32 ELR 11018 9-2002

ELR
NEWS & ANALYSIS

Preventing Pollution? U.S. Toxic Chemicals and Pesticides Policies and Sustainable Development

by Lynn R. Goldman

Introduction

This Article considers the extent to which the United States has made progress in the management of chemicals and pesticides in light of the commitments it made in 1992 to promote sustainable development. While pesticides are types of chemicals, they are managed differently and this Article will employ the legal distinctions between the two. The term "chemicals" refers to substances that are manufactured, processed, or used in commerce, other than those marketed as pesticides, pharmaceuticals, or food additives. Thus, the term includes a wide spectrum of substances, including metals and both organic and inorganic chemicals. "Pesticides," on the other hand, means substances that are marketed as having the ability to kill or repel "pests," chemicals such as insecticides, fungicides (kill molds and fungi), herbicides (weed killers), and rodenticides (rat killers). This Article encompasses environmental management efforts to directly regulate chemicals, promote "right-to-know," encourage pollution prevention, and regulate pesticides. In addition, it examines several cross-cutting issues: persistent organic pollutants (POPs) or, as they are sometimes called in the United States, persistent bioaccumulating toxics (PBTs), and biotechnology (genetically modified organisms (GMOs) that manufacture chemicals or are used as chemicals). It does not, however, address efforts to set standards for chemicals as pollutants in the context of the regulation of air and water pollution and in the case of waste disposal.

The basic structure of the domestic laws of the United States with respect to chemicals was established in 1972 for pesticides (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA))[1] and in 1976 for industrial chemicals (Toxic Substances Control Act (TSCA)).[2] In the face of widespread concern about the proliferation of chemicals and pesticides in commerce, and the unknown risks, the U.S. Congress had given the U.S. Environmental Protection Agency (EPA) authority over testing of chemicals and pesticides, review of new introductions, and assessment and management of risks of existing chemicals. In 1988, Congress had amended and strengthened FIFRA. In 1986, it enacted the Emergency Planning and Community Right-To-Know Act (EPCRA),[3] thereby establishing the toxic release inventory (TRI) for tracking the releases and transfers of chemicals from industry. In 1990, it adopted the Pollution Prevention Act (PPA).[4] Together, these four statutes form the legal framework for regulation of chemicals and pesticides in the United States.

In 1992, at the Rio Summit, our country made a number of commitments to go beyond existing statutory requirements. By agreeing to the Rio Declaration on Environment and Development,[5] the United States agreed to incorporate the precautionary principle in environmental policy. As part of Agenda 21,[6] the United States committed to implementation of Chapter 19, Sound Management of Chemicals, which laid out a number of very specific goals for the year 2000. In addition, Chapter 14 of Agenda 21 deals with pest management in the context of sustainable agriculture.

This Article reviews the policies, principles, objectives, targets, and goals set forth in the Rio Declaration and in Chapters 14 and 19 of Agenda 21. It then summarizes some of the basic features of FIFRA, TSCA, chemical right-to-know, and pollution prevention programs (with particular emphasis on the changes that have occurred since the Rio Summit), and how these relate to aspects of sustainable development. The Article then considers relevant international accords and the extent to which the United States is contributing to their successful implementation.

What are the principles applicable to chemicals and pesticides regulatory policy that would promote the movement toward sustainable development? Five principles are identified that are most relevant to this effort: the precautionary principle, intergenerational equity, control of the trade of hazardous chemicals in commerce, and access to information and integrated decisionmaking. Agenda 21 adopted a number of specific goals for sound management of chemicals, which are described in detail in this Article. In addition, the Intergovernmental Forum on Chemical Safety has iden-

Dr. Goldman (M.D., M.P.H.) is a Professor, Environmental Health Sciences, at The Johns Hopkins University, Bloomberg School of Public Health. She served as Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency, 1993-1998.

[*Editors' Note: In June 1992, at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, the nations of the world formally endorsed the concept of sustainable development and agreed to a plan of action for achieving it. One of those nations was the United States. In August 2002, at the World Summit on Sustainable Development, these nations gathered in Johannesburg to review progress in the 10-year period since UNCED and to identify steps that need to be taken next. Prof. John C. Dernbach has edited a book that assesses progress that the United States has made on sustainable development in the past 10 years and recommends next steps. The book, published by the Environmental Law Institute in July 2002, is comprised of chapters on various subjects by experts from around the country. This Article appears as a chapter in that book. Further information on the book is available at www.eli.org or by calling 1-800-433-5120 or 202-939-3844.*]

1. 7 U.S.C. §§136-136y, ELR Stat. FIFRA §§2-34.
2. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
3. 42 U.S.C. §§11001-11050, ELR Stat. EPCRA §§301-330.
4. *Id.* §§13101-13109, ELR Stat. PPA §§13101-13109.
5. Rio Declaration on Environment and Development, U.N. Conference on Environment and Development (UNCED), U.N. Doc. A/CONF.151/5/Rev. 1, 31 I.L.M. 874 (1992) [hereinafter Rio Declaration].
6. UNCED, Agenda 21, U.N. Doc. A/CONF.151.26 (1992) [hereinafter Agenda 21].

tified a number of areas for future work. In a nutshell, countries have agreed that it is necessary to more thoroughly assess the hazards of chemicals in commerce, develop an international system of classification and labeling of chemicals, implement a procedure for prior informed consent for trade in hazardous chemicals, take a product life-cycle approach to reduce risks to chemicals, minimize public exposure to the most toxic and unmanageable chemicals, and reduce the frequency of accidental releases. In the case of pesticides, this means encouraging the adoption of pest control alternatives that are less toxic and persistent and therefore less likely to harm the environment.

This Article concludes that the United States has, since Rio, made significant progress in moving toward a more sustainable approach to chemicals and pesticides, but still has a long way to go. In the case of chemicals, it is generally agreed that TSCA has fallen short in achieving its original legislative objectives,[7] much less the goals of sustainable development articulated in Agenda 21 (which, of course, did not exist as at the time of enactment). There has been little progress in assessing the hazards of chemicals.[8] The enactment by Congress of legislation requiring the screening and testing of chemicals for endocrine disruptor potential[9] is one bright spot; however, the implementation of that legislation has been slow and uncertain. Certain voluntary information initiatives, such as the high production volume chemical test program with the chemical industry and Environmental Defense and the voluntary children's testing program (phase I) with industry,[10] are promising; however, it remains to be seen whether these efforts will go beyond a mere screening level assessment of chemicals. Moreover, even these small steps have run into opposition from the animal rights movement.

The process of managing chemical risks was bogged down in a cumbersome set of statutory requirements and has not reflected the precautionary principle. The United States has been creative in its use of the limited tools provided by TSCA and has devised new approaches such as design for environment, which show promise to encourage the replacement of more risky chemicals with more benign ones. TSCA has not proven to be a successful tool for managing existing chemicals; indeed, it has created a situation in which new chemicals, which may be more benign, are subject to substantially more risk management activities and reviews than older and possibly more risky ones (which are not managed at all). Likewise, the TSCA procedure of referring chemicals to other EPA programs or agencies for risk management has not been effective.

In 1992, Congress amended TSCA to specifically regulate lead in housing.[11] EPA did subsequently succeed in putting into place standards for lead in paint, soil, and dust, as well as a framework for inspection and abatement and for notifying families about lead hazards at the time of real estate transactions and during renovation activities.[12] This is a major accomplishment in the area of intergenerational equity and risk reduction.

For new chemicals under TSCA, the United States requires so little information that there is a considerable amount of scientific judgment[13] that is used to assess them; additional test data such as that required in the European Union (EU) is generally not available. Moreover, because the process is invoked during the premanufacture stage, EPA expends the same amount of effort for a chemical that will go into market as for one that never will (thus giving chemicals that are actually introduced into the market an inadequate degree of review). (It has been estimated by EPA that only one-tenth of new chemicals manufactured ever go to market.) Thus, the regulation of new chemicals does not reflect a precautionary approach.

In addition, TSCA has not provided much information for the public on chemicals, mostly because of its overly protective confidential business information (CBI) provisions. To some extent, other laws have filled the breach; the United States has, in fact, enjoyed a degree of international leadership in the area of chemical right-to-know pursuant to EPCRA. In the 1990s, there was a significant expansion in the breadth of the TRI. However, it continues to address only a small slice of the chemicals universe.

The pollution prevention activities under the PPA have promoted a new ethic of source reduction (reducing the use of toxic chemicals at the source). Source reduction is very much aligned with the precautionary principle but also appeals to a "bottom line" financially focused mentality and addresses the principle of integrated decisionmaking.

In the case of pesticides, the outlook is somewhat brighter. Here, EPA has been granted much more authority than for industrial chemicals; it may gather information about pesticides and actively seek to manage their risks. EPA's actions in the 1980s resulted in the termination of use of some of the most persistent and toxic pesticides. However, in 1992, EPA's pesticide program was under fire from all quarters for lack of productivity in reregistering older pesticides, data management problems, and lack of risk re-

7. *See, e.g.*, David Roe, *Toxic Chemical Control Policy: Three Unabsorbed Facts*, 32 ELR 10149 (Feb. 2002).

8. *See* Environmental Defense Fund, Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States ch. V, "Recommendations" (1997) [hereinafter Toxic Ignorance].

9. Passage, in 1996, of the Food Quality Protection Act (FQPA), Pub. L. No. 104-170, 110 Stat. 1489 (1996), and amendments to the Safe Drinking Water Act (SDWA), 42 U.S.C. §300j-17, ELR Stat. SDWA §1457, reflected these concerns and required EPA to "develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effect as the Administrator may designate." 21 U.S.C. §346a(b)(2)(D)(viii). EPA established the Endocrine Disruptors Screening and Testing Advisory Committee; its tasks were to (1) identify, select, and validate both initial and sequential screening mechanisms; (2) develop criteria to decide when more thorough tests are needed; and (3) initiate a flexible process to select and prioritize the pesticides that will undergo initial screening. *See* Endocrine Disruptors, Notice of Public Meeting, 61 Fed. Reg. 60280, 60281 (Nov. 27, 1996). *See also* Pesticide Regulation Deskbook (Envtl. L. Inst. 2001); U.S. EPA, *Endocrine Disruptor Screening Program*, *at* http://www.epa.gov/scipoly/oscpendo/index.htm (last visited Mar. 30, 2002).

10. Both are described in TSCA Deskbook 47 (Envtl. L. Inst. 1999).

11. 15 U.S.C. §§2681-2692, ELR Stat. TSCA §§401-412 (adding Subchapter IV).

12. *See* Claude E. Walker, *The Lead-Based Paint Real Estate Notification and Disclosure Rule*, 8 Buff. Envtl. L.J. 65 (2000); *but see* Clifford Rechtschaffen, *How to Reduce Lead Exposures With One Simple Statute: The Experience of Proposition 65*, 29 ELR 10581 (Oct. 1999) (noting limitations of federal authority).

13. EPA largely bases this judgment on evaluation of structure activity relationships, that is, comparing the structure of new chemicals with the structure of existing chemicals with more toxicity information to predict the possible toxicity of new chemicals.

duction capabilities. In 1996, new pesticide legislation enacted by Congress was intended to increase the safety of pesticides for children, and to address cumulative and aggregate risks.[14] Today, the most hazardous pesticides in commerce in the United States are organophosphates, the remaining organochlorines, and a number of pesticides that have been classified as being probable carcinogens. The United States shows some signs of beginning a downturn in its overall use of pesticides, as well as in use of some of the riskiest ones. It remains to be seen, however, whether the strong precautionary and child protective provisions of the pesticide legislation (cumulative and aggregate risk assessment and increased safety for children) will rub off on the regulation of chemicals and influence statutes that regulate chemicals and pesticides as pollutants. While the full impacts of the 1996 legislation are unknown at this time, there already have been major reductions in residential uses of the organophosphates as well as allowable food uses.

In concert with Canada and Mexico, under the United States/Canada Binational Toxics Agreement[15] and the North American Commission on Environmental Cooperation (CEC), the United States has begun to achieve progress in controlling the most persistent and toxic pollutants that have caused harm to the Great Lakes and to developing children. However, due to the limitations of TSCA, other persistent compounds, such as brominated flame retardants, which have not yet been shown to cause extensive damage continue to be used, and there is little evidence that precautionary action is underway.

Under TSCA, the United States has made progress in the regulation of new GMOs.[16] However, it has neglected to put in place a framework for regulating the new GMO plants that are being bred to produce chemicals. Also in the 1990s, EPA moved to regulate genetically modified plants that produce pesticides, the plant incorporated protectants (PIPs), adopting final rules in 2001.[17] However, PIPs already on the market produce challenges in terms of the potential for damage to nontarget species and for allergenicity.

This Article recommends a number of reforms to U.S. chemicals laws in light of the sustainable development objectives of Agenda 21. In particular, it urges that TSCA be amended to place a greater burden on industry to prove the safety of chemicals in commerce, especially those that are most likely to expose sensitive populations and the environment. It calls for a leveling of the playing field between new and existing chemicals, which today perversely creates disincentives for bringing forward new and safer technologies to the market. It calls for an increased use of pollution prevention and right-to-know as environmental policy tools in chemical regulation. For pesticides, it urges a focus on implementation of the Food Quality Protection Act (FQPA)[18] and in strengthening certain other areas, especially with regard to monitoring pesticide uses and levels. It encourages increased enforcement authority as well. For POPs, stronger authority for EPA is recommended. Likewise, a reassessment of authorities to regulate biotechnology, in both the chemical and pesticide contexts, is needed. At the international level, it calls for ratification of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam Convention)[19] and the Convention on Persistent Organic Pollutants,[20] increased assistance for capacity building in developing nations, and accelerated efforts in the area of global harmonization. Finally, it notes some general cross-cutting issues. There is a need to address animal welfare concerns (perhaps by moving to greater use of new in vitro technologies such as genomics and proteomics). There is a lack of information about usage patterns for chemicals and pesticides that needs to be filled. There is an opportunity to transfer the new risk procedures under development for the FQPA (cumulative and aggregate risk assessment and increased safety for children) to chemicals and to other statutes. Last, and not least, is a general recommendation that the United States participate more actively in multilateral efforts in order to assure global chemical safety.

The Rio Declaration, Agenda 21, and What Sustainable Development Means in the Context of Management of Chemicals

What is a sustainable approach to the management of chemicals and pesticides? There are a number of criteria that will be utilized throughout this Article; they are keyed to the principles enunciated in the Rio Declaration as well as to actions that were agreed to in Agenda 21. The principles that would appear to be of greatest relevance are the precautionary principle, intergenerational equity, control of transfer of substances that cause severe environmental degradation or are hazardous to health, access to information and the decisionmaking process, and integrated decisionmaking. In Agenda 21, specific actions are recommended. For pesticides, these are contained in Chapter 14, "Promoting Sustainable Agriculture and Rural Development." The recommendations applicable to chemicals management and regulation are found in Chapter 19, "Sound Management of Chemicals." Progress toward sustainability should be judged not only against the principles, but also against commitments to action.

