefly established a somewhat more uniform federal policy regarding the export of potentially hazardous merchandise. Exec. Order No. 12,264, enacted five days before the close of the Carter administration, was revoked by Exec. Order No. 12,290, *supra* note 13, about one month later. Exec. Order No. 12,264 limited its reach to products for which a federal agency had taken some prior regulatory action and, thus, would have excluded items such as infant formula. Exec. Order No. 12,264, *supra* at 4659-61. Alcohol, tobacco, firearms, military supplies, narcotic and psychotropic substances, nuclear fuels, hazardous production facilities, and chemical or radioactive hazardous wastes will not be discussed in this Note. Most nations devote special legislation to those subjects.

regulatory reaction and the less restrictive approaches aimed at developing access to product information.

II. Exports of Potentially Hazardous Merchandise: Selected Examples

A. Infant Formula

The Twenty-Seventh World Health Assembly (WHA) in 1974 expressed concern over a decline in breast feeding in many parts of the world.[15] On May 21, 1981, the WHA endorsed an International Code of Marketing of Breast-Milk Substitutes (Code).[16] The vote on the resolution proposed by the World Health Organization (WHO) was 118 in favor to one opposed.[17] The one vote opposed was that of the United States.

Many sources suggest that mother's milk is clearly superior to that of artificial formulas.[18] Few object to infant formula per se, a product widely and successfully marketed in developed nations.[19]

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15. World Health Organization, Res. WHA 27.43, *reprinted in* 2 Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board 58 (4th ed. 1981) [hereinafter cited as WHA Handbook]. The matter was addressed again by the thirty-first World Health Assembly (WHA) in May 1978. That assembly recommended that member states should, *inter alia,* regulate "inappropriate sales promotion of infant foods that can be used to replace breast milk." *Id.* at 62. A joint WHO/UNICEF meeting on infant and young child feeding convened October 9-12, 1979, in Geneva. Over 150 representatives of governments, United Nations organizations, inter-governmental bodies, nongovernmental organizations, and the infant food industry attended the meeting. *1980 Hearings on Infant Formula, supra* note 2, at 2, 7, 28. In May 1980 the thirty-third WHA endorsed the recommendations of the joint WHO/UNICEF meeting. *See* WHA Handbook, *supra,* at 54. In January 1981, the WHO Executive Board recommended a draft of the Code to the WHA in a resolution by which it would be adopted as a recommendation. *See* World Health Organization, Res. EB67.R12, *reprinted in* World Health Organization Code, *supra* note 6, at 23; *see also infra* text accompanying notes 217-20.

16. World Health Organization Code, *supra* note 6.

17. Argentina, Japan, and the Republic of Korea abstained.

18. Studies have indicated that breast-feeding established a much closer psychological relationship between the mother and child. World Health Organization Code, *supra* note 6, at 10. Moreover, immunological agents are present in human milk which are passed from the mother to the baby. *Id.* Human milk also promotes growth more readily than formula and aids in the absorbtion of iron in the infant's gastrointestinal tract. *Id.* Finally, and vitally for areas with severe overpopulation, there is a positive correlation between breast-feeding and childbirth spacing. *Id. See 1980 Hearings on Infant Formula, supra* note 2, at 19, 50.

19. *See Implementation of the World Health Organization (WHO) Code on*

Protests stem from the high probability that this otherwise safe product will be misused in an underdeveloped nation. Economical packaging requires that the formula be delivered in concentrated form and prepared with water. Even industry spokesmen repeatedly warn that contaminated water supplies are common in many less developed countries.[20] Unsanitary preparation of the formula can cause serious or fatal illness in infants, who have far less resistance to water-borne diseases than adults.[21] Furthermore, a mother's abandonment of breast-feeding for even a relatively brief period decreases the probability that she will be physiologically able to resume that method.[22] Return to this cost-free source may be impossible by a family which, after an initial use of infant formula, decides that the product is too expensive. It is thus common practice for many families which are only marginally able to afford the formula to further "water down" the concentrate, resulting in undernourishment of the infant.[23]

The debate outside of the health profession has resulted from accusations that the problem is largely attributable to inappropriate marketing efforts in Third World nations by large scale producers of infant formula.[24] Mass media campaigns that reduce product information to "small print" and that are directed to an unsophisticated general public have been a focus of criticism.[25] Even the usually innocuous distribution of free samples has been attacked.[26] Unlike typical sample promotions, free samples "hook" the mother on the formula because after the initial use the mother may be unable to resume breast-feeding. Aggressive promotional campaigns aimed at health care personnel as a conduit to feeding mothers contribute to the notion that "[i]nfant formula is somehow more preferable, more sophisticated, more modern, more Western."[27] Exaggerated and inaccurate allegations

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Infant Formula Marketing Practices: Hearings Before the Subcomm. on Internation Economic Policy and Trade and Human Rights and International Organizations of the Comm. on Foreign Affairs, 97th Cong., 1st Sess. 82 (1981) [hereinafter cited as *1981 WHO Code Hearings*].

20. *1980 Hearings on Infant Formula, supra* note 2, at 39, 124.
21. *Id.*
22. *Id.* at 47.
23. *Id.* at 33.
24. *Id.* at 82-84.
25. *Id.* at 33, 56-59.
26. *E.g., id.* at 47-48.
27. *Id.* at 51. Practices challenged by critics of the industry include the dis-

of corporate misconduct, however, have also been made.[28]

All parties to the controversy admit that there is a major social basis for the decline in breast-feeding: the altered lifestyle of mothers following increased urbanization in the Third World.[29] Nevertheless, many critics outside of the infant formula industry believe that the problem originates in a largely unregulated[30] industry's assumption that a safe and profitable item may be transferred, without variation in marketing practice or product, to a radically different population of consumers.

B. TRIS-treated Children's Sleepwear

Until February 1977, TRIS (2-3, dibromoprophyl phosphate) was commonly used for treating children's sleepwear to ensure compliance with federal antiflammability standards. In 1977, however, the National Cancer Institute released evidence which indicated that this fire-retardant product could cause cancer in children exposed to the TRIS-treated sleepwear.[31] The Consumer

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tribution of allegedly misleading literature, gift certificates for nurses, vinyl carry-all bags with company and brand names, and posters of "chubby" babies bearing messages such as "MAMALAC is just like Mother's Milk!" or "The Logical Alternative to Mother's Milk." *Id.* at 56-59.

28. *E.g., id.* at 76. When criticized for posting billboards that advertised its "SMA" brand formula in Indonesia, the Wyeth International subsidiary of American Home Products discovered that the billboards were actually high school signs. *Id.* at 77. The words in the Indonesian language that translate into "senior high school" begin with the letters "SMA." Some manufacturers have recently taken steps to mention the superiority of breast-feeding in their advertisements. *Id.* at 30, 77.

29. *E.g., id.* at 42-43.

30. For example, in 1978 a major producer of infant formula reformulated two of its soy products by discontinuing the addition of salt. This change resulted in products which contained inadequate amounts of chloride, an essential nutrient. The result was a substantial number of cases of hypochloremic metabolic alkalosis syndrome in infants. A recall was initiated, but did not result in the efficient removal of the defective products from the market. Subsequently, the Infant Formula Act of 1980, 21 U.S.C. § 350a (Supp. IV 1980), was enacted as an amendment to chapter IV of the Federal Food, Drug and Cosmetic Act. The new Act "provides for more stringent . . . control over infant formula manufacturing and processing," but makes no special provision for exports. Infant Formula Recall Requirements, 47 Fed. Reg. 2331 (1982) (to be codified at 21 C.F.R. pt. 7).

31. *Ban on TRIS (2,3-dibromopropyl) Phosphate (Chemical Flame Retardant): Hearings on S. 1503 Before the TRIS Hearing Panel of the Senate Comm. on the Judiciary*, 95th Cong., 1st Sess. 12 (1977) (statement of Barbara H.

Product Safety Commission (Commission) subsequently designated all such fabrics as "banned hazardous substances" under the Federal Hazardous Substances Act (FHSA)[32] and ordered domestic sales and distribution stopped.[33] United States manufacturers of these products were required by the Commission to repurchase any unused TRIS-treated clothing from distributors, retailers, and consumers.[34] Faced with the accumulation of massive inventories of these banned articles, some manufacturers began exporting the goods to nations not having restrictions on TRIS-treated products. The Commission determined that it lacked authority under the FHSA to seize or otherwise interfere with any TRIS-treated product labeled or marked for export.[35] In response to congressional inquiries, the Commission stated: "Very little, if any, TRIS-treated children's sleepwear has been exported and we do not expect this situation to change" and concluded that it "did not believe an export policy was needed at present."[36] On May 1, 1978, however, a survey of one-half of the 110 manufacturers of children's sleepwear revealed that over 100,000 garments had already been exported and that negotiations for the exports of thousands more garments were being conducted.[37] Shortly thereafter the Commission announced that it would reverse its earlier position,[38] creating a rush to export the products before a possible export ban.[39] In the year between the domestic

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Franklin, Commissioner, U.S. Consumer Product Safety Commission).

32. 15 U.S.C. §§ 1261-1274 (1976 & Supp. IV 1980).

33. 42 Fed. Reg. 18,849 (1977).

34. *Id.* at 18,853.

35. HOUSE COMM. ON GOVERNMENT OPERATIONS, REPORT ON EXPORT OF PRODUCTS BANNED BY UNITED STATES REGULATORY AGENCIES, H.R. REP. No. 1686, 95th Cong., 2d Sess. 33 app. (1978) [hereinafter cited as BANNED PRODUCTS REPORT].

36. *Id.* at 34 app.

37. *Id.* at 10.

38. *Id.* at 38 app.

39. *Id.* at 10. After banning domestic sales of TRIS-treated articles, the Commission obtained an *ex parte* warrant to seize and condemn TRIS-treated children's sleepwear offered for export by the Troxler Hosiery Company of Greensboro, North Carolina. Although the district court granted Troxler's motion to quash the seizure warrant, the Fourth Circuit Court of Appeals later reversed, holding that the seizure and condemnation did not violate Troxler's fifth amendment due process rights. United States v. Articles of Hazardous Substance, 588 F.2d 39, 43-44 (4th Cir. 1978), *rev'g*, 444 F. Supp. 1260 (M.D.N.C. 1978). The appellate court refused to accept the company's argument that exportation of the goods would bring them into compliance with the Federal Haz-

ban on TRIS-treated products and the Commission's final interpretation of the FHSA, a total of eighteen manufacturers exported, or attempted to export, TRIS-treated sleepwear.[40] Approximately 2.4 million garments, valued at $1.2 million, were reportedly shipped abroad.[41]

C. Pesticides

Approximately forty percent of the United States $7 billion annual production of pesticides is exported.[42] The WHO reports that pesticides poison approximately one-half million persons each year, many of whom reside in underdeveloped nations.[43]

In Central America intensive cultivation and the evolution of pests resistant to toxins have resulted in the world's heaviest per capita use of chlorinated hydrocarbons and the more lethal organophosphates.[44] In 1974 approximately 3380 pounds of chemicals were applied for every square mile of land—some 4.4 pounds for each inhabitant of this region.[45] Agricultural workers often live, draw water, and grow food in close proximity to fields which re-

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ardous Substances Act, 15 U.S.C. § 1261-1274. The Fourth Circuit concluded that while the Act "exempts from seizure any hazardous substance appropriately intended for export, there is no indication that articles which have been offered for sale in domestic commerce can avoid the consequences of seizure and forfeiture by resorting to export after condemnation has occured." *Id.* at 44. While the case stands as authority that exporters may not "dump" products abroad after being forced to remove the same products from the home market, it remains uncertain to what extent the Commission has the power to regulate the export of hazardous products which have never been offered for domestic sale, but are manufactured solely for export. *See infra* text accompanying notes 79-93.

40. BANNED PRODUCTS REPORT, *supra* note 35, at 10 (quoting *1978 Hearings on Banned Products, supra* note 4, at 15,215).

41. *Id. HSEP Report, supra* note 3, at 7807. In a similar development, over 500,000 baby pacifiers linked to choking deaths in infants were exported after the Commission's proposed ban on June 30, 1977. *1978 Hearings on Banned Products, supra* note 4, at 2.

42. Wolterding, *supra* note 1, at 63.

43. *HSEP Report, supra* note 3, at 7807.

44. Wolterding, *supra* note 1, at 64.

45. *Id.* Chlorinated hydrocarbons are cumulative; they are stored in the body, usually in fat, for years. Long term exposure results in brain and liver damage. High levels in a woman's body will pass to infants via her milk. Organophosphates attack the nervous system. Low level poisoning produces vomiting, dizziness, tremors, blurred vision, diarrhea, and cramps. High levels produce paralysis, convulsions, coma, and death. *Id.*

ceive aerial spraying of pesticides as many as forty times per season.[46]

One pesticide, Leptophos, was never registered for use in the United States but was produced in Texas for export.[47] About fourteen million pounds of the pesticide were shipped to fifty countries between 1971 and 1976.[48] In 1971 and 1972 a number of Egyptian farmers suffered hallucinations, impaired vision, and loss of speech after exposure to Leptophos.[49] Over one thousand water buffalo were reported to have died from exposure to the chemical.[50] Egypt refused in 1976 to purchase further supplies of the chemical.[51] Despite this reaction, the manufacturer continued to market Leptophos abroad, while advertising its safety.[52]

Exported pesticides also threaten the United States because pesticide residues naturally disperse throughout the global environment.[53] Of greater congressional concern is the likelihood that

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46. *Id.*

47. *1978 Hearings on Banned Products, supra* note 4, at 36, 48.