Rio Declaration

Several principles in the Rio Declaration are of key importance in the context of sound management of chemicals. The first of these is the notion of the precautionary principle. As articulated in the Rio Declaration, "the precautionary approach shall be widely applied by States according to their

14. 21 U.S.C. §346a(b)(2)(C)(ii)(I).

15. U.S. EPA & Environment Canada, Great Lakes Binational Toxics Strategy: Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes (1997) [hereinafter Binational Strategy].

16. *See generally* Biotechnology Deskbook (Envtl. L. Inst. 2002).

17. 66 Fed. Reg. 37772 (July 19, 2001); Biotechnology Deskbook, *supra* note 16, at 36-40.

18. Pub. L. No. 104-170, 110 Stat. 1489 (1996).

19. U.N. Doc. UNEP/FAO/PIC/CONF/5, Annex 3, Sept. 11, 1998. *See also* Prior Informed Consent Rotterdam Convention website, *available at* http://www.pic.int/finale.htm#convention_text_e (last visited Apr. 30, 2002); Jane A. Dwasi, *Regulation of Pesticides in Developing Countries*, 32 ELR 10038, 10058-60 (Jan. 2002) (describing "system for the management of pesticides in international trade," *id*. at 10059, envisioned by the Rotterdam Convention).

20. For background on the development of the Rotterdam Convention, see David P. Fidler, *Challenges to Humanity's Health: The Contributions of International Environmental Law to National and Global Public Health*, 31 ELR 10048, 10069 (Jan. 2001).

capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[21] In the case of chemicals, is has been true internationally (as well as in the United States) that introduction of tens of thousands of chemicals into the market preceded regulation of chemicals.[22] So-called existing chemicals have been presumed safe (grandfathered) under statutory schemes that have required review of new chemicals but not ones already on the market.[23] Adoption of the precautionary principle would imply a duty to take cost-effective measures to reduce environmental degradation without the demand for full scientific certainty. Application of the precautionary principle in the management of chemicals is important to avoid some of the disasters of the past: contamination of the environment by persistent pollutants that cannot be cleaned up and now appear in the food chain and even breast milk; contamination of drinking water supplies by pesticide runoff; cancer and other chronic diseases in workers and communities; depletion of the ozone layer by ozone-depleting substances, and costly and expensive cleanups.

A second principle that is critical to the assessment of chemicals management is that of intergenerational equity. The Rio Declaration states that "[t]he right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations."[24] In the case of chemicals, of particular concern has been the creation of long-term messes that will incur costs to future generations. POPs such as 1,1,1-Trichloro-2,2-bis-(4'-chlorophenyl)ethane (DDT), polychlorinated biphenyls (PCBs), methyl mercury and dioxins have contaminated agricultural and aquatic ecosystems, leaving a legacy of pollution for future generations. Poorly controlled pesticides and solvents have seriously polluted groundwater resources. Lead and other metals have extensively polluted our urban environments. In many cases, these pollutants have toxicities with the greatest likely impact on the next generation, e.g., lead, PCBs, and methyl mercury exposure all are known to be neurotoxic to developing children.

A third principle has to do with the movement of hazardous substances in commerce. As stated in the Rio Declaration, "[s]tates should effectively cooperate to discourage or prevent the relocation and transfer to other States of any activities and substances that cause severe environmental degradation or are found to be harmful to human health."[25] This has obvious implications for the trade in hazardous chemicals. The principle is of critical importance to the United States, because we have learned that pollutants and contaminated foods and products do not necessarily respect political boundaries.

A fourth principle of Rio that is relevant in this context is that of access to information and the decisionmaking process. As articulated in the Rio Declaration:

> At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available.[26]

Thus, access to information about hazardous chemicals and activities in communities has been agreed to be an important element of sustainable development. Shared information and input into decisionmaking is also a key element of any democratic process.[27]

A fifth principle which was endorsed at Rio is that of integrated decisionmaking. The Rio Declaration emphasized that "[i]n order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it."[28] This means that chemical and pesticide manufacturers, exporters, and users should incorporate environmental considerations and results into their decisionmaking process. This is of key importance in the United States, since there are so many business entities that make decisions about chemical manufacture and use.

Agenda 21

Turning to Agenda 21, there are two chapters, Chapter 14 and Chapter 19, that are most relevant to the issue of sustainable management of chemicals and pesticides. In these chapters, governments, including the United States, made commitments to contribute to a number of actions. These commitments were not binding; moreover, it is not always clear what the contribution of the United States (as part of a global effort) was to be. Nevertheless, the provisions of Agenda 21 provide another yardstick by which to measure progress in sustainable development since 1992.

Agenda 21, Chapter 14, "Promoting Sustainable Agriculture and Rural Development," includes program area (i), "Integrated Pest Management and Control in Agriculture." Under this commitment, countries agreed to adopt "mechanisms to control the distribution and use of pesticides, and to implement the International Code of Conduct on the Distribution and Use of Pesticides"[29]; to control and monitor distribution and use of pesticides; and to "encourage research and development into pesticides that are target-specific and readily degrade into harmless constituent parts after use."[30] Governments agreed to cooperate to "consolidate and harmonize existing information and programmes on the use of pesticides that have been banned or severely restricted in

21. Rio Declaration, *supra* note 5, princ. 15. *See* The Precautionary Principle and International Law: The Challenges of Implementation (David Freestone & Elley Hey eds., 1996).

22. *See generally* Michael G. Faure & Jurgen G.J. Lefevere, *An Analysis of Alternative Legal Instruments for the Regulation of Pesticides*, *in* Regulating Chemical Accumulation in the Environment: The Integration of Technology and Economics in Environmental Policymaking 253 (Timothy Swanson & Marco Vighi eds., 1998); Dwasi, *supra* note 19.

23. A good example of a statute that regulates new pesticides but not existing uses is Kenya's Environmental Management and Coordination Act, enacted in 2000 and described in Dwasi, *supra* note 19.

24. Rio Declaration, *supra* note 5, princ. 3.

25. *Id*. princ. 12.

26. *Id*. princ. 10.

27. *See* Carl Bruch & Roman Czebiniak, *Globalizing Environmental Governance: Making the Leap From Regional Initiatives on Transparency, Participation, and Accountability in Environmental Matters*, 32 ELR 10383 (Apr. 2002).

28. Rio Declaration, *supra* note 5, princ. 4; *see also id*. princs. 11, 25.

29. Agenda 21, *supra* note 6, ¶ 14.75(a).

30. *Id*. ¶ 14.76(b).

different countries"[31] and to promote the use of biological control and organic pesticide products.[32]

Agenda 21, Chapter 19, "Environmentally Sound Management of Toxic Chemicals, Including Prevention of Illegal International Traffic in Toxic and Dangerous Products," established an ambitious international agenda for industrial chemicals. Six program areas were established, with a number of specific targets under each area: (1) expanding and accelerating the international assessment of chemical risks[33]; (2) harmonizing classification and labeling of chemicals[34]; (3) increasing information exchange on toxic chemicals and chemical risks[35]; (4) establishing new risk reduction programs[36]; (5) strengthening national capabilities and capacities for management of chemicals[37]; and (6) preventing illegal international traffic in toxic and dangerous products.[38]

31. *Id*. ¶ 14.77(a).

32. *Id*. ¶ 14.77(b).

33. *Id*. ¶ 19.4(a). The specific target was that "[s]everal hundred priority chemicals or groups of chemicals, including major pollutants and contaminants of global significance, should be assessed by the year 2000, using current selection and assessment criteria 500 new international chemical assessments." *Id*. ¶ 19.13(a).

34. *Id*. ¶ 4(b). The target was a globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols, by the year 2000. *Id*. ¶ 19.27.

35. *Id*. ¶ 19.4(c). The target was "[f]ull participation in and implementation of the Prior Informed Consent (PIC) procedure, including possible mandatory applications through legally binding instruments contained in the Amended London Guidelines and in the FAO [Food and Agriculture Organization] International Code of Conduct," *id*. ¶ 19.38(b), by the year 2000. *See* United Nations Environment Program, London Guidelines for the Exchange of Information on Chemicals in International Trade (1989), *available at* http://www.chem.unep.ch/pic/longuien.htm (last visited Mar. 30, 2002).

36. Agenda 21, *supra* note 6, ¶ 19.4(d). The target was a commitment to "eliminate unacceptable or unreasonable risks and, to the extent economically feasible, to reduce risks posed by toxic chemicals, by employing a broad-based approach involving a wide range of risk reduction options and by taking precautionary measures derived from a broad-based life-cycle analysis." *Id*. ¶ 19.48.

    Governments committed to the following activities:

    > "Consider adopting policies based on accepted producer liability principles, where appropriate, as well as precautionary, anticipatory and life-cycle approaches to chemical management, covering manufacturing, trade, transport, use and disposal." *Id*. ¶ 19.49(a);
    > Undertake concerted activities to reduce risks for toxic chemicals, taking into account the entire life cycle of the chemicals. These activities could encompass both regulatory and non-regulatory measures, such as promotion of the use of cleaner products and technologies; emission inventories; product labeling; use limitations; economic incentives; and the phasing out or banning of toxic chemicals that pose an unreasonable and otherwise unmanageable risk to the environment or human health and those that are toxic, persistent and bio-accumulative and whose use cannot be adequately controlled. *Id*. ¶ 19.49(b);
    > Adopt policies and regulatory and non-regulatory measures to identify, and minimize exposure to, toxic chemicals by replacing them with less toxic substitutes and ultimately phasing out the chemicals that pose unreasonable and otherwise unmanageable risk to human health and the environment and those that are toxic, persistent and bio-accumulative and whose use cannot be adequately controlled. *Id*. ¶ 19.49(c);
    > Increase efforts to identify national needs for standard setting and implementation in the context of the FAO/WHO [World Health Organization] Codex Alimentarius in order to minimize adverse effects of chemicals in food. *Id*. ¶ 19.49(d);
    > Develop national policies and adopt the necessary regulatory framework for prevention of accidents, preparedness and response, inter alia, through land-use planning, permit systems and reporting requirements on accidents, and work with the OECD [Organization for Economic Cooperation and Development]/UNEP [United Nations Environment Program] international directory of regional response centers and the APELL program. *Id*. ¶ 19.49(e);
    > Promote establishment and strengthening, as appropriate, of national poison control centers to ensure prompt and adequate diagnosis and treatment of poisonings. *Id*. ¶ 19.49(f);
    > Reduce over dependence on the use of agricultural chemicals through alternative farming practices, integrated pest management and other appropriate means. *Id*. ¶ 19.49(g);
    > Require manufacturers, importers and others handling toxic chemicals to develop, with the cooperation of producers of such chemicals, where applicable, emergency response procedures and preparation of on-site and off-site emergency response plans. *Id*. ¶ 19.49(h); and
    > Identify, assess, reduce and minimize, or eliminate as far as feasible by environmentally sound disposal practices, risks from storage of outdated chemicals. *Id*. ¶ 19.49(i).

    The international community committed to the following activities:

    > Collaborate to develop common criteria to determine which chemicals are suitable candidates for concerted risk reduction activities. *Id*. ¶ 19.52(a);
    > Coordinate concerted risk reduction activities. *Id*. ¶ 19.52(b);
    > Develop guidelines and policies for the disclosure by manufacturers, importers and others using toxic chemicals of toxicity information declaring risks and emergency response arrangements. *Id*. ¶ 19.52(c);
    > Encourage large industrial enterprises including transnational corporations and other enterprises wherever they operate to introduce policies demonstrating the commitment, with reference to the environmentally sound management of toxic chemicals, to adopt standards of operation equivalent to or not less stringent than those existing in the country of origin. *Id*. ¶ 19.52(d);
    > Encourage and support the development and adoption by small- and medium-sized industries of relevant procedures for risk reduction in their activities. *Id*. ¶ 19.52(e);
    > Develop regulatory and non-regulatory measures and procedures aimed at preventing the export of chemicals that are banned, severely restricted, withdrawn or not approved for health or environmental reasons, except when such export has received prior written consent from the importing country or is otherwise in accordance with the PIC procedure. *Id*. ¶ 19.52(f);
    > Encourage national and regional work to harmonize evaluation of pesticides. *Id*. ¶ 19.52(g);
    > Promote and develop mechanisms for the safe production, management and use of dangerous materials, formulating programs to substitute for them safer alternatives, where appropriate. *Id*. ¶ 19.52(h);
    > Formalize networks of emergency response centers. *Id*. ¶ 19.52(i); and
    > Encourage industry, with the help of multilateral cooperation, to phase out as appropriate, and dispose of, any banned chemicals that are still in stock or in use in an environmentally sound manner, including safe reuse, where approved and appropriate. *Id*. ¶ 19.52(j).

37. *Id*. ¶ 19.4(e). Agenda 21 urged that "[b]y the year 2000, national systems for environmentally sound management of chemicals, including legislation and provisions for implementation and enforcement, should be in place in all countries to the extent possible." *Id*. ¶ 19.58.

38. *Id*. ¶ 19.4(f). There were a number of specific targets:

    > To reinforce national capacities to detect and halt any illegal attempt to introduce toxic and dangerous products into the territory of any State, in contravention of national legislation and relevant international legal instruments. *Id*. ¶ 19.68(a); and
    > To assist all countries, particularly developing countries, in obtaining all appropriate information concerning illegal traffic in toxic and dangerous products. *Id*. ¶ 19.68(b).

Given that Agenda 21 is not legally binding, and that it appears to commit the United States to participating in a large number of actions, the question arises as to why U.S. participation is important. The United States, and other industrialized nations (especially the EU and Japan) are key to the achievement of most of the actions agreed to in Chapters 14 and 19.[39] Most chemicals and pesticides in the world are manufactured by companies based in those three areas; the large multinational corporations who form the core of the manufacturing industry globally are headquartered in these regions. Likewise, those regions house most of the world's toxicology, chemical engineering, and industrial science expertise. Employed mostly in industry but also in government and universities, these experts provide the capacity to achieve goals such as research and development into alternative pest control systems and classifying and labeling of chemicals. To state the obvious, "information exchange" is a two-way street; to accomplish this goal requires that those who have the information, e.g., the United States, participate as well as those who require it, e.g., the global South. The United States, as well as the EU and Japan but also other nations such as Australia, Brazil, Canada, Mexico, and South Korea, also play a key role in capacity building. Although the United States could have chosen to sit this one out, it has participated in international efforts, as described below. Most likely, this was for two reasons. One, given that pollution can cross boundaries, there was a real concern that measures should be successful, and early on, nations agreed that they all would need to participate in order to make headway.[40] And, two, the United States has realized that there is a national interest in being a participant, in that global actions will likely have an affect on commerce and trade, and the chemical and pesticide industry is an important component of the U.S. economy. Thus, it would be disadvantageous to U.S. interests for global approaches to issues such as risk assessment, chemical classification, and risk reduction to be developed in the absence of meaningful U.S. input.[41]

Chemical and Pesticide Management in the United States Pre- and Post-1992

This review will consider the very broad array of substances that are classified as chemicals. For the purpose of discussion, activities to assure the health and safety of industrial chemicals and initiatives regarding chemicals used as pesticides are considered separately. Finally, two cross-cutting areas that involve both industrial chemicals and pesticides are examined; these are POPs and biotechnology.

Industrial Chemicals

Industrial chemicals are broken down into subcategories as follows: "existing" chemicals (those grandfathered by TSCA); national program chemicals (existing chemicals that have specific requirements set by Congress); and "new" chemicals (chemicals manufactured post-TSCA). Specific efforts (right-to-know and pollution prevention) to manage industrial chemicals in groups are also described.

Industrial Chemical Regulation Prior to 1992

The science of chemistry began to develop in the 15th century with the work of the alchemists. As described by the early physician Paracelsus, the materials used were quite limited:

> What, then, shall we say about the receipts of Alchemy, and about the diversity of its vessels and instruments? These are furnaces, glasses, jars, waters, oils, limes, sulphurs, salts, salt-petres, alums, vitriols, chrysocollae, copper-greens, atraments, auri-pigments, fel vitri, ceruse, red earth, thucia, wax, lutum sapientiae, pounded glass, verdigris, soot, crocus of Mars, soap, crystal, arsenic, antimony, minium, elixir, lazarium, gold-leaf, salt-nitre, sal ammoniac, calamine stone, magnesia, bolus armenus, and many other things. Moreover, concerning preparations, putrefactions, digestions, probations, solutions, cementings, filtrations, reverberations, calcinations, graduations, rectifications, amalgamations, purgations, etc., with these alchemical books are crammed. Then, again, concerning herbs, roots, seeds, woods, stones, animals worms, bone dust, snail shells, other shells, and pitch.[42]

If this constituted a basic inventory of chemicals in use at that time, it is obvious that a revolution in materials sciences has since occurred such that, on a global basis, there have been around 100,000 chemicals put in commerce. An explosion in chemical sciences occurred in the 19th century, with the identification of elements and a number of discoveries that laid the groundwork for the ability to synthesize (or break apart) known or new compounds. This revolution in science and technology resulted in an enormous growth in the use of chemicals and materials derived from chemicals in industrial production. In the United States, this growth has been remarkable, showing a 3.7 fold increase between 1966 and 1994 (from 40 to 149 million tons, see Figure 1). By 1998, the chemical industry in the United States directly contributed $158.7 billion of the $8.76 trillion or about 1.8% of gross domestic product.[43] In 1997, it directly employed 820,000 people.[44] In addition to synthetic chemicals, production and use of metals and inorganic chemicals has also increased, along a similar trajectory. The increase in volume and numbers of chemicals in commerce during the last century created the necessity for government intervention to assure that chemicals were being used safely. Today, the chemical industry is undergoing a new revolution with the increased production of specialty chemicals, e.g., detergent enzymes, by genetically modified microbes.

39. Since 1979, these nations have cooperated on chemicals assessment and management in the context of the Organization for Economic Cooperation and Development Chemicals Forum.

40. In 1994, the government of Sweden convened a meeting of governments, which led to the formation of the Intergovernmental Forum on Chemical Safety (IFCS). The forum was chartered to provide a base for international cooperation on implementation of Chapter 19.

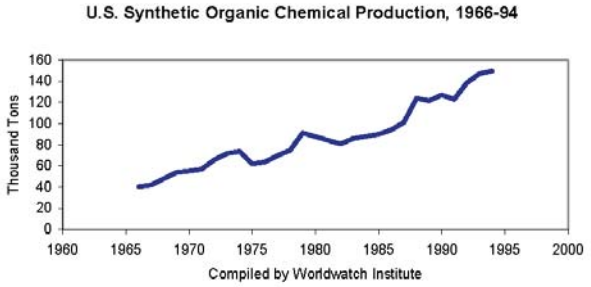
41. That being said, the United States has not led this effort. Rather, the initiative has been taken by smaller (and arguably less economically interested) nations. For example, the presidency of the IFCS has successively been held by Sweden, Canada, and Brazil.

42. Paracelsus (aka Theophrastus Phillippus Aureolus Bombastus von Hohenheim), Preface to the Colelum Philosophorum (1531).

43. U.S. Bureau of Economic Analysis, Survey of Current Business (1999), tbl. 1229.

44. *Id*. tbl. 1230.

Figure 1



Regulation of chemicals lagged significantly behind the growth and development of the industry. Until 1976, there were no laws in the United States specifically related to the introduction of chemicals into commerce and the control of hazards of existing chemicals. Up to that point, regulation of chemicals was limited to food additives, cosmetics, and pharmaceuticals by the Food and Drug Administration (FDA) and pesticides (initially by the U.S. Department of Agriculture (USDA) and the FDA and in 1972 by the newly created EPA). By 1976, it was estimated that there were 60,000 chemical substances in commerce in the United States; however, the government did not have an inventory of chemicals manufactured in or imported into the country. Congress identified a need for a comprehensive framework for the prevention of risks that might be posed by those chemicals. In 1976, Congress enacted TSCA to address three major policy purposes:[45]

> Those who manufacture and process chemical substances and mixtures should develop adequate data "with respect to the effect of chemical substances and mixtures on health and the environment";[46]
>
> The government should have adequate authority to regulate chemical substances and mixtures which present "an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards";[47] and
>
> Government's authority over chemical substances and mixtures should be exercised "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation" while assuring that such substances and mixtures do not present "an unreasonable risk of injury to health or the environment."[48]

Further, Congress made clear its intent that government "shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter."[49] Most of the regulatory authority for TSCA is delegated to EPA's Office of Prevention, Pesticides, and Toxic Substances. Enforcement efforts currently are organized in EPA's Office of Enforcement and Compliance Assurance and research is housed in EPA's Office of Research and Development.

TSCA covered all chemicals that were not already regulated as food additives, drugs, cosmetics, and pesticides. (It also did not cover tobacco products, alcoholic beverages, and firearms.) In addition to general provisions related to chemicals and substances, TSCA from the start specifically contained requirements for the regulation of PCBs.[50] Over the years, TSCA was amended to specifically regulate asbestos (1986, Title II),[51] and radon (1988, Title III).[52] These chemicals are referred to collectively by EPA as "national program" chemicals; the radon program is located in EPA's Office of Air and Radiation.

TSCA provides the authority for EPA to assess and control chemicals in commerce or new chemicals. These provisions broadly direct EPA to assure that the public will be protected from "unreasonable risk" to health and the environment.[53] While the statute did not clearly define "unreasonable risk," the term has come to be interpreted as including aspects of both risk analysis, i.e., the severity and magnitude of health and environmental effects, and economic analysis, i.e., the economic benefits of the use of the substance as well as the availability and costs of switching to alternatives.[54] In the case of PCBs, asbestos, radon, and lead, Congress saw fit to identify that unreasonable risks did indeed exist and gave EPA very specific direction for how to address those risks. In essence, the TSCA framework treats existing and new chemicals very differently. The presumption for an existing chemical is that it is safe unless EPA makes a regulatory finding to the contrary. However, new chemicals must be reviewed by EPA prior to manufacture. Although this review is not very extensive, it nonetheless provides additional safety for new chemicals.

Industrial Chemical Progress Since 1992

Several aspects of TSCA's chemical regulatory regime have been studied extensively by the National Academy of Sciences (NAS),[55] the congressional Office of Technology Assessment,[56] the U.S. General Accounting Office (GAO),[57] and EPA.[58] The verdict has been that the progress under

45. *See* TSCA Deskbook, *supra* note 10.
46. 15 U.S.C. §2601(b)(1), ELR Stat. TSCA §2(b)(1).
47. *Id*. §2601(b)(2), ELR Stat. TSCA §2(b)(2).
48. *Id*. §2601(b)(3), ELR Stat. TSCA §2(b)(3).
49. *Id*. §2601(c), ELR Stat. TSCA §2(c).
50. *Id*. §2605(e), ELR Stat. TSCA §6(e).
51. *Id*. §§2641-2656, ELR Stat. TSCA §§301-311.
52. *Id*. §§2681-2692, ELR Stat. TSCA §§401-412.
53. *Id*. §2601(b)(2), ELR Stat. TSCA §2(b)(2).
54. *See id.* §2605(c)(1), ELR Stat. TSCA §6(c)(1).
55. National Research Council (NRC), Commission on Life Sciences, Toxicology Testing: Strategies to Determine Needs and Priorities (1984) [hereinafter NRC].
56. Congress of the United States, Office of Technology Assessment, Screening and Testing of Chemicals in Commerce: Background Paper (1995).
57. U.S. General Accounting Office (GAO), Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective (1994) [hereinafter GAO TSCA].
58. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? EPA's 1998 Baseline of Hazard Information That Is Readily Available to the Public (1998), *available at* http://www.epa.gov/opptintr/chemtest/hazchem.htm (last visited Apr. 30, 2002) [hereinafter EPA].

TSCA has not achieved the goals that were set out by Congress. Likewise, utilization of the statute falls well short of satisfying, much less exceeding, the commitments made under Agenda 21.

Existing Chemicals

Adequate regulation of existing chemicals is critical to assure protection of communities located near facilities, and to protect consumers and the environment from hazardous discharges to air, water, and land. In this sense, TSCA is a keystone for many other regulatory efforts, including those affecting occupational health, consumer products, and the environment. It would be expected that large and obvious threats to health and the environment would be detected under virtually any regulatory system. However, longer term and subtler effects are more difficult to discern and thus require a strong regulatory framework. As will be seen, this aspect of chemical regulation is probably the weakest link, fundamentally because TSCA grandfathered more than 60,000 chemicals at the time the legislation was enacted, EPA needs risk information in order to evaluate them, and little is known about the risks they may pose.

Regulation of existing chemicals under TSCA has been modest. The GAO, in 1994,[59] concluded that EPA regulates few chemicals under TSCA, listing only five (PCBs, chlorofluorocarbons, dioxin, asbestos, and hexavalent chromium), and noted that the Act itself required the regulation of one of the five, PCBs. In only two cases, those of PCBs and asbestos, did EPA take a comprehensive approach to the regulation of chemicals—and in one of these cases, asbestos, the promulgated regulation was essentially overturned upon judicial review.[60] The GAO also concluded that the referral of chemical risks to other agencies, such as the Occupational Safety and Health Administration (OSHA), for control of adverse exposures to workers had not succeeded. It found that EPA had formally referred only four chemicals to other agencies for control under their statutes, namely 4,4-methylene dianiline (to OSHA, in 1985), 1,3-butadiene (to OSHA, in 1985), glycol ethers (to OSHA, in 1986), and dioxin in bleached wood pulp and papers used for food packaging (to the FDA, in 1990).[61] TSCA's "unreasonable risk" provision has set a hurdle that is too high for the routine regulation of chemicals and does not reflect application of the precautionary principle. Not surprisingly, the United States has not achieved much risk reduction (a goal of Agenda 21, Chapter 19) through the use of TSCA since 1992. The burden of proof in TSCA needs to be shifted more to the manufacturers, processors, and users of chemicals, in line with the precautionary principle as well as the "polluter-pays" principle.

Where progress has been achieved by EPA regarding existing chemicals risk management, it has been in instances in which there has been a concerted focus on higher risk substances. Additional progress in the areas of POPs, right-to-know, and pollution prevention is outlined below.

Access to information on chemicals is hampered by the strict CBI provisions of TSCA. The GAO pointed to the breadth of the CBI protections and the significant costs to EPA in assessing claims made by manufacturers under the law.[62] According to EPA, in 1998, 65% of the information filings directed to the Agency through TSCA were claimed as confidential.[63] Submissions under the Inventory Update Rule show that about 20% of facility identities were alleged to be CBI. Approximately 40% of TSCA substantial risk notices assert confidentiality claims for chemical identity.[64] The states, in their independent regulatory capacity, have no more access to TSCA information that is claimed as CBI than do private citizens.[65] Although EPA can deny spurious CBI claims,[66] there are too few resources to mount serious challenges to the large volume claims. The GAO has concluded that the CBI provisions of TSCA need to be amended.[67] Clearly, the provisions thwart access to information, not just by members of the public, but also by state regulatory agencies. In light of recent concerns about terrorism, any efforts to expand access to information under TSCA will need to be done in the context of national security interests.

Likewise, the gathering of new information about existing chemicals pursuant to TSCA has been largely unproductive.[68] Obviously, the point of such information gathering is to identify and to manage new risks. Under TSCA, this is critical given that EPA must make a finding of "unreasonable risk" in order to take regulatory steps to address use of an existing chemical. Although §4 of TSCA provides EPA with authority to impose health and environmental effects testing requirements on chemical manufacturers and processors, few test rules have been promulgated.[69] In the 1980s, EPA participated in an OECD process to develop the so-called Screening Inventory Data Set (SIDS), a set of screening toxicity studies designed to identify higher risk chemicals.[70] The Organisation for Economic Cooperation and Development's (OECD's) voluntary program has, with the cooperation of industry, slowly tested such chemicals at a pace of about 50 per year. Recently, industry has begun to voluntarily develop "screening level" test data for the approximately 2,800 high production volume (HPV) chemicals in commerce in the United States, those produced in volumes of at least one million pounds per year. An environmental group (Environmental Defense) had conducted a

59. GAO TSCA, *supra* note 57.

60. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 22 ELR 20037 (5th Cir. 1991).

61. GAO TSCA, *supra* note 57.

62. *Id*.

63. *See* Sara Thurin Rollin, *Reporting: Official Suggest Special TSCA Fee to Overhaul, Maintain Confidential Data*, 21 Chem. Reg. Rep. (BNA) 1610 (Mar. 13, 1998). *See also* U.S. EPA, Office of Pollution Prevention and Toxics, Final Action Plan: TSCA Confidential Business Information Reform (1994) (available from the ELR Document Service, ELR Order No. AD-227).

64. *See generally* TSCA Deskbook, *supra* note 10, at 80-81; *id*. at 81 ("excessive and unwarranted CBI claims have inhibited the dissemination of data to the public about specific toxic chemicals and the Agency's chemical management activities").

65. Indeed, "[t]he statute provides for criminal penalties when a United States employee (including contractors and their employees) has knowingly and willfully disclosed CBI to any person not entitled to receive it." *Id*. at 81 (citing 15 U.S.C. §2613(d), ELR Stat. TSCA §14(d)). CBI may, however, be shared with a committee of Congress. *See id*. §2613(e), ELR Stat. TSCA §14(e).

66. *See* 40 C.F.R. pt. 2, subpt. A.

67. GAO TSCA, *supra* note 57.

68. NRC, *supra* note 55; GAO TSCA, *supra* note 57; EPA, *supra* note 58.

69. Pursuant to TSCA §4, 15 U.S.C. §2603, ELR Stat. TSCA §4. *See* TSCA Deskbook, *supra* note 10, at 40-56.

70. TSCA Deskbook, *supra* note 10, at 47.

study that showed a very high level of ignorance about the toxicity of HPV chemicals.[71] EPA, in turn, conducted a complete assessment and found that no publicly available basic toxicity information existed for 43% of all HPV chemicals; full data sets were publicly available for only 7%.[72] In response, the chemical producers, Environmental Defense, and EPA joined in an effort to fill the gaps. Industry is gathering data on a voluntary basis, and EPA is issuing regulatory requirements for companies that do not come forward on their own. In addition, EPA and industry are cooperating with the OECD on a parallel process involving international HPV chemicals. This effort will go a long way toward meeting goals for international assessments of chemical hazards as decided in Chapter 19 (although governments collectively did not reach the year 2000 numeric goal). However, until it is completed, the United States is very much in the dark as to whether the chemicals that are most likely to cause severe environmental degradation or hazards to health have been identified.