48. *Id.* at 35.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.* at 48. Many incidents are attributable to faulty labeling, or labeling incomprehensible to often illiterate workers in the importing nation. For example, in 1972 Iraq imported wheat and barley seeds for planting purposes, treated with an organic mercury fungicide that was banned in the United States and other developed nations. The seeds were mistakenly used in food. Over 6,000 hospitalizations, with 459 reported hospital deaths, were attributed to methyl mercury poisoning. 1981 Report on Information Exchange, *supra* note 4, at 11 n. 16.

53. DDT, for example, has been used extensively throughout the world for agricultural purposes and to eradicate pests carrying malaria and other diseases. DDT residues are now so pervasive that scientists attempting to measure their danger to human health are unable to locate any uncontaminated population in the world against which to measure its effects. Henahan, *Whatever Happened to the Cranberry Crisis?—A status report on the great environmental controversies,* ATLANTIC MONTHLY, Mar. 1977, at 29, 30. Fluorocarbons are another example of a chemical whose environmental effect, the depletion of the vital ozone layer of the stratosphere, has an inescapably world-wide impact. *See* COUNCIL ON ENVIRONMENTAL QUALITY, FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY, FLUOROCARBONS AND THE ENVIRONMENT: REPORT OF FEDERAL TASK FORCE ON INADVERTANT MODIFICATION OF THE STRATOSPHERE (IMOS) (1975). Besides dispersal by natural means, or direct reimportation, chemicals may become contaminants in consumer products through unsuspected routes. *See, e.g.,* Comment, *Controlling the Environmental Hazards of International Development,* 5 ECOLOGY L.Q. 321 (1976) (for example, "[D]ieldrin used in Colombian forests

foods contaminated abroad by hazardous chemicals will be imported into the United States. Food and Drug Administration (FDA) statistics for 1977 and 1978 indicated that ten percent of imported raw agricultural commodities contained residues of pesticides which the EPA has banned.[54] A General Accounting Office (GAO) report[55] and a House Subcommittee report[56] have concluded that the FDA's enforcement methods, which spot check less than one percent of imports, fail to effectively eliminate reimported contaminants.[57]

The domestic hazards of pesticide exports are not limited to food contamination. The Life Science Products Company, which operates a small plant at Hopewell, Virginia, ceased production of the pesticide Kepone in 1975 after seventy persons associated with the plant, including wives and children of employees, became seriously ill from overexposure.[58] Between twelve and twenty former workers suffered permanent disabilities.[59] In that year, ninety-nine percent of the domestic production of Kepone was exported.[60]

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penetrates into the wood of teak trees. The trees are cut and shavings from the logs are shipped to Canada for cow litter. The cows munch on the shavings and the result is an unacceptable level of Dieldrin in their milk.") *Id.* at 353.

54. BANNED PRODUCTS REPORT, *supra* note 35, at 28. Some products of Mexican origin, including tomatoes, beans, peppers, cucumbers, peas, cantalopes, eggplant, and squash, have been contaminated with Leptophos. Wash. Post, Feb. 25, 1980, at A1, col. 1. The EPA revoked the residue tolerance for Leptophos in November 1976. The FDA's analytical methods, moreover, lack tests for 600 food tolerance levels of carcinogenic pesticides. Wolterding, *supra* note 1, at 66.

55. Comptroller General, General Accounting Office, Rep. No. CED-79-43, Better Regulation of Pesticide Exports and Pesticide Residues in Imported Foods is Essential 12-19 (1979).

56. BANNED PRODUCTS REPORT, *supra* note 35, at 5.

57. Assuming that violations are spotted, recalls may be difficult or impossible, because the bulk of a shipment customarily is sent into the marketplace pending the outcome of test results. In one instance, USDA inspectors in Dallas noticed a strong "insecticide-like" smell in a shipment of cabbage imported by a businessman with a history of dealing in contaminated products. The FDA allowed the cabbage to go to market, despite USDA's complaint. Tests later indicated the presence of illegal levels of BHC, a carcinogenic pesticide, the EPA registration for which had been cancelled in 1976 at the request of its manufacturer, Hooker Chemical. The cabbage was beyond the reach of recall. Wolterding, *supra* note 1, at 66.

58. *1978 Hearings on Banned Products, supra* note 4, at 69.

59. *See* C. MUSGROVE, KEPONE POLLUTION: A SUMMARY REVIEW 1 (1978).

60. *1978 Hearings on Banned Products, supra* note 4, at 68. Examination of

D. Pharmaceuticals

Approximately eighty-five percent of the world's pharmaceutical products originate with multinational enterprises based in developed nations.[61] The United Nations Economic and Social Council (ECOSOC) has expressed concern that this concentration of marketing power inhibits the investigation of exported drugs which do not meet the same quality control requirements for drugs in domestic use.[62] Despite strict FDA regulation of domestically available drugs,[63] United States law concerning exports has permitted "adulterated, contaminated, unsafe, ineffective, or misbranded products [to be] dumped on the market in Latin America, Africa, and Asia . . . when the shelf-life of a batch of a product has expired, and it is no longer safe and effective."[64]

Chloramphenicol is a potent antibiotic used in this country only against life-threatening diseases such as typhoid fever. Its application must be confined to critical cases because of possible side effects producing aplastic anemia, which has a thirty percent to sixty percent mortality rate.[65] In the United States, informational materials accompanying a drug must caution whether it is

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the plant, discharges of which were responsible for the contamination of fisheries in the James River and Chesapeake Bay, was conducted by the Senate Subcommittee on Agricultural Research and General Legislation the following year. S. REP. No. 334, 95th Cong., 1st Sess. (1977). The Subcommittee concluded that under existing law, plants manufacturing pesticides solely for export did not have to comply with the Federal Insecticide, Fungicide, and Rodenticide Act's provision regarding registration of production facilities; *see infra* text accompanying notes 106-15.

61. International Co-operation and Co-ordination Within the United Nations System: Consumer Protection. Report of the Secretary-General, U.N. Economic and Social Council (prov. agenda item 18) at 23, U.N. Doc. E/1981/75 (1981) [hereinafter cited as 1981 International Co-operation Report].

62. *Id.* at 24.

63. *See* Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-381 (1976 & Supp. IV 1980).

64. *Drug Regulation Reform Act of 1978: Hearings on H.R. 11611 Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce*, 95th Cong., 2d Sess. 1323 (1978) (statement of Milton Silverman, senior faculty, health policy program, University of California, San Francisco) [hereinafter cited as *1978 Drug Regulation Hearings*]. Dr. Harold Hubbard, Chief of the Food and Drug Control Section, Division of Disease Control, Pan American Health Organization, stated that there are few Latin American countries presently capable of evaluating safety and efficacy claims of products that are now being imported into their health services. *Id.* at 1330-31.

65. *1978 Hearings on Banned Products, supra* note 4, at 51.

to be used only for minor infections.[66] Despite such controls, chloramphenicol has been exported to Latin America for use against such routine diseases as measles, tonsillitis, chicken pox, and the common cold and has been sold without warnings of its possible side effects.[67]

Conversely, some beneficial exports may have been prematurely banned. The controversy surrounding the FDA's decision not to approve domestic use of Depo Provera, an injectable long-term contraceptive, thereby automatically barring any current export,[68] illustrates the incongruency of domestic and foreign cost-benefit equations. The use of Depo Provera was rejected after researchers found evidence that it might produce cancer and birth defects.[69] Many severely overpopulated Third World nations, although recognizing the adverse effects of the contraceptive, nevertheless requested permission to import the drug.[70]

III. UNITED STATES MECHANISMS FOR EXPORT REGULATION

An array of inconsistent export statutes wielded by sometimes inattentive agencies have made these incidents of product misuse and misapplication possible. Despite congressional and executive efforts to construct a uniform federal policy concerning exports of

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66. *Id.*

67. *Id.* at 51-52. Lomotil, produced by the G.D. Searle Company in the United States, provides relief of diarrhea associated with mild stomach disorders. In developing countries, where contaminated water supplies are often the norm, the use of Lomotil may only mask symptoms of extremely serious diseases such as bacillary dysentery and enteritis. *Id.* Such diseases were the leading causes of death in Paraguay, Guatamala, and El Salvador in 1970 and 1971. *Id.* In addition, Lomotil is especially hazardous for use by children. *Id.* The distinction between an appropriate and a toxic dose is difficult to ascertain. Lomotil can only be purchased by prescription in the United States. In one developing nation, Lomotil has been marketed over the counter in packages displaying the message: "Used by astronauts during Gemini and Apollo space flights." *Id.* It has also been recommended for use in young children. *Id.*; *see* Muller, *Lomotil: a Case of Moral Incontinence*, 73 NEW SCIENTIST 786, 786 (1977).

68. *See infra* text accompanying note 101.

69. Depo Provera "is approved for use in the United States only for palliative treatment of endometrial and renal cancer." HSEP Report, *supra* note 3, at 7807. For a detailed analysis of the drug's uses, and the controversy over its use in this country and abroad, see *1980 Hearings on Hazardous Products, supra* note 1, at 166-70, 250-369 apps.

70. *Id.*

potentially hazardous merchandise,[71] this policy does not presently exist. Nevertheless, these efforts have filled glaring gaps in the regulatory skeleton. The following federal agencies divide responsibilities for those hazardous exports with which this Note is concerned:[72]

> (1) The Consumer Product Safety Commission, which administers three recently amended statutes—the Consumer Product Safety Act (CPSA),[73] the Flammable Fabrics Act (FFA),[74] and the Federal Hazardous Substances Act (FHSA),[75]
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> (2) The Food and Drug Administration, which derives its authority from the Federal Food, Drug, and Cosmetic Act (FD&CA),[76] and
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> (3) The Environmental Protection Agency, which manages programs under the authority of the Toxic Substances Control Act (TOSCA)[77] and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[78]

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71. *See infra* text accompanying notes 134-57.

72. Pursuant to the Export Administration Act, the Department of Commerce has general authority over all exports. *See infra* note 136.

73. 15 U.S.C. §§ 2051-2081 (1976 & Supp. III 1979). The CPSA governs safety standards for consumer products: articles used in and around a residence, school, or for recreation for the personal use, consumption, or enjoyment of the consumer, except tobacco, motor vehicles, pesticides, boats, ammunition, aircraft, foods, drugs, cosmetics, or medical devices. *Id.* § 2052(a)(1).

74. *Id.* §§ 1191-1204 (1976 & Supp. III 1979). Items within the scope of the FFA include wearing apparel, fabric, or related materials.

75. *Id.* This statute includes substances which are (1) irritants, strong sensitizers, or toxic, corrosive, flammable, combustible, or which generate pressure and which may cause substantial personal injury, and (2) toys. The Commission also exercises authority under the Poison Prevention Packaging Act, 15 U.S.C. §§ 1471-1476 (1976), which establishes standards for the special packaging of household substances with which children are likely to come into contact, and the Refrigerator Safety Act, 15 U.S.C. §§ 1211-1214 (1976), which requires household refrigerators shipped in interstate commerce to be equipped with safety locks allowing them to be opened from the inside.

76. 21 U.S.C. §§ 301-392 (1976 & Supp. III 1979). The FDA governs the use of biological products under 42 U.S.C. § 262 (1976), and regulated cosmetics, new drugs, medical devices, and drugs approved for use in the United States under 21 U.S.C. §§ 351-363 (1976 & Supp. III 1979).

77. *Id.* §§ 2601-2629 (1976 & Supp. III 1979). TOSCA covers chemical substances or mixtures except those occurring in pesticides, tobacco, nuclear materials, and firearms.

78. 7 U.S.C. §§ 136-136y (1976 & Supp. III 1979). The Act covers substances

Although no consistent principles have emerged from the current amendments, Congress has avoided extremes. Congress instead has chosen a moderate approach consisting of notification, labeling, disclosure, and monitoring requirements, with limited bans on the export of the more dangerous items.