Chemicals that disrupt or modulate endocrine (hormone) systems are of particular concern because of their potential to impact wildlife and the health of future generations. Such chemicals are more likely to cause adverse effects such as birth defects and other developmental abnormalities and cancer, in ways that challenge traditional risk assessment models. In 1996, Congress inserted language in two statutes, the Safe Drinking Water Act (SDWA) of 1996[73] and the FQPA of 1996,[74] relating to the testing of chemicals that have the potential to cause estrogenic and other endocrine effects. The language in the SDWA applies to chemicals that might appear in drinking water "or sources of drinking water." The language in the FQPA applies to pesticides and chemicals that could act in concert with pesticides. In response, EPA created an advisory committee, the Endocrine Disruptor Screening and Testing and Advisory Committee (EDSTAC), which met over a two-year period between 1996 and 1998.[75] The committee developed a framework for screening and testing chemicals and pesticides for endocrine disruptor potential; the tests are now being developed and validated. It recommended that all pesticides and existing chemicals in production at 10,000 pounds or more a year (approximately 15,000 chemicals) be put through this process.[76] When implemented, the endocrine disruptor screening and testing program (EDSTP) will very much increase information about chemicals, and will facilitate the goal of intergenerational equity.

EPA and chemical manufacturers have agreed to initiate the so-called Voluntary Children's Chemical Evaluation Program (VCCEP) Pilot.[77] The VCCEP Pilot is a voluntary effort to do "First Tier" testing of 24 chemicals identified by EPA because they are known to have caused exposures to children. However, the data to be submitted for first tier chemicals are a rather meager set; they include acute oral and inhalation toxicity, a couple of in vitro mutagenesis screens, reproductive and developmental toxicity screens, and screens for repeated oral dose toxicity. Data that would allow for actual assessments of risk to children are deferred to Tier 2 (subchronic toxicity, reproductive and developmental toxicity, immunotoxicity, and metabolism) and Tier 3 (carcinogenicity, screening neurotoxicity, and developmental neurotoxicity). EPA has not announced how it will determine which chemicals should move from Tier 1 to Tier 2 and from there to Tier 3. Nor has industry committed to providing any information beyond Tier 1, which in any case is nearly identical to the information that will be developed under the screening battery. Thus, the United States has not evidenced a willingness to employ a precautionary approach in the identification of chemical exposures to people, even to children, and likewise has not demonstrated a strong commitment to intergenerational equity.

The good news regarding hazard assessment is that industry has, to some extent, stepped up to the plate to increase the information available to the public on HPV chemicals and chemicals that may adversely affect children. However, EPA needs enhanced capacity to investigate the hazards of chemicals that already are on the market. As was the case with pesticides in 1988, today there are too many chemicals in common use for which we have insufficient information. EPA now has a hodgepodge of voluntary and mandatory testing efforts—HPV chemicals, EDSTP, and the VCCEP, to name the most significant ones—that need to be brought together into a logical and methodical process of evaluating existing chemicals. This is of particular importance given that, in the absence of information, EPA is unable to manage the risks of existing chemicals under TSCA.

An area in which progress was made concerns the development of EPA's "Design for the Environment" program, which according to the Agency works "with individual industry sectors to compare and improve the performance and human health and environmental risks and costs of existing and alternative products, processes, and practices."[78] EPA has carried out partnerships with a number of industries that are significant users of chemicals, including printing, adhesives, automotive refinishing, printed wiring board manufacturers, computer display, textile and garment care, and cleaning product formulators. These projects employ life-cycle assessment analysis and cleaner technologies substitutes assessments[79] to analyze the environmental impacts, performance, and costs of alternatives for producing

71. Toxic Ignorance, *supra* note 8. *See also* David Roe & William S. Pease, *Toxic Ignorance*, Envtl. F., May/June 1998, at 24.

72. EPA, *supra* note 58. A Chemical Manufacturers Association (now American Chemistry Council) study found an even worse result: 6%. *See* Chemical Manufacturers Ass'n, Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals (1998).

73. Pub. L. No. 104-182.

74. *See* Kenneth Weinstein et al., *The Food Quality Protection Act: A New Way of Looking at Pesticides*, 28 ELR 10555 (Oct. 1998). *See also* Vern A. Walker, *Some Dangers of Taking Precautions Without Adopting the Precautionary Principle: A Critique of Food Safety Regulation in the United States*, 31 ELR 10040 (Jan. 2001). For a discussion of the political obstacles that were successfully confronted through enactment of the legislation, see Thomas O. McGarity, *Deflecting the Assault: How EPA Survived a "Disorganized Revolution" by "Reinventing" Itself a Bit*, 31 ELR 11249, 11259-60 (Nov. 2001).

75. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Endocrine Disruptor Screening and Testing Advisory Committee, Final Report (1998).

76. Endocrine Disruptor Screening Program, 63 Fed. Reg. 42852 (Aug. 11, 1998).

77. Voluntary Children's Chemical Evaluation Program, 65 Fed. Reg. 81700 (Dec. 26, 2000).

78. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Design for the Environment: Partnerships for a Cleaner Future (2001).

79. U.S. EPA, Cleaner Technologies Substitutes Assessment: A Methodology and Resources Guide (1996).

products. These partnerships show great promise for reduction of chemical risks to health and the environment; however, there are not yet enough data to substantiate their effectiveness. Design for the Environment also includes the Green Chemistry Challenge. This is an annual competition for the development of safer chemicals that are judged likely to replace less environmentally friendly alternatives.[80] These efforts have provided an important impetus to integrated decisionmaking within companies that manufacture, process, and use chemicals. There is evidence that at least some sectors of industry are beginning to adopt more of a precautionary approach to chemical use.

Recommendations

(1) A reformed statute should articulate a clearer standard for the protection of health and safety. Possible alternatives to the current approach are either more of a pure public health and environmental protection standard (like the Clean Air Act (CAA))[81] standard for priority pollutants), or one that is more technology forcing (such as the CAA maximum achievable control technology standard)[82] and would encourage pollution prevention.

(2) TSCA should be amended to shift the presumption that chemicals are "innocent until proven guilty" to impose a burden upon manufacturers to prove that chemicals are safe as used in the market. Such a shift will need transition time, however, as was learned in the experience with pesticide reregistration. Further, unless Congress sets clear expectations and schedules very little can be expected to occur. Such a set of expectations should include the following principles: precaution—chemicals will be removed from the market by time certain if they are not shown to be safe; intergenerational equity—children will be protected and will not be left with new legacies of persistent chemicals that will be difficult to cleanup; pollution prevention—the system will reward the development of safer and cleaner industrial technologies and source reduction and multimedia approaches to pollution reduction.

(3) EPA ought to broaden its use of tools for the management of chemical risks, by adopting standards calling for environmentally friendly labels and hazard classification systems similar to those that are being used successfully in Europe. This approach could be coupled with consideration of more use of consumer right-to-know approaches to educate consumers and chemical users about the relative risks of different chemical products, thus enabling the use of integrated decisionmaking processes.

(4) TSCA should be amended to replace the referral process with a coordination one, whereby EPA could regulate chemicals under TSCA as long as the regulation is coordinated with other agencies and other EPA statutes, to prevent duplication or overlap. A good example for the need for such coordination is the situation with the fuel additive methyl tert butyl ether (MTBE).[83] EPA has attempted to cobble together its authorities under TSCA, the Clean Water Act (CWA),[84] and the CAA to reduce MTBE contamination to the environment. TSCA should require collaboration, rather than referral, between EPA and OSHA to manage worker risks and with the Consumer Products Safety Commission (CPSC) to manage consumer risks, to assure that the tools to effectively reduce risks exist and are employed. A stronger TSCA with a clearer focus on risk reduction could achieve this goal more effectively.

(5) Improved alignment of information-gathering efforts could be accomplished administratively; however, as in the case of endocrine disruptor screening and testing, EPA needs clearer direction from Congress on the assessment of chemical risks.

(6) EPA also needs authority, akin to the "data call-in" ability that it has for pesticides, to require the submission of appropriate data from manufacturers of existing chemicals.

(7) The CBI provisions in TSCA should be amended, to assure that health and safety data will be fully available to those who need it, including states and the medical and scientific communities.

(8) Design for Environment and other tools that are industry-friendly (such as voluntary testing of HPV chemicals) should be fostered and expanded to make best use of the apparently increased commitment on the part of industry to sustainable development.

National Program Chemicals

Progress on one national program chemical, PCBs, is discussed in the section on POPs, hereinbelow. There has been little progress in the areas of radon and asbestos regulation since 1992. In 1992, Congress acted to add a new chemical, lead, to those that are specifically regulated under TSCA (Title IV). This was an important step given the special risks of lead poisoning to children and consequent intergenerational inequities that have been created. Although there were some initial delays (missed deadlines) by EPA, the statute has resulted in a number of important new policies, including hazard standards for lead in residential paint, dust, and soil[85]; a training and certification program for lead-based paint inspection and abatement in housing and "child-occupied facilities"[86]; disclosure of lead hazards to occupants prior to renovation of older housing[87]; and disclosure of lead hazards to families at the time of real estate

80. U.S. EPA, The Presidential Green Chemistry Challenge Awards Program: Nomination Package for 2002 Awards (2001).

81. 42 U.S.C. §§7401-7671q, ELR Stat. CAA §§101-618.

82. Discussed in Arnold W. Reitze Jr., Air Pollution Control Law: Compliance and Enforcement (Envtl. L. Inst. 2001).

83. MTBE is a gasoline additive "that may cause cancer and present environmental risks." William T. Warren, *Paying to Regulate: A Guide to* Methanex v. United States *and NAFTA Investor Rights*, 31 ELR 10986, 10986 (Aug. 2001).

84. 33 U.S.C. §§1251-1387, ELR Stat. FWPCA §§101-607.

85. Lead; Identification of Dangerous Levels of Lead; Final Rule (40 C.F.R. Part 745), 66 Fed. Reg. 1206 (Jan. 5, 2001).

86. Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities; Final Rule (40 C.F.R. Part 745), 61 Fed. Reg. 45777 (Aug. 29, 1996).

87. Lead; Requirements for Hazard Education Before Renovation of Target Housing; Final Rule (40 C.F.R. Part 745), 63 Fed. Reg. 29908 (June 1, 1998).

transactions.[88] In 2000, the President's Task Force on Environmental Health Risks and Safety Risks to Children issued a plan for eliminating childhood lead poisoning from paint on housing.[89] This report contained a number of important recommendations, including actions to make available affordable and safe housing for children, heightened compliance monitoring and enforcement of lead paint regulations, increased education and intervention for families at highest risk, and more vigorous screening efforts for children covered by Medicaid (who are at highest risk). The task force also called for more efficient use of resources to minimize residential lead paint hazards, such as combining window paint lead abatement with weatherization efforts and development of financial incentives for abatement of lead paint on housing not served by Department of Housing and Urban Development (HUD) programs.

Recommendation

The United States should stay the course on preventing lead poisoning in children. The recommendations of the President's Task Force must be aggressively implemented; otherwise, yet another generation of children in contaminated older housing will be lead poisoned.

New Chemicals

New chemicals regulation is essential to assuring that additional hazards are not introduced into the environment. EPA's process of premanufacture approval is the only safeguard used by the federal government to guard against such risks. Fortunately, industry itself now examines new chemicals from the standpoint of health and environmental safety; however, there are many gaps in the process. This review will describe progress in this area since 1992.

In 1994, the GAO found that of 23,971 new chemicals that had been reviewed, action to reduce risks was taken on only about 10% (2,431 chemicals).[90] There is little evidence that this deficiency has been remedied. According to EPA, by 1999 it had reviewed over 30,000 TSCA submissions for new chemical substances.[91] Every year, EPA receives between 1,500-3,000 such premanufacture notices (PMNs); most of these chemicals are never brought to market. This is an area that is ripe for harmonization with Europe; the EU chemical law requires review prior to market rather than prior to manufacture and thus results in between 200-300 applications per year. Such a system could allow EPA to focus on the 10% of new chemicals that are actually likely to go to market. Further, the EU requires a screening toxicity dataset, much as with the HPV program, allowing for a more certain prediction of hazard than the U.S. review, which relies predominantly on use of structure/function data. Given that most companies today need approvals in both the United States and the EU, harmonization could introduce efficiencies for industry as well.

Since 1992, very little progress has been made by EPA in addressing the impacts of new chemicals. EPA conducted a side-by-side analysis to determine the predictive capability of its structure activity relationship (SAR) approach compared with the screening testing approach employed by the EU.[92] This study had two sets of conclusions, one from EPA, the other from the EU. EPA concluded that "[w]hile the SAR approach has largely been successful in identifying chemicals of concern, the process could be improved by selectively incorporating specific testing schemes into the process. Results from such schemes would serve two purposes: to gain insight into chemical toxicities and to improve our predictive capabilities."[93] The EU, on the other hand, concluded that SAR methods were not sufficiently developed to assess eye/skin irritation and underestimated the severity of subchronic health effects, and that both systems had weaknesses in predicting reproductive toxicity, developmental toxicity, carcinogenicity, and neurotoxicity.[94] While both EPA and the EU agreed that there were elements in both systems that could be used to improve the other, the United States has not made progress in incorporating more testing into its review of new chemicals (with the exception of POPs). EPA needs stronger authorities to address new chemicals, standards that are better harmonized with the practices in Europe and elsewhere and reflect a precautionary approach.

Recommendations

(1) Premarket rather than premanufacture approvals would provide more time and resources for review of those chemicals that are actually slated for use in the U.S. market and assure that chemicals that actually will be in commerce are more thoroughly evaluated. Such a change would increase the potential for harmonization with the premarket approval process used in Europe.

(2) Congress should establish a clear expectation that EPA will require a screening set of data and that it will use both toxicology and SAR techniques for the assessment of new chemicals. At the same time, EPA should be able to reduce data requirements when data will not contribute to decisions in a meaningful way, while increasing levels of precaution for chemicals that are more toxic. Industry has shown a willingness to take a precautionary approach to new chemicals, and EPA needs to capitalize on this step by making sure that the assessments that are required provide meaningful data.

Right-to-Know

In 1986, Congress gave EPA additional authority over toxic chemicals when it enacted EPCRA. The TRI requires that manufacturing facilities with 10 or more employees report releases and transfers of several hundred toxic chemicals that were specifically listed by Congress. TRI has become the model for similar pollutant release and transfer registries

88. Lead; Requirements for Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards in Housing; Final Rule (24 C.F.R. Part 35 and 40 C.F.R. Part 745), 61 Fed. Reg. 9063 (Mar. 6, 1996).

89. President's Task Force on Environmental Health Risks and Safety Risks to Children, Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards (2000).

90. GAO TSCA, *supra* note 57.

91. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances, 64 Fed. Reg. 60194 (Nov. 4, 1999).

92. U.S. EPA, U.S. EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships, July 1993: Final Report (1994).

93. *Id*. at 52.

94. *Id*. at 53.

(PRTRs) worldwide. Congress also gave EPA authority to add new facilities and chemicals to the list, and to delist chemicals and facilities. Since 1992, EPA has exercised its authority to expand the TRI, very much in concert with the Rio Declaration principle on public information.

The TRI has been a major success, in terms of providing information, and has resulted in decreased pollution. Between 1988 and 1999, looking at the "core" set of industrial chemicals that have been reported consistently over time, total releases on- and off-site decreased by 45.5%, a reduction of 1.46 billion pounds. Thus, TRI has provided a tool for industry to use in integrated environmental decisionmaking. However, the category of total production waste did not increase and in fact has increased slightly over time, from 22.8 to 23.1 billion pounds (an increase of 323 million pounds).[95] Thus, TRI data would indicate that some of the risk reduction goals in Chapter 19 of Agenda 21, concerning cleaner production and less generation of waste, were not met by EPA, even with regard to chemicals that are under the close scrutiny of the TRI.

It already has been mentioned that EPA lowered reporting thresholds for a number of PBT chemicals. In addition, since 1992, EPA has taken a number of other steps that have changed the information available to the public regarding chemical releases. Two rulemakings expanded the TRI significantly. First, in 1994, EPA added 236 chemicals and chemical categories for reporting to the TRI.[96] In 1995, President William J. Clinton issued an executive order requiring that federal facilities report under the TRI.[97] In 1997, EPA further expanded right-to-know by adding new industry groups—metal mining, coal mining, electric utilities, commercial hazardous waste treatment, chemicals, and allied products-wholesale, petroleum bulk terminals and plants-wholesale, and solvent recovery services—to TRI coverage.[98] In 1999, the most recent year for which there is comprehensive data, metal mining accounted for 51% of total releases and 83% of releases to land of toxic chemicals. That year, electric utilities accounted for 40% of all releases to the air.[99] These expansions of TRI have very much increased citizen access to information and are bringing further attention to new sources of chemical releases and wastes.

Even with the expansion of chemicals on the TRI, many chemicals regulated under other statutes are still not on the TRI, perhaps providing incentives to use chemicals that will not require disclosure over those that do. It has been suggested that EPA should require reporting under TRI of all chemicals that exceed the thresholds[100]; this would require a statutory change since the current chemical addition criteria are (for the most part) hazard-based.

95. U.S. EPA, 1999 Toxics Release Inventory (TRI) Public Data Release Report (2001) [hereinafter 1999 TRI].

96. Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know, 40 C.F.R. Part 37; Final Rule, 69 Fed. Reg. 61432 (Nov. 30, 1994).

97. Exec. Order No. 12969, Federal Acquisition and Community Right-to-Know, 60 Fed. Reg. 40989 (Aug. 8, 1995), Admin. Mat. 45082.

98. Addition of Facilities in Certain Industry Sectors; Revised Interpretation of Otherwise Use; Toxic Release Inventory Reporting; Community Right-to-Know; Final Rule, 62 Fed. Reg. 23834 (May 1, 1997).

99. 1999 TRI, *supra* note 95.

100. John C. Dernbach, *The Unfocused Regulation of Toxic and Hazardous Pollutants*, 21 Harv. Envtl. L. Rev. 1, 2 n.5 (1997).

Recommendation

It is important that TRI listings be kept current as new chemical hazard information is generated by EPA through voluntary initiatives. New information should be incorporated into listing and delisting decisions in order to assure that there is a level playing field.

Pollution Prevention

The PPA defines pollution prevention as "reduc[tion] or prevent[ion] of pollution at the source through cost-effective changes in production, operation, and raw materials use."[101] The PPA established a pollution prevention effort, facilitated by EPA's chemicals office, and required that source reduction efforts occur in each office in EPA.[102] It mandated that EPA establish a pollution prevention strategy to promote source reduction and recycling,[103] and provided for the collection of such information through the TRI.[104] It provided resources for state and local pollution prevention programs[105] and the promotion of use of pollution prevention by industry. Likewise, pollution prevention (clean production) was identified in Chapter 19 of Agenda 21 as an important action area for risk reduction.

EPA has made significant progress in the development of pollution prevention tools such as environmental accounting, financing, resource exchanges, and state-based efforts. The Agency has worked closely with a number of sectors, such as metals, pulp and paper, municipal water, and printing, in order to develop case studies and tools for the promotion of pollution prevention. Within EPA, efforts have been made to incorporate pollution prevention into permitting programs and compliance efforts. And EPA has developed guidance on environmentally preferable government purchasing techniques to encourage "green" purchasing practices.[106]

Although there has been much progress in the development of pollution prevention tools and education, it is not clear to what extent pollution prevention has been adopted in practice by industry and become a part of integrated decisionmaking. Certainly, there has been some industry leadership in this area. For example, the Dow Company and the National Resources Defense Council carried out a collaborative project to evaluate source reduction possibilities at a Midland, Michigan, plant; reportedly, plant managers were surprised that they were able to reduce chemical use and save money with a relatively modest upfront investment. Similarly, it is not clear to what extent pollution prevention has been incorporated into EPA's core permitting and rulewriting processes. Certainly, though, EPA can cite some successes in this area.

Recommendations

(1) The United States should undertake an evaluation of its pollution prevention efforts, noting where they have suc-

101. 42 U.S.C. §13101(a)(2), ELR Stat. PPA §13101(a)(2).

102. *Id.* §13103(b)(3), ELR Stat. PPA §13103(b)(3).

103. *Id.* §13103(b), ELR Stat. PPA §13103(b).

104. *Id.* §13106, ELR Stat. PPA §13106.

105. *Id.* §13104, ELR Stat. PPA §13104.

106. U.S. EPA, Final Guidance on Environmentally Preferable Purchasing for Executive Agencies (1999).

ceeded and where they have failed. Does PPA reporting under the TRI provide valuable data about industry pollution prevention efforts? If so, these data are not being utilized. If not, there needs to be consideration of new information tools to order to assess this issue.

(2) The United States should expand efforts to integrate pollution prevention into core environmental regulatory efforts for air, water, and waste management.

(3) The United States needs to encourage pollution prevention efforts in industry, making clear in regulations and through the permitting process an unmistakable preference for source reduction over pollution control.

Pesticides

Pesticides constitute a variety of chemical, biologic, and other agents that are used to kill or inhibit the growth of pests of economic importance. Pesticides include insecticides, fungicides, herbicides, rodenticides, wood preservatives, and disinfectants. They include synthetic chemicals, inorganic chemicals, metals, and even biological materials such as pheromones, bacillus thuringiensis bacteria, and genetically modified plants. This review considers progress on pesticides in terms of older (pre-1985) pesticides subject to reregistration, food safety efforts under the FQPA, and new pesticides that are being brought to market. The FQPA is discussed separately because it is the most significant change since 1992.

Pesticide Regulation Prior to 1992

In 1995, 876 pesticides were in commerce in the United States. By 1997, there was about four billion pounds of usage,[107] much of which was for disinfection of water and similar uses. In addressing the goals of Agenda 21, it is important to consider trends in the use of so-called conventional pesticides, which comprise insecticides, herbicides, and fungicides with uses in sectors such as agriculture, horticulture, lawn care, and household and institutional pest control. From the mid-1960s to 1985, agricultural use of conventional pesticides doubled from 400 to over 800 million pounds per year. The annual rate of increase was, on average, 1.77%. In contrast, nonagricultural use of conventional pesticides decreased by 33%, from 300 to 200 million pounds between 1970 and the 1990s.[108] This rapid increase in agricultural pesticide use as well as the diversity of pesticides has led to an increased emphasis on regulating pesticides. Today we see the development of a new technology, so-called PIPs (plants genetically modified to have new pest resistance or pesticidal traits).

Congress enacted the first pesticide legislation in 1910[109]; this was a consumer protection statute that "aimed to reduce economic exploitation of farmers by manufacturers and distributors of adulterated or ineffective pesticides." In 1947,[110] Congress enacted FIFRA, which for the first time addressed the potential risks to human health posed by pesticide products. In 1962, Rachel Carson's book *Silent Spring* brought new public attention to the debate about pesticide risks. Initially, the USDA was responsible for administering the pesticide statutes[111]; responsibility shifted to EPA in 1970.

In 1972, Congress had become concerned about pesticide impacts to people (especially pesticide applicators and consumers) and wildlife and completely revised FIFRA[112] to strengthen EPA's authority to protect health and the environment. The 1972 law is the basis of current federal policy. Since 1972, EPA has been required to reregister older pesticides, but it was not until Congress amended FIFRA in 1988[113] that the Agency began to accelerate the process of review and update of older pesticides. In 1988, there were 612 such active ingredients on the market. Pesticides also have been regulated in food under the Federal Food, Drug, and Cosmetics Act (FFDCA).[114]

FIFRA has a number of provisions that give EPA the authority to assess and manage the risks of pesticides. These include provisions related to registration of new pesticides,[115] reregistration of older pesticides,[116] data collection,[117] pesticide import and export[118] and so forth. In addition, there is a framework related to product licensing and commerce that is not covered in this Article. In 1992, the GAO gave testimony to Congress that painted a rather bleak picture of the nation's pesticide regulatory programs. It pointed to a pesticide reregistration effort that had succeeded in the reevaluation of only two of the older pesticides on the market; difficulties in removing unsafe pesticides from the marketplace; lack of an early warning system for pesticide damage; and increasing pesticide contamination of groundwater. It noted shortcomings in a number of other areas, including food residue monitoring; import notices to other countries; farm worker safety protections; and pesticide data management.[119]

Progress Since 1992

The FQPA amended the FFDCA as well as FIFRA, and for the first time addressed coordination between the two statutes. FIFRA functions essentially as a product-licensing statute and thus has some peculiar aspects. For example, all regulations to be followed by pesticide users must be contained on the pesticide product labels (the label is the law). FIFRA and the FFDCA have different legal standards for the safety of a pesticide. Under FIFRA, the standard is "protection against any unreasonable adverse effects on the environment"; under the FFDCA, it is a "reasonable certainty

107. A.L. Aspelin & A.H. Grube, Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Pesticide Industry Sales and Usage: 1996 and 1997 Sales and Usage (1999) [hereinafter Sales and Usage].

108. *Id*.

109. Insecticide Act of 1910, ch. 191, 36 Stat. 331 (1910).

110. Pub. L. No. 80-104, 61 Stat. 163 (1947).

111. Congress amended the legislation in 1964 to provide authority to the Secretary of Agriculture to cancel existing registrations or to decline to register a new product. Pub. L. No. 88-305, 78 Stat. 190 (1964).

112. Pub. L. No. 92-516, 86 Stat. 973 (1972).

113. Pub. L. No. 100-532, 102 Stat. 2654 (1988).

114. 21 U.S.C. §§301-396.

115. 7 U.S.C. §136a, ELR Stat. FIFRA §3.

116. *Id*. §136a-1, ELR Stat. FIFRA §4.

117. *Id*. §136d(a)(2), ELR Stat. FIFRA §6(a)(2).

118. *Id*. §136o(a)(1), ELR Stat. FIFRA §17(a)(1).

119. U.S. GAO, Pesticides: Thirty Years Since Silent Spring—Many Long-Standing Concerns Remain (1992).

of no harm." In practice, this means that economic benefits and other trade offs may be considered by EPA in decisionmaking except in the case of food safety, where only public health considerations are allowed.

Reassessment and Control of Older Pesticides

The "older" pesticides are those that have been on the market in the United States since 1985. Registered prior to the development of modern safety standards, they pose the greatest risks to health and the environment. Prior to 1985, use of these pesticides was on the rise but usage leveled off at that time and has been fairly level ever since. There are also signs that pesticide users are switching to less harmful pesticides. Moreover, EPA has made much progress in reassessing these pesticides. However, major information gaps exist that make it difficult to quantify the extent to which the goal of reducing pesticides-related risks is being met.

There has been much progress in the regulation of pesticides since 1992, and especially in the reassessment of older pesticides, information management, and protection of workers. By the end of 1999, EPA reported having completed reregistration on around one-third, or 198, of these chemicals. Industry voluntarily cancelled 231 pesticides rather than undergoing reregistration, leaving 183 pending reregistration as of the beginning of 2000.[120] That being said, there are weaknesses in FIFRA's enforcement capacity that were not addressed in the 1996 Amendments and hinder efforts to prevent severe environmental degradation. Additionally, pesticides applicators and farm workers still do not yet have hazard notification information that is available to other workers (except in states that have statutes that require such notice, such as Texas).

For reregistration, particular focus has been placed on the 10 pesticides that, in 1987, were determined to have the greatest cancer risk. These are—in descending order of risk—linuron, zineb, captafol, captan, maneb, permethrin, mancozeb, folpet, chlordimeform, and chlorothalonil. The National Research Council, in 1985, determined that these pesticides accounted for 80 to 90% of the total estimated dietary cancer-causing risk from the 28 pesticides it analyzed.[121] By 1995, the GAO determined that EPA had made significant progress toward regulating some of these via the reregistration and other processes.[122] An update of this review (see Table 1) shows that there has been continued progress for eight of the 10 that were still in play in 1992. For three, mancozeb, maneb, and permethrins, neither reregistration nor tolerance reassessment has been completed.

Numerous initiatives were undertaken by EPA during the 1990s to reduce risks from existing pesticides, including specific efforts to protect farm workers,[123] endangered species,[124] and groundwater and to provide the public with clearer information on pesticide product labels.[125] In the area of integrated pest management (IPM), EPA developed an educational program on how to adopt IPM in schools. More broadly, EPA developed the Pesticide Environmental Stewardship Program (PESP), which enlisted dozens of pesticide users (ranging from the military to various grower groups) who work with EPA to identify strategies to reduce the risks from and use of pesticides in their operations. It also conducted a voluntary effort to protect endangered species from the risks of pesticides. The USDA, in 1993, adopted a goal that 75% of U.S. agriculture should employ IPM by the year 2000. Whereas the USDA, in 2001, reported that this goal nearly was reached (with 70% of agriculture in IPM), according to the GAO this was achieved by the USDA's inclusion of a number of farm management practices (cleaning equipment and monitoring for pests) that did not transform the use of pest control agents in agriculture.[126] For example, GAO noted that in the case of one crop "biologically-based IPM practices were implemented on no more than 18[%] of corn acreage."[127] The GAO concluded that the USDA IPM initiative lacks leadership, coordination, and management. It recommended strengthening the management and coordination of the IPM effort, as well as more clearly articulating and measuring progress toward achieving the goals (including the goal of pesticide use reduction). An additional problem is that there is little detailed information on pesticide usage on a national basis. Several states (Arizona, California, New York, Texas, and Washington) do collect such data (mostly at the point of sale) and could serve as models for the development of a national reporting system. Thus, U.S. efforts to move to IPM have not yet met the goals of increased use of biological control and organic pesticide products as stated in Chapter 14 of Agenda 21.