A. Consumer Product Safety Commission

Congress passed the Consumer Product Safety Act (CPSA)[79] in 1972 with the express aim of protecting the public from unreasonable risks of product-related injury. The CPSA provides for evaluations of product safety, development of safety standards, bans on unreasonably hazardous items, and research into the causes and prevention of injuries and deaths due to these articles.[80] The Consumer Product Safety Commission[81] is an independent federal agency possessing broad regulatory powers. The Commission has wide-ranging authority to enter locations where consumer products are manufactured, transported, or sold to inspect the books, records, and products of any manufacturer, private labeler, or distributor.[82]

Prior to 1978, the CPSA, the FFA, and the FHSA provided broad exemptions for the foreign sales of domestically produced articles. The most exacting restrictions upon exports were those of the FHSA, which provided that any product could be exported if it was (1) in a package branded in accordance with the specifications of the foreign purchaser, (2) labeled in accordance with the laws of the foreign country, (3) labeled on the shipping package as intended for export, and (4) in fact exported.[83] The CPSA and FFA require a manufacturer to have an "intent to export"[84] as a prerequisite for exemption of a shipment from their coverage. By November 1978 public pressure and judicial reluctance to construe broadly the "intent to export" requirement influenced Congress to amend the CPSA, FFA, and FHSA.[85] Section 2067 of the

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or mixtures for preventing, destroying, repelling, or mitigating any pest, or for use as a plant regulator, defoliant, or dessicant.

79. 15 U.S.C. §§ 2051-2081 (1976 & Supp. III 1979).
80. *Id.* § 2051(b) (1976).
81. *Id.* § 2053(a) (1976 & Supp. III 1979).
82. *Id.* § 2065 (1976).
83. *Id.* § 1265(a).
84. *Id.* § 2067.
85. Consumer Product Safety Authorization Act of 1978, Pub. L. No. 95-631,

CPSA now exempts from coverage those products "manufactured, sold or held for export."[86] Section 2067(a) also prohibits nonconforming products from being distributed in domestic commerce.[87] Furthermore, shipments can be halted, regardless of their primary destination, if the Commission determines that the export "presents an unreasonable risk of injury to persons residing within the United States."[88] Section 2067(b) introduces measures designed both to facilitate enforcement of these safeguards and to provide more meaningful notice to foreign consumers. The "intent to export" labeling requirement remains in force. In addition, exporters must now notify the Commission thirty days in advance of shipment of products which do not comply with an existing consumer product safety standard,[89] or which have been declared to be banned hazardous substances under the Act.[90] The Commission then will alert the appropriate governmental agency in the importing country of the impending shipment and inform that agency of the basis for the United States safety standard or ban.[91] Substantially identical provisions are contained in the FHSA[92] and FFA.[93]

B. Food and Drug Administration

Under the Food, Drug, and Cosmetic Act[94] the FDA can bar or remove from the market products which fail to meet designated standards.[95] These standards regarding adulteration or misbranding of products will not, however, be applied to any product if:

(1) the product meets the specifications of the foreign

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§§ 1-11, 92 Stat. 3742.

86. 15 U.S.C. § 2067(a) (1976 & Supp. III 1979).

87. *Id.*; *see supra* text accompanying notes 53-60.

88. 15 U.S.C. § 2067(a) (1976 & Supp. III 1979).

89. 15 U.S.C. §§ 2056, 2058 (1976).

90. *Id.* §§ 2057, 2058.

91. *See* 16 C.F.R. § 1019.7 (1982).

92. 15 U.S.C. §§ 1273(d) (1976 & Supp. III 1979).

93. *Id.* § 1202(c).

94. 21 U.S.C. §§ 301-392 (1976 & Supp. III 1979).

95. 42 U.S.C. § 262(a) (1976) (license to manufacture biological products); 21 U.S.C. §§ 361-62 (1976) (standards of adulteration and misbranding for cosmetics); 21 U.S.C. § 355(a) (1976) (new drugs); 21 U.S.C. § 334 (1976 & Supp. III 1979) (adulterated or misbranded food or drugs); 21 U.S.C. §§ 341-343 (foods: standards of identity, adulteration, misbranding) (1976 & Supp. III 1979); 21 U.S.C. §§ 360(d)-360(f), 360(h) (medical devices) (1976 & Supp. III 1979).

purchaser,
(2) the product is not in conflict with the laws of the country to which it is being exported,
(3) the product is labeled on the shipping package as intended for export, or
(4) the product is not in fact sold or offered for sale in the United States.[96]

FDA export policy is, however, in the words of its own Commissioner, "so internally inconsistent that it is very hard to know what the policy is."[97] Briefly that policy is as follows:

(1) Medical devices, although exempted under section 381(d)(1), remain subject to restrictions in section 381(d)(2). Devices that do not comply with performance standards, fail to receive pre-market clearance, or are banned cannot be exported unless the Secretary of Health and Human Services determines that the export is "not contrary to the public health and safety and has the approval of the country to which it is intended for export."[98]
(2) Biological products (viruses, serums, toxins, vaccines, blood, etc.) are regulated without differentiation between domestic and foreign markets; there can be no export of those products not approved for sale in the United States.[99]
(3) Foods, cosmetics, and drugs manufactured for human use that are currently approved for distribution in the United States may be exported without a permit so long as the four criteria of section 381(d)(1) are met.[100]
(4) New drugs, not yet approved for domestic use by FDA, may not be exported for commercial use under any circumstances.[101] Investigational use by a foreign purchaser may be authorized by FDA upon the agency's receipt, through the State Department, of a formal request from the government of the importing nation.[102]
(5) New animal drugs may be exported as long as they are

96. *See* 21 U.S.C. § 381(d)(1) (1976 & Supp. III 1979).
97. *1978 Drug Regulation Hearings, supra* note 63, at 194 (statement of Dr. Donald Kennedy).
98. 21 U.S.C. § 381(d)(2) (1976).
99. 42 U.S.C. § 262(a) (1976).
100. 21 U.S.C. § 381(d)(1) (1976 & Supp. III 1979).
101. *Id.* § 355(a) (1976).
102. 21 C.F.R. § 312.1 (1982).

not unsafe within the meaning of section 360b of the FD&CA.[103]

C. Environmental Protection Agency

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[104] and the Toxic Substances Control Act (TOSCA)[105] invest the EPA with authority to register, set standards for, and remove or suspend certain chemicals and pesticides from the domestic market. Both statutes contain provisions regarding exports of regulated substances.

An examination of FIFRA prior to its 1978 amendments reveals why so many lethal pesticides passed into the unprepared hands of foreign consumers. Prior to 1978 FIFRA exempted from its registration, labeling, or branding requirements any product "intended solely for export . . . and prepared or packed according to the specifications or directions of the foreign purchaser."[106] The EPA, however, was required to forward to foreign governments and international organizations a simple notice of the registration, cancellation, or suspension of any pesticide.[107]

The 1978 amendments to FIFRA[108] have significantly tightened the agency's control over pesticide exports. Although exported pesticides maintain their technically exempt status, exporters must now comply with the registration and record-keeping requirements and the extensive labeling provisions of the Act.[109] In addition, exports are now subject to detailed regulations[110] requiring that the pesticide be labeled in a form "likely to be noted by the ordinary individual under customary conditions of purchase and use," and bear the legend "Not Registered for Use in the United States of America."[111] The FIFRA provision that requires

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103. 21 U.S.C. § 381(d)(1) (1976 & Supp. III 1979).

104. 7 U.S.C. 136-136y (1976 & Supp. III 1979) (current version at 7 U.S.C.A. § 136-136y) (1980 & West Supp. 1982).

105. 15 U.S.C. §§ 2601-2629 (1976 & Supp. III 1979).

106. 7 U.S.C. § 136o (1976 & Supp. III 1979). Firms manufacturing such products for export were not exempt from the Act's basic record-keeping requirements. *Id.* § 136f.

107. *Id.* For a review of the effectiveness of this system, see *infra* text accompanying note 135.

108. Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 833.

109. 7 U.S.C. § 136(p) (1976 & Supp. III 1979).

110. *Id.* § 136(q).

111. *Id.* As a result of the requirements imposed by §§ 136(p) and 136(q), all

the EPA to notify foreign governments and international agencies of any regulatory action[112] has been broadened; upon request by the importing nation this notice must now include background information related to the agency's decision and specifications of approved pesticides which might be used in lieu of the restricted substance.[113] Prior to shipment of any unregistered pesticide, the FIFRA requires foreign purchasers to sign a statement indicating that they understand the pesticide is not registered for use by EPA and thus cannot be sold in the United States.[114] A copy of this signed statement must be forwarded to the government of the recipient nation.[115]

The Toxic Substances Control Act,[116] enacted in 1976, provides for the development of data concerning the effects of chemical substances on human health and upon the environment. Pursuant to sections 4 through 7 of TOSCA,[117] the EPA is given extensive

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exported pesticides, devices, and active ingredients used in producing pesticides must, under current regulations, bear labels which contain:

1. EPA Establishment Numbers;
2. Ingredient statements;
3. Name and address of the producer or registrant;
4. Statements of net weight and measure;
5. If highly toxic, skull and crossbones and information for practical treatment in case of poisoning;
6. Warning and caution statements;
7. No false representations;
8. No imitation of other products, and
9. In the case of an unregistered pesticide, the conspicuous and readable statement "Not Registered for Use in the United States of America."

EPA has interpreted the "likely to be read and understood by the ordinary individual" language of § 136(q) to require warning and caution statements, ingredient lists, poison warnings, and treatment information, and the "Not Registered for Use in the United States" legend to appear bilingually on the exported product's label. 45 Fed. Reg. 50,275 (1980).

112. 7 U.S.C. § 136(g).

113. *Id.* § 136o(b).

114. *Id.* § 136o(a).

115. *Id.* § 136o(a)(2). The exporter must acquire this final acknowledgement before the product is released for shipment. 45 Fed. Reg. 50,274 (1980). Such statement need only be prepared annually for the first shipment of each unregistered pesticide to a particular purchaser for each importing country. *Id.*

116. 15 U.S.C. §§ 2601-2629 (1976 & Supp. III 1979).

117. *Id.* §§ 2603-2606 (1976). EPA may require testing, impose pre-market notice requirements, require labeling, and limit or prohibit sales if tests provide a reasonable basis from which to conclude that unreasonable risks to health or the environment exist. EPA may also, by obtaining a court order, seize a sub-

authority to regulate those chemicals which it determines pose an unreasonable risk of injury. A broad export provision[118] exempts those chemical substances which are manufactured for export from all regulations under TOSCA except those concerning the reporting and retention of information.[119] This "hands off" attitude toward the welfare of foreign consumers is accentuated by the succeeding provision[120] which provides that any exported substance that presents an unreasonable risk of injury to human health or to the United States environment will be subject to TOSCA's full requirements. The TOSCA, however, does not leave the importing nation entirely without data concerning the chemicals that it imports. Section 12(b) of the TOSCA[121] requires any person who intends to export a chemical for which the submission of data has been required under the TOSCA[122] or for which certain regulatory actions have been taken[123] to notify EPA of that intention. The EPA is then required to notify the foreign government of the nature of the action taken or upon that government's request, of the availability of background information concerning that substance.[124]

D. Proposals for Change in United States Policy

Enacted over a period of forty years, and often responding to particular incidents of consumer harm, these United States stat-

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stance which poses an imminent hazard.

118. *Id.* § 2611(a).

119. *Id.* § 2607.

120. *Id.* § 2611(a)(2).

121. *Id.* § 2611(b).

122. *See id.* §§ 2603, 2604(b).

123. *See id.* §§ 2604-2606. EPA's general policy is not to require notice of export for articles unless the Agency has already specifically so required in the context of individual rulemakings or actions concerning those specific items. 45 Fed. Reg. 82,846 (1980) (to be codified at 40 C.F.R. § 707).

124. *Id.* § 2611(b). The EPA's current regulations concerning export notices apply to PCBs, CFCs, 2,3,7,8-TCDD (tetra chloridibenzo-p-dioxin), and asbestos, the articles currently restricted under § 7 of TOSCA, as well as any future items falling under the appropriate section. The notification procedure under TOSCA is analogous to that of FIFRA. For each affected chemical substance exporters must submit annually a single notice for each country to which the chemical is sent. Such notice must include the exporter's name and address, the name of the chemical substance, the export date, the country of import, and the section of TOSCA under which EPA has taken prior action regarding the substance. 45 Fed. Reg. 82,844 (1980) (to be codified at 40 C.F.R. 707).

utes address a wide variety of product categories, shipment routes, and uses. Although the recent restructuring of the EPA's and the CPSC's authority over exports of potentially hazardous merchandise has increased their control over those shipments, the situation, in the eyes of many critics, remains unacceptably chaotic.[125]

The Reagan administration is considering further retreats from Carter administration export policies. Most notably, the State Department has proposed the almost complete elimination of the current preshipment notification rules.[126] In response to President Reagan's request for recommendations following his revocation of Executive Order 12,264,[127] the State Department echoed the chief executive's belief concerning the detrimental effect of hazardous substance export regulations on domestic industry's competitiveness in the international marketplace. A proposed statute would replace the EPA's current annual notification procedure for shipments of banned or restricted goods[128] with a procedure that would provide "brief summary information" to foreign governments or international organizations following pertinent domestic regulatory action. This notice could occur years before the product's actual export.[129] Furthermore, as part of its overall anti-regulatory approach, the administration has reduced the budget of the CPSC thirty percent[130] and is seeking to cut in half the staff and the budget of EPA during the next two years.[131] It is reasonable to assume that the more limited capabilities of these agencies will be focused on issues of more immediate concern to the domestic population.