The use of pesticides in U.S. agriculture has leveled off since 1985.[128] Moreover, total pesticide use lumps together pounds of relatively benign substances with the more highly toxic pesticides that have been targeted by EPA for risk reduction, namely organophosphates, carbamates, organochlorines, and probable and possible carcinogens. The use of those pesticides was reduced in both absolute and relative terms, decreasing by 14% overall and from 50.5% to 41.5% of total conventional pesticide use.[129] Thus, the United States is beginning a transition away from the most harmful pesticides, as it agreed to do in Chapter 19 of Agenda 21.

Recommendations

(1) EPA still has much work to do to complete the reregistration of older pesticides. Reregistration and other regulatory activities need to aggressively address risks to workers, to groundwater, and to ecosystems, which may or may not be mitigated through the FQPA process. Such efforts should focus initially on the highest risk pesticides.

120. U.S. EPA, Office of Pesticide Programs Biennial Report for FY 1998 and 1999 (1999) [hereinafter Biennial Report].

121. NRC, Regulating Pesticides in Food: The Delaney Paradox (1987).

122. U.S. GAO, Reregistration Status of 10 Highest-Risk Dietary Cancer-Causing Pesticides (1995).

123. Worker Protection Standard, 57 Fed. Reg. 38151 (Aug. 21, 1992). EPA never has implemented a long-planned hazard notification system for pesticide workers (especially aimed at farm workers).

124. EPA has sought to use the Endangered Species Act to limit the use of specific pesticides in specific counties, on a voluntary basis. There has been no evaluation of the efficacy of this approach.

125. Abt Ass'n, Consumer Labeling Initiative: Phase II Report (1999). Also, multiple administrative reforms were done to make product label decisions more consistent.

126. U.S. GAO, Agricultural Pesticides: Management Improvements Needed to Further Promote Integrated Pest Management (2001) [hereinafter Agricultural Pesticides].

127. *Id*. at 2.

128. Sales and Usage, *supra* note 107; Agricultural Pesticides, *supra* note 126.

129. Agricultural Pesticides, *supra* note 126.

(2) The government should adopt a definition of IPM that gives more weight to biological and lower risk pest control alternatives. In addition, as recommended by the GAO, there needs to be stronger direction, management, and coordination of the federal IPM effort. Such an effort can support integrated decisionmaking by the pesticide user community.

(3) Regardless of the size and type of the infraction, a first violation of FIFRA can invoke no more than a warning letter from EPA. Fines are set at a low $6,000 per infraction, presumably to protect the "family farmer," but a large proportion of pesticide users are large corporations for whom larger penalties are needed to establish a sufficient incentive for compliance. EPA should be able to impose higher penalties, commensurate with the amount of damage that can be caused by pesticide misuse.

(4) Unlike other environmental statutes, FIFRA lacks a citizen suit provision. Such a provision could be added to FIFRA without endangering the family farmer (the reason given for rejecting strict enforcement of FIFRA).

(5) There is unfinished business from the 1992 worker protection regulations. EPA needs to strengthen its protection of pesticide workers by notifying them of specific pesticide hazards. In addition, EPA should use the new tools of cumulative and aggregate risk assessment to assure that workers, as well as consumers, are protected.

(6) EPA's pesticide program should provide more information about pesticide usage patterns, which could be used to inform decisions by pesticide users and to evaluate progress in reducing risks.

Food Safety and Risks to Children

This section reviews progress in implementation of the FQPA; defined by its explicit protection of children; it was passed unanimously and signed into law in August 1996. Food safety is one of the key methods of protecting public health from pesticide toxicity. Moreover, the control of uses of pesticides in foods has numerous ancillary benefits, including reduction of exposures to farm workers and pesticide applicators and improved environmental protection. Children often are more exposed and susceptible to the risks of pesticides and other chemicals. As will be shown, the FQPA has resulted in reduced risks from pesticides but its implementation is still underway and the full impact of the legislation is not yet clear.

The FQPA requires EPA to assess aggregate and cumulative risks, rather than assessing safety one pesticide and one medium at a time. The concepts for the children's health protections in the law were developed in the 1993 NRC report, *Pesticides in the Diets of Infants and Children*. The NRC concluded that the toxicity of, and exposures to, pesticides are frequently different for children and adults and that EPA did not adequately address risks to children.[130] The committee advised EPA to incorporate information about dietary exposures to children in risk assessments and to augment pesticide testing with new or improved guidelines for neurotoxicity, developmental toxicity, endocrine effects, immunotoxicity, and developmental neurotoxicity. It recommended that EPA include cumulative risks from pesticides that act via a common mechanism of action and aggregate risks from non-food exposures when developing a tolerance for a pesticide.

Shortly after publication of the report, the Clinton Administration announced an initiative to address the NRC recommendations, including asking Congress for new legislative authorities. By 1996, Congress was ready to act. The FQPA gave the Agency one uniform standard to use in setting tolerances, which are the limits of allowable pesticide residues on a food, of "reasonable certainty of no harm." Previously there were three separate standards for pesticides on food: risk/benefit balancing for fresh fruits and vegetables; the zero risk or Delaney Clause standard[131] for carcinogens on processed foods; and a public health standard for processed foods generally. Further, in establishing tolerances the Agency now must consider information on the aggregate of all nonoccupational exposures, including drinking water and exposures from lawn and household uses.[132] Previously, EPA generally took into account only pesticide exposure from food. The law also requires EPA to consider available information on the cumulative effects of pesticide residues and other substances that have a common mechanism of toxicity. Previously, EPA regulated each pesticide individually. On top of these new considerations, Congress directed EPA to use an additional tenfold (10X) factor during the decisionmaking process to account for pre- and post-natal toxicity-based results. The NRC had recommended a third 10X factor in addition to the interspecies and intraspecies factors previously employed.[133] The Agency can eliminate or reduce the additional 10X FQPA factor only if it makes a specific finding that reliable and complete data indicate a different factor will be safe for infants and children. Specifically, the FQPA instructed EPA:

> In the case of threshold effects, . . . an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such a margin will be safe for infants and children.[134]

Thus, the FQPA reflects a number of Rio principles, including the precautionary principle and the promotion of intergenerational equity. Since enactment of the FQPA, there has been much debate about its implementation. To date, the most successful aspect of the legislation has been the aggregate risk policy. A number of household pesticide registrations were revoked when EPA discovered that they led to an excessive level of exposure in children. These include household uses of chlorpyrifos, malathion, and diazinon. EPA is developing but has not yet implemented a

130. NRC, Pesticides in the Diets of Infants and Children (1993) [hereinafter NRC 1993].

131. Former 21 U.S.C. §348.

132. 21 U.S.C. §346a(f)(1).

133. NRC 1993, *supra* note 130.

134. 21 U.S.C. §346a(b)(2)(C).

policy for cumulative risk.[135] The Agency has, however, developed an FQPA safety factor policy, which has proven to be particularly controversial. Industry has often disagreed with its application. For example, EPA denied, in January 1998, the use of the carcinogenic herbicide bromoxynil on herbicide-tolerant cotton. Moreover, environmentalists have argued that the Agency too readily concludes that the data are sufficient. EPA's statements that its determinations are based on the weight of the evidence are, they contend, obscuring the reality of political pressures from manufacturers.[136]

Table 2 shows how the safety factor has been applied since enactment of the law, for pesticides in general and for organophosphates in particular.[137] Of an initial 105 pesticides reviewed, EPA decided not to retain any portion of the additional 10X factor. However, for the 39 organophosphates, a 10X (or more) factor was retained for 12 pesticides and partly retained (3X) for another 12 pesticides. Although there continue to be disagreements about the individual decisions that underlie the data shown in Table 2, it can be said that EPA does evidence a willingness to apply, at least to some extent, the precautionary principle and the notion of intergenerational equity.

The FQPA gave EPA an ambitious schedule to reassess all tolerances over a 10-year period. At the time of its enactment, there were 9,721 tolerances on the books. EPA was directed to establish a schedule to assess the riskiest tolerances first. However, EPA determined that a large proportion, 57%, fell into the highest priority category. These were mostly comprised of probable/possible carcinogens and organophosphate pesticides, which accounted for 20.7% and 17.4% of all tolerances, respectively. As of August 2001, EPA reported having completed tolerance reassessments for 3,662 pesticides, completing 43% of priority group 1, 26% of group 2, and 34% of group 3.[138] Thus, while EPA is making progress on tolerance reassessment, it is not achieving the goal of addressing the "worst first." This is probably because EPA has yet to utilize a cumulative risk assessment (and indeed has not yet adopted final policies and procedures for how it will accomplish this).

It is too soon since the passage of the FQPA to pass judgment on all of EPA's achievements in this area. Clearly, the enactment of the legislation reflects a commitment on the part of the United States to the precautionary principle, intergenerational equity, and risk reduction. However, it is unclear at this time whether EPA will fully implement some of the crucial provisions of the FQPA such as cumulative risk. EPA policies for FQPA implementation continue to evolve and there have been significant delays in the implementation of certain provisions of the Act.

Recommendations

(1) Implementation of the FQPA is, when it comes to pesticides, the most important priority for EPA. Implementation of the FQPA needs to be done in a transparent manner with full public process, to avoid the appearance (if not the reality) of "weight of evidence" approaches providing cover for political decisions.

(2) EPA should resist pressures to weaken the application of the 10X factor in order to adequately protect children.

(3) EPA should fully implement the "cumulative risk" provisions of the FQPA.

(4) EPA needs to keep pace with tolerance reassessment and make a particular effort to assess the "worst first."

New Pesticides

Registration of new pesticides plays an important role in assuring that pesticide users have safer alternatives to older, riskier pesticides. In addition, it prevents the introduction into the market of new pesticide risks that would cause damage in the future. In this area, the United States has generally had a strong track record since 1992.

From 1982-1993, EPA registered 125 pesticide-active ingredients. Of these, 25% were biological pesticides that would be considered safer to the environment.[139] Two things changed in 1994. In 1993, EPA established a "reduced risk" pesticide registration process for chemical pesticides.[140] If a pesticide manufacturer could show that a new pesticide attains a "safer" threshold, based on a number of health and environmental considerations, EPA accelerates the review, thus providing an incentive to manufacturers. And in 1994, EPA established a policy whereby new biological pesticides would be given priority for registration and established a new pesticide review division specifically to accelerate their review. Later, the FQPA included incentives for safer pesticides as well, which were reflected in a 1997 policy guidance issued by EPA.[141] From 1994-1999, the results of these new policies and laws were evident. Of 186 new pesticides that were approved during the period, fully 44% were biological pesticides, 10% were new "safer" chemical pesticides, and less than one-half were conventional chemical pesticides. By 1999, 19% of 31 approvals were for chemicals meeting the "safer" criteria.[142]

Clearly, efforts to provide incentives for industry to bring forward new safer chemical and biological pesticides are beginning to achieve success. What this demonstrates is a willingness of industry to develop new and safer products, if given appropriate market incentives by EPA. This is an important step in providing alternatives to riskier products and in achieving an action goal in Chapter 14 of Agenda 21 to encourage research and development regarding pesticides that are target-specific and which are readily degradable into harmless components.

135. U.S. GAO, Children and Pesticides: New Approach to Considering Risk Is Partly in Place (2000) [hereinafter Children and Pesticides].

136. Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act*, 53 Admin. L. Rev. 103 (2001).

137. Children and Pesticides, *supra* note 135.

138. U.S. EPA, Tolerance Reassessment (2001).

139. Biennial Report, *supra* note 120.

140. U.S. EPA, Voluntary Reduced-Risk Pesticides Initiative (1993).

141. U.S. EPA, Guidelines for Expedited Review of Conventional Pesticides Under the Reduced-Risk Initiative and for Biological Pesticides (1997).

142. Biennial Report, *supra* note 120.

Recommendation

In line with the "polluter-pays" principle, the United States should implement the registration fee provision that was established in the FQPA. Consideration should be given to charging a lower fee for chemical and biological pesticides that meet a strict "safety" screen.

POPs

In 1997, EPA established a new category of chemicals that it called PBTs. These are chemicals that possess characteristics of persistence (P) in the environment, accumulation in biological organisms (bioaccumulation (B)), and toxicity (T). Clearly, POPs are among the substances that are of greatest concern, in terms of the global transfer of substances that cause severe environmental degradation and/or health hazards, as well as with regard to intergenerational equity. In addition, Chapter 19 of Agenda 21 called for specific attention to reduce risks associated with POPs.

In 1998, EPA published a final policy for these PBT chemicals. The policy established a practice of placing controls or bans on chemicals that are above certain thresholds for persistence and bioaccumulative potential, pending further testing to prove that they are safe for humans and ecosystems.[143] In 2000, EPA received 1,650 PMNs. Of these, EPA identified 53 as having potential PBT characteristics, of which seven were dropped from review after further scrutiny. Among the remaining 46, production of 11 was banned pending further testing, and 35 were regulated to control their release into the environment.[144] EPA also developed and tested a software program called the "PBT Profiler," which the Agency uses to predict whether new chemical structures are above thresholds for PBT chemicals. EPA is making this software available to industry so that they can predict in advance whether chemicals are likely to trigger threshold levels.

EPA also lowered the reporting threshold for several of the most persistent bioaccumulative chemicals subject to reporting under the TRI: aldrin, benzo (a) pyrene, chlordane, dioxins and furans, heptachlor, hexachlorobenzene, isodrin, lead and lead compounds, mercury and mercury compounds, methoxychlor, octachlorostyrene, pendimethalin, pentachlorobenzene, polycyclic aromatic compounds, PCBs, tetrabromobisphenol A, camphechlor (toxaphene), and Trifluralin.[145] The 1999 rule also created a new category of dioxin and dioxin-like compounds under TRI and set a low reporting threshold (0.1 grams) for this category. These lower thresholds for reporting became effective for the calendar year 2000 reporting year, except for lead and lead compounds, which began in calendar year 2001, the reporting date having been extended by EPA in February 2001.[146] By lowering the thresholds for reporting, more parties will be required to report lower quantities of these substances, providing a more complete picture of where environmentally significant releases and disposals are occurring in the United States Thus, EPA has taken commendable steps to increase public access to information on PBTs.

In addition, in 1998, EPA issued an action plan for 12 of the most toxic persistent chemicals: aldrin/dieldrin, alkyl lead, benzo (a) pyrene, camphechlor (toxaphene), dichlorodiphenyltrichloroethane (DDT) and DDD/DDE, dioxins/furans, hexachlorobenzene, mercury and mercury compounds, mirex, octachlorostyrene, and PCBs.[147] These plans were issued in alignment with Canada (through the Binational Toxics Strategy) and Canada and Mexico (via the North American Commission on Environmental Cooperation) and reflect efforts to control the transfer of the most hazardous substances within and between countries. In 2001, EPA reported on progress for these action plans. The report referenced progress in the control of mercury, dioxins/furans, and PCBs.