Although legislative momentum accompanying the potentially hazardous merchandise issue has not disappeared,[132] it appears

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125. *See, e.g., 1980 Hearings on Hazardous Products, supra* note 1, at 146 (statement of Angela Blackwell, attorney, Public Advocates).

126. Mayer, *Easing of Hazardous Exports Studied,* Wash. Post, Sept. 9, 1981, at A1, col. 1.

127. Exec. Order No. 12,290, *supra* note 13.

128. *See supra* text accompanying notes 104-24.

129. Wash. Post, Sept. 9, 1981, at A16, col. 1.

130. *Id.*, May 31, 1981, at D8, col. 1.

131. Shabecoff, *Funds and Staff for Protecting Environment May Be Halved,* N.Y. Times, Sept. 29, 1981, at A1, col. 1.

132. H.R. 6587, 96th Cong., 2d Sess. (1980), *reprinted in 1980 Hearings on Hazardous Products, supra* note 1, at 215. Congressman Michael Barnes, who introduced H.R. 6587 as an amendment to the Export Administration Act, has

that the consensus within the Government remains that each nation should decide which products it shall import. Information exchange systems, therefore, will become the main thrust of any politically viable United States hazardous substance export policy.[133]

There are two prerequisites for the success of this approach. First, adequate data must exist about the product's risks and benefits. Second, this information must be accessible to the overseas decision maker. President Carter's short-lived Executive Order 12,264[134] and a recent congressional proposal, H.R. 6587,[135]

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reintroduced the measure as H.R. 2439, 97th Cong., 1st Sess. (1981). Telephone interview with Lenora Odeku, office staff member of Rep. Barnes (Feb. 1, 1982).

133. THE BANNED PRODUCTS REPORT, *supra* note 35, presents the view that notification procedures are the only feature of the United States hazardous substance export policy and ignores this nation's technical superiority in terms of data analysis, as well as the limitations of information exchange systems. Moreover, it sidesteps the moral obligations incumbent upon the possessor and originator of such information. The author of this Note believes that, given the status of the progress made to this point, concentration upon refinement of what is probably the least commercially intrusive, and therefore, the most politically viable form of export supervision, is a realistic strategy for persons concerned with this issue.

134. Exec. Order No. 12,264, *supra* note 14.

135. H.R. 6587, 96th Cong., 2d Sess. (1980). A GAO evaluation of the State Department's role in EPA's pesticide notification program found significant defects in the implementation of the EPA's pesticides export policy. Letter from Henry Eschwege, Director GAO, to Douglas Costle, *reprinted in* BANNED PRODUCTS REPORT, *supra* note 35, (app. V). The GAO found that while the EPA had cancelled or suspended registrations of fourteen pesticides, the agency's policy was to notify foreign governments only when final action was taken. As a result, notification was sent concerning only five regulatory actions. Information was entirely omitted for a number of extremely widely used suspected carcinogens, chlordane and heptachlor, because they were suspended from registration in 1975, but not cancelled until 1978. *1978 Hearings on Banned Products, supra* note 4, at 163. Even when notification was released, the GAO found substantial evidence that notices sent through the State Department often failed to reach their foreign destinations. *See id.* at 81. In one example, an embassy official told the GAO that he failed to forward such notices because such action might adversely affect United States exports to that nation. *Id.* Inadequacy in the content or form of these notices was also said to be prevalent. *Id.* Similarly, lack of coordination in FDA notification has been conceded by its Commissioner. *Id.* at 110 (statement of Dr. Donald Kennedy, FDA Comm'r, Public Health Serv., Dep't of HEW). Although it is not required to maintain any such procedures by statute, that agency's ad hoc notification techniques take several forms. The Bureau of Drugs communicates directly with several nations, as well as with WHO. *Id.* at 112. Although WHO and the State Department may be notified of a regu-

are examples of regulatory systems which derive their effectiveness from greater uniformity in export notification procedures. Increased uniformity in this respect would contribute to the formulation, accessibility, and usefulness of information concerning potentially hazardous substances without adding substantially to the regulatory burden. The resulting improvement in efficiency may help remedy serious defects in the existing notification procedures.

Despite its shortcomings, Executive Order 12,264 represents the highwater mark of United States hazardous substance export policy. The order was composed of three elements—hazard notification, an annual summary of regulatory actions, and limited export controls.

Export controls, the most restrictive element of the order, proved to be the most controversial.[136] Although the order contemplated that this country's obligations would be chiefly satisfied through its notification procedures, it recognized that for certain articles, positive action to curtail exports might be needed as

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latory action, there often is no indication that such information has been received. BANNED PRODUCTS REPORT, *supra* note 35, at 23.

136. Exec. Order No. 12,264, *supra* note 14, § 1-3, 46 Fed. Reg. 4662. Export controls under the Order were enacted under authority of the Export Administration Act of 1979, 50 U.S.C. app. §§ 2401-2422 (1981). This Act is the successor to the Export Administration Act of 1969, 50 U.S.C. app. §§ 2401-2422 (1980). In a memorandum dated Jan. 30, 1979, Leon Ulman, Deputy Assistant Attorney General, Office of Legal Counsel, advised the Department of Commerce that the 1969 statute gave the President authority to control exports of hazardous substances for reasons of foreign policy. 45 Fed. Reg. 53,768 (1980). By memorandum dated Apr. 11, 1980, Deputy Assistant Attorney General Ulman advised the Working Group that the President's ability to control such products to significantly further the foreign policy interests of the United States remained intact under the 1979 statute. *Id.* Section 6(a)(1) of the 1979 Act authorizes the President to "prohibit or curtail the exportation of any goods, technology, or other information . . . to the extent necessary to further significantly the foreign policy of the United States or to fulfill its declared international obligations." The memorandum noted that the purposes of foreign policy controls are more vague than national security controls, and therefore might sanction a wide variety of actions. Industry representatives have argued that the 1979 statute evinces an intention to use the Act as a punitive device, for instance, against nations like South Africa, rather than as a means to expand the scope of export licensing by the Department of Commerce. *See* Letter to Ed Cohen, Deputy Director, Office of Consumer Affairs, from Jack D. Early, President, National Agricultural Chemicals Association, *reprinted in 1980 Hearings on Hazardous Products, supra* note 1, at 385.

a last resort.[137] The Secretary of Commerce, therefore, in cases of "extremely hazardous substances . . . which represent a substantial threat to human health or safety or to the environment . . . export of which would cause clear and significant harm to the foreign policy interests of the United States" could require an export license.[138] The license approval procedure was particularly cumbersome[139] because of the procedures required by the Export Administration Act.[140]

The annual notification provision was to complement the other notification provisions of the order.[141] Compiled by the Regulatory Council,[142] it summarized all proposed and final regulatory actions related to products within the order's scope. The summary was to be published in the Federal Register and distributed by the State Department to appropriate foreign officials and international organizations.[143]

The working group considered the order's hazard notification

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137. HSEP Report, *supra* note 3, at 7811.

138. Exec. Order No. 12,264, *supra* note 14, § 1-301, 46 Fed. Reg. 4662.

139. An interagency task force chaired by the Department of State, and including the Department of Commerce, the EPA, CPSC, FDA, the Office of the Special Trade Representative, and other relevant agencies, was to be formed. *Id.* § 1-304, 46 Fed. Reg. 4662. This group would select, from all substances banned or restricted in this country, those to be included on a Commodity Control List. That selection would be made on the basis of the type, extent, severity, likelihood, and duration or irreversibility of damage, the potential for harm to neighboring nations and the global commons, the availability of alternatives to the substance, the benefit attached to the product's use, its availability from other sources, and other factors. *Id.* § 1-305, 46 Fed. Reg. 4663. If the task force and State Department both concluded that the export of the substance would be harmful to the nation's foreign policy interests, and that export control would benefit those interests, the State Department would recommend to the Commerce Department that the substance be placed on the Commodity Control List. *Id.* § 1-306, 46 Fed. Reg. 4663. The Commerce Department would then apply the procedures mandated by §§ 3, 4, and 6 of the Export Administration Act, 50 U.S.C. app. 2401-2422, in evaluating the recommendation. *Id.* § 1-307, 46 Fed. Reg. 4663. Section 6 of the Act would have required consultation with affected industries as well as notification by the President to Congress of the imposition of controls, with a report on the basis for their imposition. *Id.* Once the hazardous substance was placed under export controls, any intended exporter would need to apply to the Department of Commerce for a license to export the product. *Id.* § 1-301(c), 46 Fed. Reg. 4662.

140. 50 U.S.C. app. §§ 2401-2422.

141. *See* HSEP Report, *supra* note 3, at 7811.

142. Exec. Order No. 12,264, *supra* note 14, § 1-401, 46 Fed. Reg. 4663.

143. *Id.* § 1-403, 46 Fed. Reg. 4664.

provisions its core.[144] No substantive changes were proposed in the recently amended notification procedures.[145] Rather, the group stressed the need for greater procedural uniformity in the notification process[146] and thus designated the State Department as the official conduit for notices.[147] That department and the various agencies involved were to work together to determine which persons in the United States would be contacted for information about product risks and to locate "opposite numbers" in foreign governments.[148] The order also set a uniform standard for the contents of such notices. At a minimum, information forwarded by the State Department was to include:

> (1) the name of the hazardous article to be exported,
> (2) a summary of any agency's regulatory actions regarding that substance, including a timetable for any further action, and
> (3) a summary of the potential risks to human health or safety or to the environment, which formed the basis for the agency's action.[149]

The order was not without significant flaws. First, it fully excluded two major categories of potentially hazardous merchandise from its scope—hazardous production facilities and products "subject to unsafe circumstances abroad" (*e.g.* infant formula).[150] Criticism was also directed at the inadequacy of the notification procedure of the order, which was felt by some to be "virtually certain to prove ineffective."[151] Critics noted that many substances for which notification alone was to be provided were those substances for which a similar approach had already been deemed inadequate to protect the United States population. Second, brib-

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144. HSEP Report, *supra* note 3, at 7812.

145. *Id.* at 7811.

146. *Id.*

147. Exec. Order No. 12,264, *supra* note 14, § 1-201(a), 46 Fed. Reg. 4661. The order did not, however, preclude an agency from directly contacting a foreign government as a supplement to the standard State Department conduit. *Id.* § 1-202, 46 Fed. Reg. 4661.

148. HSEP Report, *supra* note 3, at 7811.

149. Exec. Order No. 12,264, *supra* note 14, § 1-201(b)(1)-(3), 46 Fed. Reg. 4661.

150. HSEP Report, *supra* note 3, at 7817.

151. *1980 Hearings on Hazardous Products, supra* note 1, at 231.

ery of foreign governmental officials[152] could obliterate any effect that simple notification to those officials might have.

H.R. 6587[153] provided that no product banned, disapproved, or restricted in use within the United States could be exported without a license. The license could be issued to an exporter only upon a joint finding by the Secretary of Commerce and the head of the agency having jurisdiction over the product:

> (1) that the government of the importing country requested the product,
> (2) that the exporting company fully informed the importing government and foreign consignee of any restrictions on the sale of the product in the United States and of the risks posed by the product,
> (3) that the potential benefits of the product outweighed the possible hazards,
> (4) for a product restricted in the United States, that the importing nation subjects it to similar restrictions,
> (5) that the product effectively provides information to protect that nation's consumers, in light of language barriers, illiteracy, or marketing practices in the importing nation, and
> (6) that the product is not an ingredient of a banned product being shipped for the purpose of manufacturing that banned product in another nation.[154]

The Barnes bill, as compared to Executive Order 12,264, has drawn less fire from environmentalists. Most criticism has been directed at inadequate provision for public participation in agency determinations concerning export licenses.[155] Critics argue that without public input the agency will be biased because the only input to the agency will be that of the very firms promoting the sale of the regulated product.[156] Even proponents of the most

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152. *See, e.g., id.* at 184 (Form 8-K report of the Upjohn Company to the Securities and Exchange Commission, indicating payments of $4,098,000 to employees of foreign governments, or intermediaries, in connection with sales).

153. H.R. 6587, 96th Cong., 2d Sess. 1980.

154. Export Administration Act of 1979, Pub. L. No. 96-72, 93 Stat. 503, §§ 2(3)(A)(i)-(iii), 2(3)(B), 2(4), 2(5) (codified as amended in scattered sections of 50 U.S.C.).

155. *1980 Hearings on Hazardous Products, supra* note 1, at 221 (statement of Public Citizen Health Research Group); *id.* at 391 (letter to Subcommittee on International Economic Policy and Trade from Consumers Union).

156. *Id.* at 221, 391.

extensive export regulations have conceded, however, that the bill's third criterion, cost-benefit analysis, would be extremely difficult to implement.[157] From industry's standpoint, the wording of the proposed amendment reaches too wide a range of domestically regulated products. Greater selectivity in the coverage of the bill would increase its effectiveness in controlling hazards of international significance.

E. Executive Order No. 12,114—A Model for Export Policy

Executive Order 12,114, Environmental Effects Abroad of Major Federal Actions (the Order),[158] is a recent clarification of the United States Government's position regarding the welfare of foreign consumers. Although the Order expressly states that it "furthers the purposes of the National Environmental Policy Act" (NEPA),[159] it rejects NEPA as the source of its authority.[160]

Its legal origins notwithstanding, the order comports with the policies articulated by NEPA, as tempered by foreign policy considerations. Federal agencies involved in actions which "significant[ly] harm . . . the [natural and physical] environment"[161] must issue regulations implementing an environmental review procedure.[162] Programs subject to review include those which affect the global commons,[163] any foreign country not participating with the United States in the program,[164] a foreign nation receiving products strictly regulated in the United States because of toxic[165] or radioactive properties,[166] or a protected global

157. *Id.* at 221.

158. Exec. Order No. 12,114, 3 C.F.R. 356 (1979) [hereinafter cited as Exec. Order No. 12,114] *reprinted in* 42 U.S.C. § 4321, app. 597 (Supp. III 1979).

159. 42 U.S.C. §§ 4321-4361 (1976). The purposes of the National Environmental Policy Act (NEPA) are: To declare a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the nation; and to establish a Council on Environmental Quality. *Id.* § 4321.

160. Exec. Order No. 12,114, *supra* note 158, § 1-1.

161. *Id.* § 3-4.

162. *Id.* § 2-1.

163. This term encompasses any areas "outside the jurisdiction of any nation (*e.g.*, the Oceans or Antarctica)." *Id.* § 2-3(a).

164. *Id.* § 2-3(b).

165. *Id.* § 2-3(c)(1).

166. *Id.* § 2-3(c)(2).

resource.[167]

The Order provides seven broad exemptions to the required review procedure. These exemptions parallel those currently employed by NEPA.[168] These exemptions grant agencies enormous flexibility in their review processes. One commentator has suggested that the Order, in providing this discretion, allows circumvention of NEPA's purposes.[169]

The Order provides, nonetheless, a model for governmental review of exports, and obliges agencies to consider their responsibility for environmental review. It thus encourages a thorough analysis of the effect of a decision to export. The Order, however, provides no standard to determine whether intended exports are acceptable. The Order suggests that those responsible for the creation and promotion of a product analyze its environmental impact. These parties, whether manufacturers or federal agencies, are more likely to have the technical and personnel resources necessary for analyzing drugs, pesticides, industrial chemicals, and consumer products than are the recipients of the merchandise.[170]

Proponents of more extensive export regulations have offered comprehensive and detailed plans for stopping the harm inflicted on foreign consumers by products originating in the United States.[171] Because the trend is toward decreasing regulation, these

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167. *Id.* § 2-3(d).

168. *Id.* § 2-5(a). Section 2-5(a) exempts agencies from environmental review requirements for:

1. actions not having a significant effect on the environment outside of the United States, as determined by the agency;
2. actions taken by the President;
3. actions involving national security, or occurring "in the course of armed conflict";
4. intelligence activities and arms transfers;
5. routine export licenses, permits, or approvals;

(The effect of this exemption is to omit from the scope of review an export transaction where the only federal tie is a review under other statutes or policies. If the Government supports the transaction with public financing, however, the review must be prepared. *See id.* § 3-4).

6. votes and other actions in international conferences and organizations; and
7. disaster and emergency relief actions.

169. *See* Note, *Agency Responses to Executive Order 12,114: A Comparison and Implications*, 14 CORNELL INT'L L.J. 481, 491-506 (1981).

170. *See supra* note 4.

171. *E.g.*, BANNED PRODUCTS REPORT, *supra* note 35, at 24. The Banned Products Report recommended that new legislation affecting the export provi-

proponents may only manage to keep the issue alive.[172] A problem with the current trend is that a policy providing little beyond total laissez-faire would result in a flood of raw data to foreign governments. These governments, in light of their capacities to digest and utilize this information,[173] would derive little benefit from this policy. A more demanding policy modeled upon the order would not be appreciably more restrictive, but would provide foreign governments with more understandable product information. Furthermore, this policy would be more attuned to the obligations and abilities of the United States as a leading exporter of potentially hazardous merchandise.

IV. INTERNATIONAL MECHANISMS FOR THE CONTROL OF POTENTIALLY HAZARDOUS MERCHANDISE

This Note has discussed the health problems resulting from the

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sions of the statutes administered by EPA, FDA and the CPSC provide:

1. authority to collect data regarding export of items banned by the agency, including evidence that the product conforms to the specifications of the foreign purchaser, and violates no laws in the importing nation;
2. a requirement that exports be conspicuously labeled "For Export Only," or a similar legend indicating that the product is not registered or approved in the United States;
3. a requirement that the agency notify foreign governments of all actions taken, and of all proposed actions which may affect importations into their countries;
4. a requirement that the foreign authorities certify that they have received such notification;
5. the authority to totally ban export of extremely hazardous substances;
6. provisions for giving technical assistance and training to proper authorities in developing nations in order to increase their decision-making capabilities.

Id. at 6. Proposals also have stressed a need for consideration of the impact of United States exports on the global commons and third-party nations. *See 1980 Hearings on Hazardous Products, supra* note 1, at 28 (statement of Faith T. Campbell, Natural Resources Defense Council). Critics of current policy have called for the establishment of a presumption of equivalent treatment for domestic and exported goods, in order to take advantage of the usually extensive proceedings before any action concerning a given product. *Id.* at 224 (statement of Public Citizen Health Research Group). A decision could be reached at some later point concerning export, if a company or foreign government offered evidence that the product's use abroad was warranted. *Id.*

172. *See* telephone interview with Lenora Odeku, Office of Rep. Michael Barnes (Feb. 1, 1982).

173. *See supra* note 4.

use of potentially hazardous merchandise by unprepared consumers,[174] the inadequacy of this nation's regulatory system regarding the use of this merchandise,[175] the inability of importing nations to fully control the use of such products,[176] and the inability of one nation's resolution of its own hazardous substance export problem to solve what is fundamentally a worldwide problem.[177] Because it is unlikely that a solution to the problems posed by the exportation of potentially hazardous merchandise will come solely from the United States or the importing nations, an international scheme of consumer protection is called for. Policies and requirements subscribed to by many nations would eliminate the competitive disadvantage faced by an exporter based in a nation that has unilaterally enacted export restrictions. Uniform labeling and information exchange rules would also result in more efficient communication of product information, lessen incidents of redundant testing,[178] broaden the data base for product analysis,[179] and reduce the need for individual labeling requirements.[180] Finally, an international system of product hazard notification would become more universally understood by consumers than would an assortment of warnings.

The international community has developed various devices for

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174. *See supra* text accompanying notes 16-70.

175. *See supra* text accompanying notes 71-124.

176. *See supra* note 4.

177. *See supra* note 53.

178. *See supra* note 4. A recent survey has indicated that the large majority of chemical companies are too small to support in-house toxicity and ecotoxicity testing facilities. ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, CHEMICAL ASSESSMENT: INDUSTRY'S APPROACH TO SAFETY TESTING ¶ 61 (1976) [hereinafter cited as OECD, CHEMICAL ASSESSMENT]. Consequently, such firms must rely upon external laboratories, the impartiality and comprehensiveness of which have been questioned. *See, e.g.*, Wash. Post, Feb. 20, 1978, at A1, col. 5.

179. *See infra* text accompanying notes 268, 283-95.

180. Any efforts to this end are significant because of the lack of inherent economic incentives for manufacturers to gather and disseminate full and accurate product information to consumers. Unlike a traditional commodity, information cannot be readily protected by a system of property rights. Consumers will not pay the optimum market value for goods they cannot "own," and the market, therefore, will fail to generate an optimum supply. Consumption of any information provided leaves such information's value largely intact and it becomes a "public" good. *See* Samuelson, *The Pure Theory of Public Expenditure*, 36 REV. ECON. & STATISTIC 387 (1954); Note, *Promoting Product-Quality Information: A Proposed Limited Antitrust Exemption for Producers*, 30 STAN. L. REV. 563 (1978).

dealing with potentially hazardous substances. This Note focuses on three of these devices: The World Health Assembly Code of Marketing for Breast-Milk Substitutes,[181] the European Economic Community (EEC)[182] sixth amendment[183] to the 1967 Directive controlling dangerous substances,[184] and information exchange systems conducted under the aegis of the United Nations, chiefly the World Health Organization (WHO) and the International Register of Potentially Toxic Compounds (IRPTC). Each device falls at a different point on a continuum having at one end strict limitation of commercial activity and at the other voluntary guidelines for the enhancement of information exchange. The approach taken by each device reflects the legal nature of the parent organization, the area of consumer protection with which it is concerned, and the political undercurrents within the sponsoring entity.

A. The Infant Formula Marketing Code

1. *Introduction*

On May 21, 1981, after substantial investigation and debate,[185] the United Nations World Health Assembly approved an International Code of Marketing of Breast-Milk Substitutes (Code).[186] The Code was approved in the form of a recommendation to member states. The House Foreign Affairs Committee conducted hearings concerning the infant formula issue early in 1980.[187] Tes-

181. World Health Organization Code, *supra* note 6.

182. Four institutions comprise the European Economic Community (EEC): the Council, the Commission, the European Parliament and the Court of Justice. The special Council of Ministers is the decision making body of the EEC; it establishes community policy through directives, regulations, and decisions. The Commission is the executive branch of the EEC. It carries out directives of the Council, makes recommendations for Council action, and participates in Council meetings. The European Parliament consists of delegates; some may be elected directly by each member state, who "deliberate" Council directives, report on Commission proposals, and review the annual General Report. The Court of Justice has three areas of competence. It functions as an international court, a constitutional court, and an administrative tribunal. A. ROBERTSON, EUROPEAN INSTITUTIONS 182-95 (3d ed. 1973).

183. 22 O.J. EUR. COMM. (No. L 259) 10 (1979).

184. 10 O.J. EUR. COMM. (No. L 196) 1 (1967).

185. *See supra* note 15 and accompanying text.

186. World Health Organization Code, *supra* note 6.

187. *1980 Hearings on Infant Formula, supra* note 2.

timony at those hearings by infant formula industry representatives indicated that a number of United States companies worked with the WHO on development of the proposed code.[188] Under mounting pressure from the WHO and other critics, companies made substantial changes in their marketing practices.[189] These concessions, coupled with intensive lobbying by the International Council of Infant Food Industries (ICIFI) at the WHO Geneva meeting,[190] failed to defeat the resolution calling for the adoption of the Code. Only the United States was convinced by the industry's argument for self-regulation and voted against adoption of the Code.[191] Although the industry in the United States has obtained successful results from self-regulation, only three compa-

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188. *See, e.g., id.* at 27 (statement of David O. Cox, president, Ross Laboratories).

189. *See, e.g., id.* at 73 (statement of John R. Stafford, executive president, Home Products Corp.).

190. *See 1981 WHO Code Hearings, supra* note 19, at 97-98.

191. Prior to the WHA vote on the World Health Organization Code, *supra* note 6, the United States publicly announced its intention to vote against adoption, claiming it had serious difficulty accepting the Code's provisions on constitutional, economic, and commercial grounds. 81 DEP'T ST. BULL. 54 (1981) (press statement of Elliot Abrams, Assistant Secretary for International Organization Affairs, May 15, 1981); *see infra* text accompanying note 265. The Reagan administration also voiced opposition to the involvement of any United Nations agency in the regulation of economic activity. 81 DEP'T ST. BULL. 54 (1981) (press statement of M. Peter McPherson, Administrator, AID, May 18, 1981). Government spokesmen further explained the United States position by linking the infant formula code with other proposed U.N. actions, notably the U.N. Educational, Scientific and Cultural Organization (UNESCO) proposal for a "new world information order." These officials claimed that the infant formula action was part of an attempt "to undermine respect for press integrity and legitimize attempts by the Soviet bloc and its allies to control the flow of information." *Id.* Following the Code's passage both the House and the Senate overwhelmingly approved resolutions expressing their "dismay" and "concern" regarding the administration's stance. *See* H.R.J. Res. 287, 97th Cong., 1st Sess., 127 CONG. REC. 2962 (1981); S. 1193, 97th Cong., 1st Sess., 127 CONG. REC. 6484 (1981). The United States vote was criticized widely. *See* 127 CONG. REC. 2953 (1981) (citation of editorials). The vote prompted the resignation of two AID officials. N.Y. Times, May 19, 1981, at A6, col. 1. Criticism of the president's nomination of Ernest Lefever for Secretary of State also heightened as a result of the United States vote. Mr. Lefever's strong stance against the Code was attributed to his association with the Nestle Corporation, the major corporate target of activist proponents of the Code. *Id.* at A7, col. 1; *id.*, May 22, 1981, at A1, col. 1.

nies[192] marketing infant formula in the Third World are based in this country. No matter how favorable the experience of the United States firms in matters of ethical business practice, no significant percentage of all companies marketing infant formula can be reached through legislation by a single nation.