Since 1992, much progress was made in addressing risks posed by methylmercury; however, there is still much more to do. Mercury is a metal that is very toxic to the brain; an organic form (methylmercury) is produced naturally by microorganisms. Methylmercury is especially toxic to the brain of the developing fetus. The most significant source of mercury in the environment is air emissions. According to EPA, a large majority (72%) of the emissions are (in order of importance) from the burning of coal, municipal waste, and medical waste; chloralkali production of chlorine; operation of motor vehicles; and the burning of hazardous waste. In 2000, after a multiyear process to determine risks, EPA announced that it would regulate mercury and other air toxics from coal-fired electric utility plants.[148] By the end of 2000, EPA had completed maximum available control technology (MACT) standards for mercury emissions from municipal waste, medical waste, and hazardous waste burners.[149] When these are fully implemented, such facilities will show a 90% reduction in their mercury emissions. In addition, EPA is engaged in a voluntary program to eliminate uses of mercury in the hospital industry. In 1996, the U.S. chlorine industry announced a commitment to voluntarily reduce mercury emissions by 50%; it achieved 51% reduction by 2000 (44% after adjusting for facility shutdowns). According to EPA, in 1999, 10% of women and 400,000 babies born each year had mercury levels above thresholds it considers "safe."[150] Given that coal-fired power plants are the largest contributor to mercury emissions, there is reason for concern as to whether the largest source, coal combustion, will be controlled. Disappointingly, the utilities industry has taken no action, other than steps designed to obstruct regulation of these emissions by EPA. In addition, EPA has not yet

143. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances (Policy Statement), 64 Fed. Reg. 60194 (Nov. 4, 1999).

144. U.S. EPA, 2000 PBT Accomplishments (2001) [hereinafter PBT Accomplishments].

145. Persistent Bioaccumulative Toxic Chemicals: Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Amendments to Proposed Addition of Dioxin and Dioxin-Like Compounds Category; Toxic Chemical Release Reporting; Chemical Right-to-Know: EPA 49 C.F.R. Part 372, Final Rule, 64 Fed. Reg. 58666 (Oct. 29, 1999) [hereinafter PBT Rule]; Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting, 40 C.F.R. Part 372; Final Rule, 66 Fed. Reg. 4500 (Jan. 17, 2001).

146. Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting: Delay of Effective Date, 66 Fed. Reg. 10585 (Feb. 16, 2001).

147. U.S. EPA, Draft Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Pollutants (1998).

148. Regulatory Finding on the Emissions of Hazardous Air Pollutants From Electric Utility Steam Generating Units, 65 Fed. Reg. 19825 (Apr. 13, 2000).

149. PBT Accomplishments, *supra* note 144.

150. *Id*. at 20-21.

issued regulations to establish approved disposal practices for mercury. Thus, while it has encouraged efforts to reduce the use of mercury, EPA still has not approved mercury disposal technologies that would allow industry to readily dispose of it as waste in nonhazardous waste landfills. This failure to act provides a perverse incentive to reuse mercury.

Since 1992, many steps were taken by the United States to reduce emissions of dioxins and furans. Dioxins and furans are a family of chemicals that are produced inadvertently as byproducts of manufacture of other chemicals (for example, 2,4,5-trichlorphenol, Agent Orange) and in incineration. The most toxic dioxin is 2,3,7,8-TCDD; it is known to cause cancer[151] and has the potential to induce developmental toxicity in the fetus. In the case of dioxins, EPA, in 1982, embarked on a process to "reassess" the risks of dioxins. While the reassessment continues, it appears that the final product will be released in 2002, fully 20 years after initiation of the study. In the meantime, EPA cites a number of regulatory actions (such as the MACT rules noted above and rules governing the pulp and paper industry) that are expected to reduce the emissions of dioxins by 95%.[152] However, despite the many years of reassessing dioxins, the U.S. government has yet to regulate the quantities in the food supply. In sharp contrast, the European Commission established a standard for tolerable weekly intake of dioxins and dioxin-like PCBs in the diet. This regulation will become effective in mid-2002. Meanwhile, in the United States, the FDA has requested a new dioxin study from the NAS, in order to decide what course of action it should take.

PCBs are among the POPs that have generated much effort since 1992. PCBs were manufactured in the United States between 1929 and 1979 and were widely used in electrical and consumer products, as well as by the military, for their heat capacity and flame retardant properties. PCBs are believed to cause cancer and are without doubt toxic to the developing fetus. Although PCB manufacture was banned in the United States in 1979, PCBs remained in use in certain transformers and capacitors and continued to be present as contaminants in waste sites and sediments. In 1997, the United States committed to phase out 90% of its continued use of PCBs over a 10-year period as part of the United States/Canada Binational Toxics Strategy.[153] These efforts have focused on voluntary reductions in the automobile, utilities, and government sectors. In addition, the United States has assisted Russia in halting the production and use of PCBs.[154] This is important, as Russia is the last country to continue to manufacture PCBs. On the other hand, despite numerous recent food adulteration episodes, the FDA has yet to establish a monitoring program to assure that food is safe from PCBs and dioxins. Dioxins in the food supply particularly impact future generations since they are transferred to the fetus in utero and to the infant via breast milk. In 2001, the FDA requested a study by the NAS on recommended options for the management of dioxins and PCBs in the food supply.

Since 1992, two new classes of persistent substances have received increased scientific attention and have been the subject of considerable concern. First, it was observed that levels of so-called polybrominated diphenyl ethers (PBDEs) (flame retardants) were increasing in the breast milk of Swedish women.[155] Despite this observation, and activities in Europe to ban or restrict these chemicals, EPA has neither taken action to determine exposure levels in the U.S. population nor has undertaken steps to control exposures. While these chemicals were included by EPA in the VCCEP, described above, the first phase of the program will not address issues relating to toxicity to the fetus and infant.

Likewise, in May 2000, perfluorooctanyl sulfonate, a chemical used to produce a range of products, including 3M's stain repellant Scotchguard®, was found to persist in the environment, and to accumulate in human and animal tissues. The manufacturer conducted tests that identified toxic effects to developing animals at high doses. In consequence, EPA and 3M agreed that the chemical would be phased out on a voluntary basis. In October 2000, EPA proposed a "significant new use rule" to limit the introduction of new uses of the class of compounds,[156] perfluorooctyl sulfonates (PFOS).[157] In March 2001, EPA held a public meeting to hear the concerns of public commentors. It therefore would appear that EPA's efforts to regulate new uses of PFOS have been delayed, perhaps indefinitely; moreover, there is no indication that existing uses, other than those voluntarily withdrawn by 3M, will be examined. The pattern that emerges is an inability to regulate existing chemicals, even when they are found to persist in the environment and in humans, minus strong voluntary efforts by industry.

Recommendations

(1) Congress should enact the utility pollutants legislation that is needed for final action to sufficiently control emissions of mercury (as well as several other pollutants) from coal-fired power plants. Such legislation is important to protect children and future generations and to prevent the transport of mercury globally.

(2) EPA should stop encouraging mercury use by adopting an approved set of processes for containment and/or disposal of mercury wastes.

(3) The United States should establish a comprehensive approach for monitoring the food supply for dioxins and PCBs and should consider doing so for other POPs as well.

(4) EPA's authorities to regulate POPs should be strengthened. Congress could establish POPs (and possibly other classes of chemicals as well) as a category warranting the most stringent control. A good example for the need for such control is mercury. Through EPA's PBT task group, the Agency is employing scattered authorities under TSCA, RCRA, the CWA, and the CAA to reduce mercury

151. Public Health Service, U.S. Department of Health and Human Services, National Toxicology Program, 9th Report on Carcinogens (Revised) (2001).

152. PBT Accomplishments, *supra* note 144.

153. Binational Strategy, *supra* note 15.

154. PBT Accomplishments, *supra* note 144.

155. K. Hooper & T.A. McDonald, *The PBDEs: An Emerging Environmental Challenge and Another Reason for Breast-Milk Monitoring Programs*, 108 Envtl. Health Persp. 387 (2000).

156. This class includes perfluorooctanesulfonic acid (PFOSA) and certain of its salts, perfluorooctanesulfonyl fluoride (PFOSF), certain higher and lower homologues of PFOSA and PFOSF, and certain other chemical substances, including polymers, that contain PFOSA and its homologues as substructures.

157. Perfluorooctyl Sulfonates; Proposed Significant New Use Rule, 65 Fed. Reg. 62319 (Oct. 18, 2000).

contamination to the environment. A stronger TSCA with a clearer focus on risk reduction could achieve this goal more effectively.

(5) The United States should continue international cooperation, particularly with Canada, Mexico, and Russia, aimed at the reduction of global pollution attributed to POPs.

Biotechnology

GMOs are increasingly the technology of choice for the manufacture of chemicals and pesticides. As noted in Agenda 21, the production of chemicals and pesticides by plants holds promise to be cleaner and more specific, and to use more benign inputs, compared to production in factories. However, there is also the potential for gene spread into other crops and weeds, adverse impacts on nontarget organisms, and inadvertent contamination of the food supply or the environment. It will be important to follow a precautionary approach to ensure against irreversible damage. This section reports on where this is (and is not) the case in the United States post-1992.

Neither TSCA nor FIFRA include a word specifying how EPA should approach the regulation of GMOs. Under the federal coordinated framework for biotechnology,[158] EPA has patched together an approach, based on its authority to regulate new chemicals under TSCA and the pesticide registration and tolerance rulemaking authorities granted under FIFRA and the FFDCA. Microorganisms and plants that produce food additives, vaccines, and pharmaceuticals are regulated under the authority of the FDA. All plants are regulated by the USDA.[159]

One area in which EPA has made significant progress is the regulation of new GMOs that produce or are used as chemicals under TSCA.[160] Such products are assuming a greater share of the market. An important aspect of the Agency's rule was identification of organisms with the potential for pathogenicity or for adverse ecosystem effects. However, EPA has yet to clearly articulate its policies for the regulation of chemical production by agricultural plants, a new and rapidly growing technology.

In addition, EPA, in 2001, issued a final FIFRA rule governing the regulation of PIPs.[161] The rule establishes regulatory procedures under FIFRA and the FFDCA for the evaluation of pesticides that are incorporated into plants using the techniques of biotechnology. These safety evaluations include consideration of both the environmental and the health impacts of geneticially modified products. In 2000, the NAS listed what those hazards would be.[162]Among the ecological risks are impacts on nontarget organisms, gene flow to weeds or other crops, and the possible development of pesticide-resistant organisms. The health risks include allergenicity, toxic compounds in plants, and the potential for long-term health impacts. EPA's assessment processes for PIPs intends to address all of these areas of risk.

EPA has approved nine PIPs, all since 1992; most of these are products which incorporated genes that encode bacillus thuringiensis (Bt) proteins, which are insecticidal toxins. One (Event 176) has been withdrawn from the market because it expressed high enough levels of Bt toxin in pollen to raise theoretical concerns for nontarget organisms such as monarch butterflies. A second, Cry 9C or StarLink®, was pulled from the market because of irresolvable concerns regarding potential allergenicity.[163]

The area of biotechnology is a large and rapidly evolving one, in terms of both the diversity of products that are coming forward from industry and the efforts by the United States and other governments to manage those products. EPA has not articulated an approach to address the production of chemicals in plants. Although there are few of these in development, industry is moving in the direction of producing all kinds of products in plants, including chemicals. EPA has not yet announced how it will exercise its authority in this area. It could be expected that such plants could have many of the same potential hazards as PIPs (except pesticide resistance) and in addition could pose unique potentials for environmental contamination in the life cycle, including groundwater and waste issues. These plants are regulated as "agricultural pests" under the PPA[164]; however, the USDA does not have authority under the legislation to protect the health of people and the natural environment.

In the case of PIPs, the United States has elected not to label foods that are derived from GMOs, whereas the EU is labeling these foods.[165] The articulated basis for this decision has been that the food safety regulatory framework is based on assuring that food is safe, rather than on allowing unsafe food to be marketed (and labeling it as such).

In addition, as noted hereinbelow, the Convention on Biological Diversity has adopted the Cartagena Biosafety Protocol,[166] which incorporates elements of both risk assessment and the precautionary principle by establishing a notification scheme for trade in genetically modified living organisms and seeds. EPA is not cosignatory to the Biodiversity Convention, and therefore cannot be a Member of the Biosafety Protocol.

While EPA has made much progress with the regulation of biotechnology products, there is reason for concern about whether the current approach is adequate in terms of reflecting the precautionary principle, in providing information to the public, and in fostering appropriate international institutions.

Recommendations

(1) It is time to revisit this framework for the regulation of biotechnology, to assure that it will cover the products that are on the market today, and those that are in research and

158. White House Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology: Announcement of Policy and Notice for Public Comment, 51 Fed. Reg. 23302 (June 26, 1986).

159. The USDA regulates such "plant pests" under the PPA.

160. Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act; Final Rule, 62 Fed. Reg. 17909 (Apr. 11, 1997).

161. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37771 (July 19, 2001).

162. NRC, Genetically Modified Pest-Protected Plants: Science and Regulation (2000).

163. L. Bucchini & Lynn R. Goldman, *Starlink Corn: A Risk Analysis*, 110 Envtl. Health Persp. 5 (2002).

164. 7 U.S.C. §7702(14); 7 C.F.R. §340.1.

165. European Commission, Regulation (EC) No. 2000/49 (2000); European Commission, Regulation (EC) No. 1139/98 (1998).

166. United Nations Environment Programme, Cartegena Protocol on Biosafety to the Convention on Biological Diversity.

development. EPA needs to be adequately prepared for the new wave of plants that will be developed to produce (or act as) chemicals. Likewise, FDA needs to be better equipped to take similar decisions regarding plants that are genetically modified to manufacture vaccines and pharmaceuticals. Although these products would seem to be benign, their dispersal—especially of pharmaceuticals—in the environment has the potential to create hazards for wildlife and human health (if for example, they were to create antibiotic resistant microbes in the environment).

(2) EPA should assert clear authority under TSCA to regulate the production in plants of "new" or "existing" chemicals regulated by the Act.

(3) The United States should seriously consider whether a labeling approach might have a place in enhancing consumer confidence in, if not the safety of, such foods.

(4) The United States ought to be a full participant in addressing legitimate international concerns regarding the potential for the development of risky plant biotechnology products.

International Conventions/Activities Regarding Chemicals

Generally, international conventions and activities are intended to address the specific goals of Agenda 21. This section describes progress in this area and the role of the United States as a participant.

OECD Harmonized Test Guidelines

The OECD has adopted a set of internationally harmonized test guidelines for assessing health and the ecological hazards of chemicals. Such harmonized guidelines are a fundamental basis for the development of international understandings on the hazards of chemicals to health and the environment. They also are important in minimizing the use of test animals for approvals by eliminating the necessity for duplicative testing between countries (on, for example, different species of rodents, birds, and fish). EPA has adopted these harmonized guidelines, for both pesticides and industrialized chemicals. This agreement addresses one of the harmonization actions recommended in Chapter 19 of Agenda 21.

Globally Harmonized System (GHS)

The International Labor Organization (ILO), the OECD, and the U.N. Committee of Experts on Transport of Dangerous Goods (UNCETDG) have completed the technical basis for the GHS for the classification and labeling of chemicals. The United States played an important role in the development of the technical framework for classification. In July 2001, work began on the development of a globally harmonized labeling process. This effort is directly in response to action agreed in Chapter 19 of Agenda 21 and at this point appears likely to succeed.