2. *Provisions of the Code*

The preamble to the Code indicates that the WHO's action is based upon the "right of every child and every pregnant and lactating woman to be adequately nourished . . . ."[193] The preamble reviews the advantages of breast-feeding, acknowledges that social and economic forces affect breast-feeding, and admits that there are situations in which recourse to formula is appropriate.[194] It closes by calling upon governments to take action in the marketing of breast-milk substitutes set out in the Code.[195]

The Code focuses upon the sources of public information concerning formula. Extensive proscriptions begin with article 4, which reiterates the Code's assignment of regulatory duties to individual governments.[196] The article then lists the information which is to be included on all informational or educational materials "dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children."[197]

Article 5 of the Code imposes a strict ban on public advertising of breast-milk substitutes.[198] The article also prohibits manufac-

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192. Those companies are: Abbott/Ross Laboratories, Mead Johnson Nutritionals, and Wyeth International, Ltd. *1980 Hearings on Infant Formula, supra* note 2, at 41. Other nations where such firms operate include France, Mexico, the Netherlands, England, Denmark, Hungary, Argentina, South Korea, Switzerland, Japan, India, Indonesia, and South Africa. *Id.*

193. *World Health Organization Code, supra* note 6, preamble at 10.

194. *Id.*

195. *Id.* at 12.

196. *Id.* § 4.1, at 15.

197. *Id.* § 4.2, at 16. Such materials are to provide "clear information on: (1) the benefits and superiority of breast feeding, (2) maternal nutrition, (3) the negative effect of partial bottle/feeding or breast/feeding, (4) the problem of resuming breast/feeding following its abandonment, and (5) where needed, the proper use of infant formula." If the manufacturer exercises its option to convey information about the uses of its product on such materials, a discussion of the social and financial implications and the health hazards involved in improper infant feeding must be included. These materials may not, in addition, use "any pictures or text which may idealize the use of breast milk substitutes." *Id.*

198. *Id.* § 5.1, at 16.

turers and distributors from furnishing, directly or indirectly, samples of formula to its most likely users.[199] The article continues its assault on infant formula promotion by prohibiting marketing personnel from contacting those whom the drafters feel are most susceptible to their persuasions.[200]

Article 6 begins by encouraging health authorities in individual nations to promote the objectives of the Code.[201] It prohibits manufacturer access to health care facilities for the purposes of promoting products within the Code's scope,[202] except as provided by article 7, and attacks direct consumer contact by company representatives.[203] Article 6, however, does permit manufacturers to offer donations or low price sales of products or equipment to institutions, but only the company name or logo, not the brand name of a formula product, may accompany the equipment or products.[204]

Article 7 deals with contact between company representatives and health care professionals. It extends the prohibition found in article 4[205] against creating the impression that formula feeding is superior to breast-feeding to the professional sphere.[206] Financial or material inducement to health care professionals by manufacturers or distributors is flatly prohibited.[207] Samples of formula may be given only for "professional evaluation or research at the institutional level."[208] Health care professionals may not then turn over samples of the product to pregnant women and other potential customers.[209]

Article 8 is limited to practices entirely within the trade. Quotas for sale of articles within the scope of the Code are forbidden and formula sales are to be excluded from calculations of bonus

199. *Id.* § 5.2, at 16.

200. Sections 5.3-5.5 detail the prohibitions of the preceding sections in an attempt to eliminate consumer exposure to point-of-sale advertising, giving of samples, and other promotional devices such as "special displays, discount coupons, premiums, special sales, loss/leaders, and tie-in sales," as well as gifts of utensils which may promote bottle feeding. *Id.* §§ 5.3-.5, at 17.

201. *Id.* § 6.1.

202. *Id.* § 6.2.

203. *Id.* §§ 6.3-.5 at 17-18.

204. *Id.* §§ 6.6-.8, at 18.

205. *Id.* § 4.2, at 16.

206. *Id.* § 7.2, at 19.

207. *Id.* § 7.3, at 19.

208. *Id.* § 7.4, at 19.

209. *Id.*

payments to sales personnel.[210] Unless specifically requested by authorities within an individual nation, company representatives are barred from direct contact with consumers through "educational" functions.[211]

Article 9 applies the minimum information requirements contained in article 4[212] to all product labeling, by requiring that a "clear, conspicuous, and easily readable and understandable" version of those same notices accompanies each container of formula.[213]

Article 10 is the only section of the Code dealing with the product itself. It refers to the standards of the Codex Alimentarius Commission as parameters for evaluating the composition of infant food products.[214]

Article 11, the final article of the Code, contains recommendations for implementing and monitoring the Code. It gives primary responsibility in these areas to the individual governments and encourages them to cooperate with WHO and other UN agencies.[215] This article also allocates responsibility to formula manufacturers, distributors, nongovernmental oganizations, and professional groups.[216] The Code concludes by requesting that each member state report annually to WHO's Director General regarding the Code's implementation and prepare a biennial summary of these reports on behalf of the World Health Assembly.[217]

3. *Legal Implications of the Infant Formula Code*

The Executive Board of WHO advised adoption of the Infant Formula Code as a recommendation rather than as a binding regulation.[218] The drafters reasoned that the "moral force of a unanimous recommendation" would be more useful than the passage of a regulation, which because of its binding nature would garner

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210. *Id.* § 8.1.
211. *Id.* § 8.2, at 19-20.
212. *See supra* note 197.
213. World Health Organization Code, *supra* note 6, § 9.2, at 20.
214. *Id.* § 10.2, at 21.
215. *Id.* § 11.1.
216. *Id.* §§ 11.2-.5, at 22.
217. *Id.* §§ 11.6-.7.
218. Introductory statement by the representative of the Executive Board to the 34th World Health Assembly on the Subject of the Draft International Code of Marketing of Breast-Milk Substitutes, May 20, 1981, *reprinted in id.* annex 3 at 32.

fewer votes in the World Health Assembly.[219] The Executive Board's "plea for consensus"[220] underscores the leading issue surrounding this and similar codes: the extent to which these codes affect legal relationships and duties despite their nonbinding nature.

Codes of conduct for international commercial behavior have recently increased in number and scope.[221] The development of these codes can be traced, most recently, to efforts by the "Group of 77"[222] to conform global economic relationships to a "new international economic order."[223]

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219. *Id., reprinted at* 35.

220. *Id.*

221. While codes of conduct are now developed primarily within the United Nations, such codes have been produced by other international organizations. *E.g.*, INTERNATIONAL CHAMBER OF COMMERCE, GUIDELINES FOR INTERNATIONAL INVESTMENT (1972). The United Nations agencies have given birth to a number of such codes. At its second session, the Commission on Transnational Corporations organized an Intergovernmental Working Group on a Code of Conduct for Transnational Corporations. 61 U.N. ESCOR Supp. (No. 5), ¶¶ 10-17, U.N. Doc. E/C 10/16 (1977). The United Nations Conference for Trade and Development (UNCTAD) has proposed two major codes of conduct. The most recent, a draft code on restrictive business practices, has been said to contain "an obvious bias against the behavior of developed nations' enterprises . . . ." *ABA Antitrust Section, International Trade Committee, Report on the Proposed UNCTAD Code on Restrictive Business Practices,* 49 ANTITRUST L.J. 399, 402 (1980) [hereinafter cited as *ABA Antitrust Section*]. UNCTAD has also conducted a major portion of the work on a Code of Conduct on the Transfer of Technology. *See* United Nations Conference for Trade and Development, U.N. Doc. TC/CODE TOT/33 (1981). *See generally Symposium: Transnational Technology: Current Problems and Solutions for the Corporate Practitioner,* 14 VAND. J. OF TRANSNAT'L L. 249 (1981) (analyzing select aspects of the technology transfer process).

222. The "Group of 77" coalesced in 1974 at the first session of UNCTAD in Geneva. The bloc currently includes approximately 120 countries and has been identified as the "south," or the "less developed countries." Joyner, *U.N. General Assembly Resolutions and International Law: Rethinking the Contemporary Dynamics of Norm-Creation,* 11 CAL. W. INT'L L. REV. 445, 445-46 & n.1 (1981).

223. The "new international order" proclaims the duties owed by developed nations to their less developed counterparts and demands redistribution of the economic wealth of the world in favor of less developed nations. *See* Fatouros, *The International Law of the New International Economic Order: Problems and Challenges for the United States,* 17 WILLAMETTE L. REV. 93 (1980). Its arguments often echo those used by promoters of affirmative action within the United States. *Id.* at 100. The program aims to enhance control by developing nations over their own economies, encourage indigenous economic development, create an international system of assistance to those countries, and promote

That which is nonbinding, however, cannot give rise to legal liability such as claims for damages or judicial remedies.[224] Developing nations argue that mere guidelines cannot satisfy their needs. This position stems from apprehension about the preeminence of multinational enterprises in the world economy[225] and an appreciation of the barriers standing between the status quo and increased corporate regulation in the Third World. As might be expected, industrialized countries generally regard the multinational corporation as a positive force in world economic development.[226] These nations are thus of the opinion that the Code and others like it should serve only as ethical guidelines without creating legal rights or obligations for states or commercial enterprises.[227]

It cannot be denied that the moral suasion of the Code, backed by an almost unanimous consensus, has significant impact. This unanimity also indicates the possibility that the Code may become customary international law.[228] Analysis of any code of con-

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preferential, nonreciprocal treatment for those nations in matters of international trade. *See* Declaration of the Establishment of a New International Economic Order, G.A. Res. 3201, U.N. GAOR Supp. (No. 1) (6th Special Sess.) at 3, U.N. Doc. A/9559 (1974); Programme of Action on the Establishment of a New International Economic Order, G.A. Res. 3202, U.N. GAOR Supp. (No. 1) (6th Special Sess.) at 5, U.N. Doc. A/9559 (1974); Charter of Economic Rights and Duties of States, G.A. Res. 3281, 29 U.N. GAOR Supp. (No. 31) at 50, U.N. Doc. A/9631 (1974).

224. Schachter, *The Twilight Existence of Nonbinding International Agreements*, 71 AM. J. INT'L L. 296, 300 (1977). The State Department, pursuant to the Case Act of 1972, 1 U.S.C. § 112(b) (1976), must transmit to Congress all international agreements other than treaties no later than 60 days after their entry into force. The State Department's criteria for defining an international agreement under that Act include a requirement that the parties intend their agreement to be legally binding, beyond any political or moral weight it may carry. Schachter, *supra* at 302 (citing Memorandum by the State Department Legal Advisor, Case Act Procedures and Department of State Criteria for Deciding What Constitutes an International Agreement (Mar. 12, 1976)).

225. Origins of the political assault on multinationals may be traced to more than their role within international business. *See* R. VERNON, STORM OVER THE MULTINATIONALS: THE REAL ISSUES 145-46 (1977).

226. *See Review of the 1976 Declaration and Decisions on International Investment and Multinational Enterprises*, at 5, *reprinted in ABA Antitrust Section*, *supra* note 221, at 412 n.30.

227. Davidow & Chiles, *The United States and the Issue of the Binding or Voluntary Nature of International Codes of Conduct Regarding Restrictive Business Practices*, 72 AM. J. INT'L L. 247, 254 (1978).

228. *See* Joyner, *supra* note 222, at 457.

duct, therefore, should not stop with the conclusion that it must be legally enforceable.[229]

Despite strenuous resistance, a large number of multinational corporations have altered practices and policies under pressures expressed by a "voluntary" code of conduct. The WHO Code is too recent to evaluate in terms of its behavioral effect on corporations. Its precedential value, however, extends far beyond its benefit to the health of young children. Its impact as a voluntary behavior control device has not been overlooked by opponents of the United Nations involvement in the regulation of economic activity.[230]

B. The EEC Sixth Amendment

1. *Provisions*

In 1979 the Council of Ministers of the EEC culminated over twelve years of work by passing the sixth amendment to the 1967 Directive[231] controlling dangerous substances.[232] The sixth

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229. The UNCTAD Intergovernmental Group on the Transfer of Technology, for example, was instructed to draft its code "without prejudice to its legal nature." U.N. Doc. TD/AC 1/4, at 2 (1976); *see* Davidow & Chiles, *supra* note 227, at 249.

230. *See* 81 DEP'T STATE BULL. 255 (1981) (statement by Assistant Secretary Abrams before the Subcommittee on International Operations of the House Foreign Affairs Committee, May 20, 1981); *see also WHO Code Hearings, supra* note 19, at 87.

231. Sixth Amendment, *supra* note 183. 22 O.J. EUR. COMM. (No. L 259) 10 (1979).

232. EEC regulation of dangerous substances began in 1965, with the introduction in the Council of Proposed Directives 179 and 180. *See* Alignment of Rules Concerning Dangerous Substances, European Economic Community Press Release IP (65) 89 (May 12, 1965). Two years later, the Council adopted the substance of those proposals into the 1967 Directive. This Directive based upon broad provisions of the Treaty of Rome dealing with worker safety (articles 2 and 117) and barriers to trade (article 101). *See* Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11, 15, 54, 61 [hereinafter Treaty of Rome]. The 1967 Directive was comparatively limited in its scope. It excluded all preparations, i.e. mixtures of two or more substances, 10 O.J. EUR. COMM. (No. L 196) 10 (1967) (preamble), and exports to non-EEC countries. *Id.* art. 1, para. 3. Implementation of the 1967 Directive took four years, and it still lacked the compliance of Ireland and Luxembourg as of 1978. European Report No. 566: Internal Market 5 (Dec. 9, 1978). From 1972 until 1979, a number of directives were issued concerning such specific areas as solvents, certain technical standards, national environmental legislation, damages from pollution, and revisions in the 1967 Directive's wording. *See* Recent Development,

amendment revises the scope, notification, packaging requirements, and implementation provisions of the Directive to more effectively regulate and collect information on the problems of trading hazardous substances.[233]

The scope of the amended Directive includes all chemicals manufactured within EEC states and intended for export to foreign nations.[234] Exempt from the Directive are medicinal products, narcotics and radioactive substances, transport of substances by common carrier,[235] certain aerosols, explosives,[236] foodstuffs, waste substances, and materials in transit which are under custom supervision.[237]

The amended Directive's definition of "substances" expands the scope of the 1967 Directive. "Substances" now includes chemical elements and compounds in either a manufactured or natural state.[238] Furthermore, added to the existing classes are carcinogens, teratogens, mutagens, very toxic substances, extremely flammable substances, and substances dangerous to the environment.[239]

A broad "grandfather" provision effectively limits the premarket notification provisions for substances which entered the market after September 18, 1981.[240] The notification process mandates that at least forty-five days before introducing a new substance into the market, the manufacturer must submit to an

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The Sixth Amendment: Toxic Substance Control in the EEC, 12 LAW & POL'Y IN INT'L BUS. 461, 466-70 (1980).

233. *See infra* text accompanying notes 241-51.

234. *Compare* 100 O.J. EUR. COMM. (No. L 196) 1 (1967) (preamble) ("to protect man and the environment against potential risks which could arise from the placing on the market of new dangerous substances") *with* the purposes expressed by NEPA, *supra* note 159. The preamble also outlines the amendment's subsequent methodology.

235. 22 O.J. EUR. COMM. (No. L 259) 10 (1979) (art. 1).

236. *Id.* art. 1, paras. 3, 4.

237. *Id.* art. 1, para. 2; *see* Council Directive of 20 March 1978 21 O.J. EUR. COMM. (No. L 84) 43 (1978) (toxic and dangerous waste); Council Directive of 15 July 1975, 18 O.J. EUR. COMM. (No. L 194) 39 (1975) (waste).

238. 22 O.J. EUR. COMM. (No. L 259) 10 (1979) arts. 1-2, para. 1(c)-(e).

239. *Id.* art. 2, para. 2(e),(f),(k)-(n). Briefly, carcinogenic chemicals cause cancer, mutagens induce inheritable changes in genetic material, and teratogens induce non-transmittable birth defects.

240. *Id.* art. 5, para. 2. Notification procedures apply to substances, even those combined in "preparations," but not to preparations themselves. *See id.* art. 5, para. 1; *see also id.* arts. 6-8.

EEC member state a proposed classification, labeling, and analysis of the substance's adverse effects, precautions needed, and other technical information.[241] The member state receiving notification must forward a copy of that information and any related studies to the commission[242] for distribution to all of the member states for examination. The originating member state has forty-five days to oppose the marketing of that substance.[243] Article 8 exempts from the notification provision small amounts of substances which are to be used only for market or laboratory research[244] and certain other specific compounds.[245]

Article 7 requires each member state to appoint "competent authority" to examine new substance applications.[246] Redundant testing is avoided by providing that approval by one member state constitutes approval in each member state.[247] Each authority has some discretion in requesting either additional test data from the manufacturer, or changes in classification or labeling through the Technical Adaptation Committee.[248] The competent authority in each state may, as provided by article 7, make suggestions concerning that substance to the originating state. Disagreement between any two member states on such points may be resolved by the Commission.[249] This system of cross-checks largely eliminates any incentive for producers to "forum shop" for lenient authorities.

Classification and packaging requirements are set out in articles 13 through 18. Regardless of whether a substance is classified as "old" or "new,"[250] if a manufacturer improperly classifies, packages, or labels a substance it will be banned from the market, despite an exemption from the notification procedures.[251]

Implementation provisions, articles 20, 21, and 22, provide that no member state may restrict from its home market any dangerous substance once it has fulfilled the requirements of the amend-

241. *Id.* art. 6, at 12 (quoting Dr. Louis Slesin).
242. *Id.* art. 9.
243. *Id.* art. 6.
244. *Id.* art. 8, para. 1.
245. *Id.*
246. *Id.* art. 7, para. 1.
247. *Id.* art. 22.
248. *Id.* art. 7, paras. 1, 2.
249. *Id.* art. 10, para. 2.
250. *Id.* art. 13, para. 2; *see supra* note 240.
251. *Id.* arts. 15-18.

ment.[252] This provision thus eliminates some nontariff trade barriers.

2. *The Sixth Amendment's Implications for Export Regulation*

The United States passage of TOSCA[253] in 1976 presented a potentially difficult trade barrier to the EEC, and encouraged the EEC to negotiate with the EPA.[254] European manufacturers were fearful that TOSCA would become the model for a variety of national hazardous substance laws within the European Community.[255] Conflicts between the EPA and the EEC in both scientific[256] and legal circles[257] confront both parties with a need for

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252. *Id.* arts. 20-22.

253. *See supra* note 116.

254. European Report No. 493: Business Brief, at 1 (Mar. 18, 1978). The EEC and United States shares of the $122.5 billion world chemical market in 1979 were, respectively, just over half for the EEC, and 14% for the United States. Harrison, *Toxic Substances Legislation,* BUS. EUR. May-June 1981, at 11.

255. The coverage of TOSCA is more complete. It does not exempt any "old" chemicals as does the sixth amendment. 15 U.S.C. § 2607 (b) (1976) (inventory of existing chemicals). TOSCA, however, requires manufacturer testing only when the EPA has determined that the product may present an unreasonable risk of injury to humans or the environment, and that existing data is inadequate. *Id.* § 2603(a). TOSCA's premarket notification provision, *id.,* § 2604, only requires a relatively simple summary of information from manufacturers, which is estimated by the EPA to cost between $1200 and $8900 per chemical. *Id.* § 2604; *see* Recent Development, *supra* note 232, at 494. In contrast, costs for EEC premarket compliance may run as high as $55,000 per substance. *See EEC's Toxic Watch,* ECONOMIST, July 21, 1979, at 78. The EPA's pre-manufacturing notices have been termed "a joke" because such notices lack significant test data. Harrison, *supra* note 254, at 12 (quoting Dr. Louis Slesin).

256. Contrasting approaches to gathering information present an obvious difference. The United States has argued that the sixth amendment's strict requirements lead to inadequate testing of some chemicals and unnecessary testing of others. *See* [1979 Current Reports] INT'L ENVIR. REP. (BNA) at 885. Establishment of standard "good laboratory practices," which the United States has advocated, is also a controversial point. *Id.*

257. The gap between EEC and EPA understandings of negotiation technique is illustrative. When EEC representatives in the United States have proposed off-the-record discussions at meals or parties, EPA spokesmen have had to inform them that "[although] it doesn't engender good relations if we say we can't talk to you about some things . . . we are very, very sensitive to . . . the risk of the entire rulemaking being invalidated or remanded." Transcript of Proceedings, EPA/European Community Discussions on Toxic Substances in Wash-

harmonization. Although both the EEC nations and the United States, as members of OECD, are under some pressure to reach a satisfactory arrangement,[258] the current conclusion, at least within the chemical industry, is that "[t]hings are in substantial disarray."[259]

A common ground may be found, however, in the EEC's sixth amendment approach and that offered by NEPA[260] and Executive Order 12,114.[261] All emphasize an in-depth review of potential environmental impacts, although sharply limited in scope. Both the EEC and NEPA, although covering entirely different subjects, achieve some certainty in warning of threats to persons and the environment, without sacrificing room for flexibility in decision making. Multilateral participation in such a system of information exchange and processing could provide a scientifically workable and politically acceptable conduit between developed nations concerning potentially hazardous merchandise exports. This type of system may, if applied to both those nations and to the Third World, avoid the tensions engendered by more rigid strategies such as the WHO infant formula code. Loss of the certainty inherent in a code of conduct may be offset by the broader cooperation encouraged by a less stringent approach.

C. United Nations Information Exchange Systems

1. *Introduction*

A multilateral system of information exchange mitigates the problems of exporting potentially hazardous merchandise. An informal method of information exchange has been adopted by the Organization for Economic Cooperation and Development (OECD).[262] There are, however, inherent inadequacies in both

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ington, D.C., at 88-90 (Sept. 25, 1979).

258. *See infra* note 262.

259. Harrison, *supra* note 254, at 12 (quoting George S. Dominguez, director of government relations CIBA-Geigy Corporation).

260. *See supra* note 159.

261. *See supra* text accompanying notes 158-73.

262. The OECD was established in 1960. Its current membership includes Australia, Austria, Belgium, Canada, Denmark, Finland, France, the Federal Republic of Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States. Within those member states the non-Communist world's twenty largest chemical manufacturing concerns are

major multilateral conventions. Both the OECD and the EEC agreements have no legal impact beyond their signatories. Furthermore, because both agreements have been formed by nations that produce and export such products,[263] any beneficial impact will be largely confined to those nations.

Left with the shortcomings of the industrialized nations' unilateral and multilateral approaches,[264] developing countries lack safeguards against an enormous quantity of imported chemicals, consumer products, pesticides, pharmaceuticals, and agricultural products. Developing countries have thus relied upon the United Nations for a solution. United Nations actions, such as the WHO infant formula code, lack formal sanctions yet achieve highly desirable moral and political milestones for the Third World. The

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based. *See* OECD, Chemical Assessment, *supra* note 184, at 8. The OECD's approach to the problem of hazardous products is multifaceted. In 1969, it created a Committee on Consumer Policy (CCP), a voluntary system for product safety information exchange. The CCP has been a means of hazard notification for chain saws, asbestos, toys, and other children's products. The CCP contemplates extension to such products as automobiles. Moreover, a refinement of the current system, and the incorporation of an export notification system is expected. *1980 Hearings on Hazardous Products, supra* note 1, at 95 (statement of Susan B. King, Chairman, Consumer Product Safety Commission). In 1974 the OECD Environment Committee recommended development of a comprehensive system for data exchange regarding manufacture, import, and sales of chemicals. OECD Council Recommendation, The Assessment of the Potential Environmental Effects of Chemicals, *reprinted in* Organization for Economic Cooperation and Development, OECD AND THE ENVIRONMENT 37 (1976). Following this recommendation, the OECD Chemicals Groups has considered a set of draft "guidelines" in an attempt to coordinate disparate approaches of member states. *See* Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment, OECD Doc. ENV/CHEM./76.13 Rev. (1976). The OECD goal is a maximum of information exchange with a minimum of regulatory burden, stressing concerns such as the manufacturer's need to protect trade secrets. *See* The International Control of Chemicals Within the OECD Context, OECD Doc. ENV/CHEM 79.22 (1979).

263. In 1972 the Third World imported approximately $7.75 billion worth of chemicals from OECD member nations. OECD, CHEMICAL ASSESSMENT, *supra* note 178, at 9.

264. Bilateral agreements have been common among developed nations for promoting cooperation and reducing each party's testing costs. These arrangements are primarily of use to major producing or importing nations, and may focus on rather specialized concerns. *E.g.,* UNITED STATES FOOD AND DRUG ADMINISTRATION, INTERNATIONAL ACTIVITIES: A SITUATIONAL ANALYSIS 60 (1976) (agreement between the United States and Brazil pertaining to the sanitary quality of chocolate liqueur imports).

United Nations has also been the forum for passage of coordinated information exchange systems. This sharing of information treads much more lightly upon the political and commercial toes of industrialized nations than do the extensive demands of items akin to the WHO infant formula code.[265] Too often, however, the

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265. United States opponents of the World Health Organization Code, *supra* note 7, have repeatedly, although vaguely, raised the spectre of antitrust and first amendment violations implicit in this nation's possible approval of the Code. *E.g., 1981 WHO Code Hearings, supra* note 19, at 39, 86 (testimony of former Senator Sam Ervin, lobbyist for the Grocery Manufacturers Association). It has also been viewed as part of an attempt to "legitimize attempts by the Soviet bloc and its allies to control the flow of information." 81 DEP'T ST. BULL. 54 (1981) (statement by M. Peter McPherson, Administrator, Agency for International Development). A closer analysis of the Code reveals, however, little basis for the legal, if not political, allegations. *See* Letter from William F. Baxter, Assistant Attorney General, Antitrust Division, U.S. Department of Justice to Juan Del Real, Acting General Counsel, Department of Health and Human Services (April 8, 1981), *reprinted in 1981 WHO Code Hearings, supra* note 19, at 66. First, the Code is entirely voluntary under the WHO constitution. *See supra* text accompanying notes 18-21. Moreover, the Department of Justice concluded that the Code's "potentially broad or otherwise ambiguous terms . . . make it difficult to assess the seriousness of these [antitrust and first amendment] questions; this would turn on just how the Code is interpreted and how and by whom it is implemented." *1981 WHO Code Hearings, supra* note 19, at 67. Given this latitude for expression, and the Code's emphasis on implementation "appropriate to [each nation's] social and legislative framework," the Department of Justice determined that the United States could vote for its approval. *See also* 22 U.S.C. § 290(d) (1976) (United States Government does not commit itself to any WHO policies or practices).