Recommendation

The United States should play a leadership role in the development and adoption of the GHS. It can be expected that the GHS will reflect elements of the current U.S. system but will also include elements from other systems that exist in Australia, Canada, Europe, and Japan (and possibly other countries). Inevitably, certain segments of U.S. industry, as well as entrenched bureaucracies, will attempt to block and later will resist adoption of the GHS.

Rotterdam Convention on Prior Informed Consent

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was signed in 1998, two years before the date identified in Chapter 19 of Agenda 21. The convention requires that chemicals and pesticides that have been added to the convention because they are banned or severely restricted in at least one country in each of two regions shall not be exported unless explicitly agreed by the importing country. It also includes pesticide formulations that are too dangerous to be used in developing countries. The Rotterdam Convention will come into force 90 days after 50 countries have ratified it; until then, an interim voluntary procedure is being applied. The FAO and UNEP jointly provide the secretariat to the Rotterdam Convention as well as the interim procedure. The United States has signed but has not yet ratified the agreement. (At this writing, there are 73 signatories and 17 parties to the convention, so it is not yet in force.) This effort was in direct response to a goal in Chapter 19 of Agenda 21.

Recommendation

The United States should promptly step forward to ratify the new convention on prior informed consent (PIC). Once the Conference of Parties (COP) is in place it will be possible to address the Agenda 21, Chapter 19 goal of preventing illegal international traffic in toxic and dangerous products.

Stockholm Convention on Persistent Organic Pollutants

In May 2001, the Stockholm Convention on Persistent Organic Pollutants was signed by the Parties. The treaty takes measures to protect health and the environment from 12 POPs or groups of POPs, includes provisions to add additional POPs to the treaty and prevent the introduction of new POPs into commerce, and provides for technical and financial assistance to developing countries and countries with economies in transition. It will come into force three months after 50 countries have ratified the agreement. At this time, 110 countries have signed, including the United States. Two countries have ratified, Canada and Fiji. This agreement addresses one of the risk reduction actions of Chapter 19 of Agenda 21.

Recommendation

The United States should act promptly to ratify the new convention.

Cartagena Biosafety Protocol of the Biodiversity Convention

In 2001, the COP of the Biodiversity Convention adopted the Cartagena Protocol on Biosafety.[167] This protocol sets up an international framework for managing the trade of GMOs and seeds. Once it is in place, countries will be able to use a combination of risk assessment and the precautionary principle to make decisions about whether to accept the import of such products. In addition, the protocol will seek to develop a databank on the genetics of plants grown for foods, and closely related weeds, to provide tools to assist nations in protecting biodiversity by preventing the interbreeding of GMOs with native plants. The United States is not a party to the biodiversity convention, yet is the world's largest developer of GMOs.

Recommendation

The United States should join the Biodiversity Convention, including the Cartagena Protocol. U.S. expertise on biotechnology is needed for proper implementation of the Biosafety Protocol.

Intergovernmental Forum on Chemical Safety (IFCS)

The IFCS was created by the International Conference on Chemical Safety held in Stockholm in 1994. The forum acts as a noninstitutional arrangement for representatives from governments, NGOs, and intergovernmental organizations for the promotion of chemical risk assessment and the environmentally sound management of chemicals. The World Health Organization serves as the administering agency for the forum and its secretariat. The U.S. government has played an active role in the IFCS's efforts to implement Chapter 19 of Agenda 21. The IFCS plays a number of coordinating functions for other global efforts such as the GHS, the process that led to the PIC Convention, and the process of doing assessments that led up to the POPs Convention. The 82 countries that participated in the third IFCS forum in October 2000 adopted the Bahia Declaration, which called for a number of new priorities for international chemical safety in the future.[168] The first goal is promotion of global cooperation for chemicals management, pollution prevention, sustainable development, and cleaner processes. The IFCS also stressed information flow, capacity building, and ratification of chemical conventions and agreements (including international action on illegal trafficking in chemicals). Increasing right-to-know and community participation was also a major goal. The Bahia Declaration set forth a timetable for achieving various actions in the next decade, which should serve as a basis for further work on international chemical safety.[169] It is clear that the strengthening of national capabilities and capacities for the management of chemicals called for in Chapter 19 of Agenda 21 has not yet been achieved. This is not surprising, given the breadth of the goal.

Recommendation

The United States should actively assist developing countries in the responsible management of chemicals. The Bahia Declaration sets forth a number of challenges for such capacity building in the next decade. If the United States fails to play a significant role, it again risks being left behind and losing not only in terms of environmental objectives but also in the area of leadership in chemicals expertise.

---

167. *See id*.

168. Intergovernmental Forum on Chemical Safety, IFCS/FORUM III/23w, *Bahia Declaration on Chemical Safety*, *in* THIRD SESSION-FORUM III FINAL REPORT (2000).

169. Specifically, countries made the following commitments:

> By 2001:
>
> The Convention on Persistent Organic Pollutants will have been adopted.
>
> By 2002:
>
> Most countries, through a multi-stakeholder process, will have developed a National Profile on chemicals management, ensured national coordination for the sound management of chemicals and designated an IFCS National Focal Point.
>
> Seventy or more countries will have implemented systems aimed at preventing major industrial accidents and systems for emergency preparedness and response.
>
> Poison centers will have been established in 30 or more countries that do not have such centers and further strengthened in at least 70 more.
>
> By Forum IV in 2003:
>
> The Rotterdam Convention will have entered into force.
>
> The GHS will have been adopted.
>
> An effective Information Exchange Network on Capacity Building for the Sound Management of Chemicals will be operating.
>
> The Forum will consider recommendations for prevention of illegal traffic in toxic and dangerous products, and countries will have elaborated their national strategies.
>
> A report will have been prepared on the problem of acutely toxic pesticides and severely hazardous pesticide formulations and recommending sound management options.
>
> All countries will have reported on risk reduction initiatives they have taken on other chemicals of major concern.
>
> By 2004:
>
> Recommendations to establish common principles and harmonized approaches for risk methodologies on specific toxicological endpoints will be available.
>
> An additional 1,000 chemical hazard assessments will have been completed and made available to the public in a timely manner.
>
> Most countries will have procedures in place to ensure that hazardous materials carry appropriate and reliable safety information.
>
> Most countries will have integrated and ecologically sound pest and vector management strategies.
>
> Most countries will have established action plans for safe management of obsolete stocks of pesticides and other hazardous chemicals and at least two countries in each IFCS region will have commenced implementation of their action plans.
>
> Following its adoption in 2001, the Convention on Persistent Organic Pollutants will have entered into force.
>
> At least two additional countries in each IFCS region will have established a PRTR or emissions inventory.
>
> By 2005:
>
> At least five countries in each IFCS region will have full arrangements in place for the exchange of information on hazardous chemicals.
>
> Most countries will have developed national policies with targets for improving the management of chemicals.

Id.

North American Commission on Environmental Cooperation (CEC)

The CEC is a regional organization that was established as one of the side agreements of the North American Free Trade Agreement. Under the auspices of the CEC, there are a number of cooperative efforts, including one pertaining to the Sound Management of Chemicals. The most significant activities include North American Regional Action Plans (NARAPs) for a number of POPs chemicals (most notably, PCBs, DDT, and chlordane) and the establishment of the PRTRs, which at this time primarily involves the United States and Canada although Mexico is developing capacity in this area. This effort addresses areas of risk reduction and strengthening national capabilities and capacities, as identified in Chapter 19 of Agenda 21.

Conclusion

With regard to chemicals, it is impressive that EPA has accomplished much with a very outmoded statute, TSCA. EPA has been creative in the use of this law; however, it fair to state that the results have come nowhere close either to the original congressional intent or to the goals of sustainable development (which are quite similar). It is clear that TSCA, a statute over 25 years old, needs reauthorization. Although Congress has shown little interest in doing so, there are many examples of sections that need to be reformed and strengthened. Probably the weakest area concerns the management of risks from chemicals. Because of the Act's inadequate coverage, when EPA is confronted with new risks, such as PBDEs or PFOS, it is unable or unwilling to take action to reduce risks, unless industry is willing to step forward voluntarily on its own. TSCA currently places too high of a bar for EPA to jump to assure the health of the public and protection of the environment. Under TSCA, existing chemicals are assumed safe until proven guilty, even when found in breast milk and even as toxicology evidence accumulates. New chemicals are barely assessed. Thus, the responsibility for precaution and sustainability, when it comes to chemicals that already are on the market, is almost completely in the hands of industry. While there are many good examples of industry coming around to a precautionary approach through voluntary efforts, there needs to be a strong regulatory "floor" underpinning such efforts.

In the area of pesticides regulation, the United States made great progress with the enactment of the FQPA; however, it remains to be seen whether this laudable legislation will be fully implemented. The tools that were adopted in the FQPA, for assessment of cumulative and aggregate risk and for the protection of children, should be transferable to the risk assessment and decisionmaking processes for other EPA statutes, including TSCA (as well as for regulation of air, water, and waste).

For both chemicals and pesticides, better metrics are necessary to monitor the success (or failure) of regulatory efforts. We know very little about human and environmental exposure to pesticides and chemicals and we do not track successes of our efforts on a performance basis. In addition, we know very little about use patterns of chemicals and pesticides and thus are unable to directly assess the decisions that are being made by industry.

Another general issue that has come to the fore more recently is animal rights. EPA had long ignored the concerns of animal rights activists, until they recently emerged to criticized the proposed HPVC and EDST initiatives and began to question testing under FIFRA as well. EPA is now, appropriately, reviewing testing requirements to identify ways in which to reduce the numbers and suffering of animals used in testing. In the future, EPA and the other federal agencies that use toxicology will need to work together to aggressively address the animal rights issue. The Interagency Coordinating Committee for the Validation of Alternative Test Methods has established a framework for these efforts.

In the international arena, the U.S. government is at this point well positioned when it comes to chemicals and pesticides. Generally, the United States has been at the table for negotiations and has been among the world's leaders in developing and adopting international standards for chemicals. However, there are a number of near-term challenges. The United States should promptly step forward to ratify the new conventions on PIC and POPs. Although neither of these would appear troublesome, the United States has an unfortunate history of failing to ratify conventions, thus allowing them to evolve further without full input. In the longer term, the United States needs to recognize that many of the major chemical risks today do not respect boundaries.

In addition to a number of specific recommendations set forth in earlier sections, there are five general actions that the United States needs to undertake.

General Recommendations

(1) With the adoption of aggregate and cumulative risk assessment tools for pesticides, the United States should consider how these tools could be extended to the regulation of chemicals and to other statutes that regulate chemicals and pesticides as pollutants. For example, how will drinking water standards incorporate cumulative and aggregate risk and risks to children?

(2) The recent Centers for Disease Control environmental report, which monitors levels of chemicals in people on an annual basis, is a starting point for beginning to establish a system of performance indicators to track the success of exposure reduction efforts.

(3) Both TSCA and FIFRA could benefit from incorporation of stronger reporting requirements about the use of chemicals. In the case of TSCA, consumers and regulators would benefit from more information about where chemicals are in commerce and in products, as is already reported in certain states, e.g., Massachusetts and New Jersey. This could be provided broadly, without threatening business secrets. Nor would it be necessary to require a level of detail that would be excessively burdensome. In the case of FIFRA, a national system of pesticide use reporting, modeled on existing systems in Arizona, California, New York, and other states, would serve a similar purpose.

(4) With the availability of new approaches to toxicology that will use our newfound knowledge of the sequence of the human genome and evolving knowledge about protein structures (genomics and proteomics), it may be possible to develop and validate new in vitro methods that will replace

some of the earlier animal tests. Such advances would not only provide benefits for animal welfare but also would speed the assessment that is needed of the thousands of chemicals with unknown toxicity.

(5) The United States should actively and willingly assume its share of the responsibilities for assuring global chemical safety. While the United States has been influential in developing agreements, it has been slow to ratify them.

Table 1: Regulatory Status of the "Top Ten" Carcinogens in the Diet as Identified in 1985 by the National Research Council

Pesticide	Reregistration Start	RED Issued	Tolerance Reassessment	Notes
Captafol	NA	NA	21 tolerances 18 revoked	Complete by 1992. This pesticide was first considered cancer causing in 1984. A special review ended after the registrant voluntarily canceled all uses in 1987.
Captan	1986	1999	66 tolerances 6 raised 6 same 47 lowered 7 revoked	The pesticide was first considered cancer causing in 1980. A special review resulted in the cancellation of some registered uses in 1989. In 1999, EPA canceled uses on turf, other than golf courses, sod farms and wettable powder and modified other tolerances.
Chlordimeform	NA	NA	NA	Complete by 1992. The pesticide was first classified as cancer causing around 1985. Although EPA planned to put chlordimeform into special review, the registrant voluntarily canceled all uses of the pesticide before the review formally began.
Chlorothalonil	1984	1998	38 tolerances 37 the same	The pesticide was first classified as cancer causing in 1987. In 1998, EPA and the registrant agreed to phase down the concentration of carcinogenic HCB in the pesticide to 40 ppm by 2003. They agreed to a number of measures to protect pesticide handlers and wildlife, and to eliminate products for home lawns and over the counter sales in retail outlets, that might expose children.
Folpet	1987	1999	10 tolerances 1 raised 5 the same 4 lowered	The pesticide was first classified as cancer causing in 1986. By 1999, EPA and the registrant had agreed that only uses on avocados and in coatings and sealants would be supported. Moreover, measures were taken to further protect workers and wildlife for these few remaining uses.
Linuron	1984	1995	55 tolerances 15 revoked	This pesticide was first considered cancer causing in 1982. A special review completed in 1989 concluded that the pesticide's ability to cause cancer was weak, and no uses of this pesticide were canceled. In April 1995, EPA issued a reregistration eligibility document that did not continue uses on cotton, non-cropland, sweet corn, and potatoes.
Mancozeb	1987	?	45 tolerances 0 reassessed	This pesticide was first considered to be cancer causing in 1970. A special review, which ended in 1982, resulted in some risk-reduction measures. As a result of a second special review, which was completed in 1992, EPA canceled uses on some crops. For the remaining crop uses, the Agency has not yet completed its review of studies, including additional data requested in 1995.
Maneb	1988	?	42 tolerances 2 revoked	This pesticide was first considered cancer causing in 1970. A special review, which ended in 1982, resulted in risk-reduction measures. Because of a second special review, which was completed in 1992, EPA canceled uses on some crops. In 1998, EPA requested additional data for maneb.
Permethrin	1989	?	63 tolerances 0 reassessed	This pesticide was first considered cancer causing in 1986. EPA has not yet completed its review of the studies, including additional data requested in 1995.
Zineb	NA	NA	NA	This pesticide was first considered cancer causing in 1970. Zineb underwent two special reviews. The first, which ended in 1982, resulted in measures designed to reduce risk. During the second special review, which ended in 1992, the registrant voluntarily canceled all uses.

Table 2: EPA Application of Additional FQPA Factors (to assure safety to children): 1996-2000.[170]

Type of Pesticide Reviewed	Number Reviewed	No Additional Factor	3-Fold Factor	10-Fold Factor	>10-Fold Factor
Organophosphates	39	15	12	10	2
All Others	66	41	11	11	3
Total	105	56	23	21	5
Percentage		53%	22%	20%	5%

170. CHILDREN AND PESTICIDES, *supra* note 135.