In terms of the Code's antitrust implications, article 11.2 of the Code encourages manufacturers and other groups to carry out its measures; therefore suggesting the antitrust pitfall of concerted action. This obvious implication would likely be avoided assidously by United States firms within their "social and legislative framework." Code-approved functions by foreign nations should not, according to the Code's own scheme, run afoul of United States antitrust laws. That plan calls for enactment of national legislation towards the Code's ends. Current concepts of sovereign immunity in this country dictate judicial avoidance of such sovereign enactments so clearly lacking in any commercial overtones. *See* International Ass'n of Machinist & Aerospace Workers v. OPEC, 1979-2 T. Cas. (CCH) ¶ 62,868 (C.D. Cal. Oct. 3, 1979), (construing the Foreign Sovereign Immunities Act, 28 U.S.C. §§ 1602, 1604 (1976)). Judicial application of the Act of State doctrine to the question of the extraterritorial reach of domestic antitrust laws would reinforce this conclusion. *See* Timberlane Lumber Co. v. Bank of America, 549 F.2d 597 (9th Cir. 1976). First amendment issues are raised by the Code's extensive restriction of advertising. While this "commercial speech" is a protected right, *see* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976); Bigelow v. Virginia,

less developed nations are unprepared to use the data given to them unless it is in a highly digested form.[266] Their concern, however, is evidenced by the increase in the number of developing countries which have established governmental agencies to deal with questions of environmental management from 11 in 1972 to 102 in 1980.[267]

This Note will review two of the more established and potentially far reaching informational structures[268] established by the United Nations: the World Health Organization and the International Register of Potentially Toxic Compounds (IRPTC).

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421 U.S. 809 (1975), it is not free from governmental regulation. *See* Pittsburgh Press Co. v. Pittsburgh Comm. on Human Relations, 413 U.S. 376 (1973). Current restrictions on the advertising of distilled alcohol and tobacco products on television provide distinct examples of advertising restrictions reasonably calculated to serve a public need, and thereby valid. Finally, it should be noted that all first amendment objections pertain solely to the question of congressional enactment of the Code, not to issues surrounding a positive United States vote on the Code resolution.

266. *See supra* note 4.

267. 1981 Report on Information Exchange, *supra* note 4, at 3.

268. Such agencies include:

1. The United Nations Environment Program (UNEP), which has undertaken development of the Earthwatch system to provide warnings of environmental risks. Earthwatch is composed of the Global Environmental Monitoring System, the International Referral Service, and the IRPTC. Alston, *International Regulation of Toxic Chemicals*, 7 ECOLOGY L.Q. 397, 411-12 (1978). UNEP also manages INFOTERRA, an access center for over 8500 sources of environmental data from 112 countries. 1981 Report on Information Exchange, *supra* note 4, at 15.

2. The Codex Alimentarius Commission, established in 1964, implements the Joint Food and Agriculture Organization/WHO Food Standards Program. Standards concerning pesticide hazard differentiation have been set for 46 chemicals. *Id.* at 17.

3. The International Labor Organization (ILO) has established the International Occupational Safety and Health Hazard Alert System for rapid dispersal of information on occupational hazards via 97 nationally designated entities, and as of 1981 had issued five such alerts. *Id.* at 15. The ILO also maintains a computerized data base of published material on occupational safety matters. *Id.* at 16.

4. The International Agency for Research on Cancer, a component of WHO, has attempted to coordinate international efforts in cancer research. The IARC published monographs contain its independently formulated scientific opinions, chiefly in the field of environmental carcinogenesis. Alston, *supra* at 416.

2. *The World Health Organization*

In 1962 the World Health Organization undertook the task of investigating techniques for establishing standards for clinical and pharmacological evaluation of drugs, promoting regular exchange of information about the safety and efficacy of drugs, and securing prompt transmission to national health authorities of new information concerning serious side effects of drugs.[269] Since that time, the WHO has issued reports on various principles of toxicological testing and assessment of bioavailability, mutagenicity, and carcinogenicity.[270] The WHO also has established the International Drug Monitoring Program, the Drug Information Circulars and Bulletin, and its Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[271]

The International Drug Monitoring Program, based in Uppsala, Sweden, aids in the early detection and reporting of suspected adverse drug reactions.[272] This program provides an inherent advantage over any single national monitoring system, in that the sample population for detection of uncommon post-clinical reactions can be tremendously expanded. In 1981 twenty-two countries were participating in the program.[273] More than 140,000 reports have been filed, a figure increasing by approximately 2000 each month.[274]

In 1963 the World Health Assembly (WHA) requested member states to convey to the WHO notice of any legal actions taken concerning a drug—decisions to deny or restrict approval of new drugs or limit the availability of ones already in use.[275] Currently, the WHO Drug Information Circulars convey notices about regulatory actions taken with regard to internationally available products.[276] The quarterly Drug Information Bulletin consists of an

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269. Economic and Social Council, Report of the Secretary-General, Annex II (Preliminary list item 12) at 1L, U.N. Doc. A/36/255 (1981) [hereinafter cited as ECOSOC Report].

270. *Id.*

271. *Id.*

272. *Id.* at 1-2.

273. *Id.* at 1.

274. *Id.*

275. World Health Assembly, Res. 16.36 (1963), *reprinted in* 1 WORLD HEALTH ORGANIZATION, HANDBOOK OF RESOLUTIONS AND DECISIONS OF THE WORLD HEALTH ASSEMBLY AND THE EXECUTIVE BOARD 139 (cumulative ed. 1973).

276. ECOSOC Report, *supra* note 269, Annex II, at 3. *See also 1978 Hear-*

edited commentary on the actions reported in the Circulars.[277]

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (WHO Certification Scheme) tries to overcome the disparity in national quality control procedures by documenting the export of drugs falling short of the exporter's domestically imposed standards.[278] Adopted in 1975,[279] the WHO Certification Scheme now enrolls fifty-four countries through designated national authorities.[280] Those authorities are responsible for certifying, upon request of an interested state, whether the export in question is sold on the domestic market, and whether quality control procedures used by its manufacturer accord with the standards recommended by WHO.[281] A participating state must ensure that its pharmaceutical industry utilizes appropriate testing measures and manufacturing practices.[282]

3. *The International Register of Potentially Toxic Compounds*

The International Register of Potentially Toxic Compounds (IRPTC), was initiated in 1972 at the United Nations Conference on the Human Environment.[283] The IRPTC was integrated into Earthwatch in 1976.[284] Its capabilities were reinforced in 1978 through finalization of UNEP's outline for a system of national

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ings on Banned Products, supra note 4, at 115-31.

277. ECOSOC Report, *supra* 269, Annex II, at 3 (the FDA informed the WHO as to changes in notice requirements and approval for the following four drugs: doramphenicol, phenformin, azaribine and diethylstilbestrol).

278. *Id.* at 2.

279. World Health Assembly, Res. 28.65 (1975), *reprinted in* 2 HANDBOOK OF RESOLUTIONS AND DECISIONS OF THE WORLD HEALTH ASSEMBLY AND THE EXECUTIVE BOARD 77 (4th ed. 1981).

280. ECOSOC Report, *supra* note 269, Annex II, at 2.

281. *Id.*

282. *Id.* Annex III, at 3.

283. The IRPTC is to encompass "a collection of available scientific data on the environmental behavior of the most important man-made chemicals and . . . production figures of the potentially most harmful . . . together with their pathways from factory via utilization to ultimate disposal or recirculation." Report of the U.N. Conference on the Human Environment, Stockholm, chap. II, recommendation 74, subpara. (e), U.N. Sales No. E.73.II.A.14 (1972).

284. ECOSOC Report, *supra* note 269, Annex I at 1. *See supra* note 268 for an explanation of Earthwatch.

correspondents,[285] workshops,[286] and information access systems. The IRPTC performs its duties by a number of mechanisms:

(1) Compiling data profiles for chemical production, use, environmental pathways, toxicity, and treatment of chemical poisoning.[287]

(2) Assembling legal data profiles, which review legal and administrative restrictions imposed in the manufacturing country on potentially toxic compounds.[288] This profile has thus far published national and international recommendations for the control of approximately 200 chemicals selected from the IRPTC's working list of priority chemicals.[289]

(3) The IRPTC Data Register consists of a global network of correspondents for the purpose of data collection and exchange of information about an extensive number of chemicals.[290] The IRPTC is presently in the process of completing data profiles for only a limited number of chemicals, with special attention to those hazards reported by developing countries.[291] As of 1981, the Register covered 350 chemicals, including 160 used in agriculture.[292]

(4) The IRPTC Query-Response Service is backed by computerized bibliographic files and other references[293] and, when necessary, the resources of WHO, the International Occupational Safety and Health Information Centre of ILO,[294] and IRPTC's national correspondents. Since 1976 the service has dealt with questions from United Nations agencies, governments, industry, and in-

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285. As of 1981, 89 countries had appointed national correspondents. IRPTC staff members regularly visit those correspondents to coordinate efforts within IRPTC and development of similar national registers. ECOSOC Report, *supra* note 269, Annex I, at 4.

286. *See, e.g.*, Report of the Workshop for National Correspondents in Asia and Pacific Region WS/AP/18 (Aug. 1-3, 1979).

287. ECOSOC Report, *supra* note 269, Annex I, at 3.

288. *Id.* The Legal Data Profiles are part of the whole Data Profile system.

289. *Id.; see supra* text accompanying note 287.

290. ECOSOC Report, *supra* note 269, Annex I, at 3.

291. *Id.*

292. *Id.*

293. *Id.* at 4.

294. *See supra* note 268 for an explanation of the ILO's functions.

dividuals on a wide range of technical matters.[295]

V. CONCLUSION

The dangers posed by exports of potentially hazardous merchandise will continue to accelerate. United States and world exports of chemicals, consumer products, pesticides, and drugs continue to increase at significant rates.[296] Rapid population growth, particularly in developing nations, drains natural resources and increases demand for these hazardous products. Continued discoveries of toxic properties in existing chemicals and innovation of new products and substances[297] increases the difficulties faced by the unprepared consumer.

Multinational information exchange systems offer one workable solution. Sufficiently broad information systems are difficult to create, and cumbersome to manage.[298] Producers are often reticent to provide data and may prefer to settle product safety questions by voluntary agreement with the producer's government rather than through widely publicized multinational enactments. Disparate international technical standards and the varying quality of test data results in government reluctance to accept results of foreign analysis.[299] The scope of the potentially hazardous merchandise problem demands efforts to launch and to maintain more uniform, long-term approaches.

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295. ECOSOC Report, *supra* note 269, Annex I, at 4.

296. *See* HSEP Report, *supra* note 3, at 7808 (United States total exports were $62.5 billion in 1970 or 6.4% of GNP. By 1978, those figures were $205 billion and 9.7% respectively); OECD Chemical Assessment, *supra* note 814, ¶ 7 (world consumption and production of chemicals grew 9.5% per year in volume from 1962 to 1972).

297. It has been estimated that there are about 3.5 million known chemical compounds. UNITED STATES COUNCIL ON ENVIRONMENTAL QUALITY, SEVENTH ANNUAL REPORT 29 (1976).

298. The Codex Alimentarius Commission illustrates this point. Since its establishment in 1967 it has enlisted 114 member states. It has proposed 130 international food standards, some 900 international pesticide residue tolerances, and 14 international codes of practice. Despite its flexible provisions for national acceptance, by 1976 only 47 countries had either fully or with qualifications accepted a number of the food standards, and only 25 had so committed themselves to several pesticide standards. G. Kermode, *International Aspects of the Codex Alimentarius* 3 (paper presented at seminar on U.S. Codex Alimentarius, Washington, D.C. Aug. 2-3, 1976), *cited in* Alston, *supra* note 268, at 433.

299. *Cf.* Ragolia, *The FDA's Acceptance of Foreign Clinical Data,* 30 FOOD, DRUG & COSMETICS L.J. 433, 434 (1975).

No nation can accurately predict the costs and benefits of a new product in a geographically and socially remote nation. Unilateral government action is more likely to result in a paternalistic imposition of policies and preferences of that nation upon the importing nation's consumers. An international system for exchange of technical and regulatory information does hold promise of political, administrative, and technical survival, although the current fragmented approach is inefficient. Public awareness of the responsibility of producing nations and the slowly increasing information handling capabilities of the developing nations may, however, portend greater recourse to these systems.

Eric Shuman