

PRECAUTIONARY APPROACHES TO PERSISTENT ORGANIC POLLUTANTS AND OTHER PROBLEMATIC CHEMICALS: EXAMPLE OF EMERGING EUROPEAN INTEGRATED CHEMICALS POLICIES

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Introduction

During the past half-century, thousands of chemical substances have been developed and put into commerce, including many everyday products, often with little information or consideration about their environmental or health implications. The result is that there is a growing body of evidence that links exposure to these materials and various adverse health effects. *For the large majority of chemical substances, however, there is little or no information on their health implications.* Studies conducted by both the U.S. Environmental Protection Agency and the European Chemicals Bureau in the late 1990s identified the serious lack of information about the toxicity of chemicals on the market today.^{1,2} Even less is known about chemicals produced in smaller volumes or mixtures of chemicals. Yet, this lack of evidence of toxicity is often misinterpreted as evidence of safety.

International voluntary testing programs for high production volume chemicals and other chemicals of concern are a step in the right direction, but slow and insufficient to protect health and the environment. While data are being developed, the status quo – allowing exposure to continue – is maintained. Even when this basic toxicity information is developed it still must be fed into a time-consuming regulatory system whereby the burden often rests on government agencies to conclusively demonstrate the risks each individual substance poses to health or ecosystems before preventive action can be taken. This is particularly problematic for persistent organic pollutants (POPs), which can persist and potentially cause adverse environmental and health effects far into the future. While collecting more data – on chemical toxicity, human body burdens and exposure - is critical to understanding how chemicals can affect human and ecosystem health, study alone will not prevent harm.

The regulation of chemicals in Europe and the United States has been reactive in nature, often responding to well-established problems by managing or reducing exposure to harmful chemicals rather than stimulating the development of safer and cleaner chemicals, production systems, and products. Regulations requiring testing and assessment of chemicals that have come on the market since the 1980s have been regarded as effective in limiting risks posed by new chemical substances. But these regulations have failed to address the risks posed by existing chemical substances, which constitute more than ninety-nine percent by volume of chemicals on the market today.^{3,4} For these chemicals, which arguably pose the greatest risks to health and the environment, governments have been able to restrict their use only after it is demonstrated that each chemical is harmful to human health. There is growing recognition that chemicals used in everyday products – which can be widely dispersed in the environment and pose significant risks to humans and ecosystems– have been largely ignored in chemicals regulation to date.

Acknowledging these problems of current chemicals management policies, the European Union and its Member States have embarked on a fundamental restructuring of chemicals management policies to address major limitations in existing chemicals regulations. This is the result of a vigorous and detailed debate in Europe on the development of an integrated chemicals policy. Such discussions are also occurring in the international community through discussions to implement the Stockholm Convention on Persistent Organic Pollutants and subsequent United Nations programs on persistent toxic substances.

This article presents the results of an eighteen month analysis of emerging integrated chemicals policies in Europe and internationally. It presents the scope of those policies as well as their strengths and limitations.

Methods and Materials

To develop an in-depth understanding of the drivers, scope, and implementation of chemicals policies in Europe, we conducted in-person or telephone interviews with approximately 100 experts from industry, government agencies, academia, and non-governmental organizations in eight countries. We collected relevant government and stakeholder documents through database and World Wide Web searches as well as direct contacts with authors. We also participated in three conferences in Europe on emerging chemicals policies to understand stakeholder positions and specific implementation. Notes from interviews and documents were analyzed by the authors based on pre-identified key analysis questions.

Results and Discussion

The impetus in Europe for a broad integrated chemicals policy comes from its member states – particularly Sweden, Denmark, the Netherlands, the United Kingdom and Germany – who, over the past decade, have developed their own chemicals policy initiatives.^{4,5,6} Because trade in chemicals is international in nature, European legislation determines to a great degree what individual member states can do with respect to regulatory chemical restrictions and phase-outs.

The Nordic countries – Sweden, Denmark, and Norway - have long set the standards for international chemicals policy debates. Their concerns over chemicals involve the contamination of waterways caused by persistent and bioaccumulative pollutants, as well as chemical exposures from everyday products. Two underlying principles of Nordic chemicals policies are: (1) substitution – the idea that if there is a safer feasible alternative to a potentially harmful chemical, it should be used; and (2) precaution, that action should be taken in cases of potential long-term and serious negative impacts even though the nature and magnitude of risks are not fully known. Another driver of these policies are long-term political commitments to environmental quality improvement and progressive reduction of hazardous chemicals - the so-called Generational Goal. Specific aspects of the Nordic policies include:

- A focus on products and product lifecycles for risk reduction. It is critical that chemicals policies address product exposures and be integrated with a product policy.
- Rapid screening processes. Authorities are trying to use whatever information is available to build a profile of the substances' hazards and to quickly prioritize chemicals for reductions rather than waiting for complete information.
- Establishment of "lists of concern". Several countries have established lists of chemicals of concern – in Denmark this is called the "list of undesirable substances". Government authorities then work with businesses and procurement agencies to assist them in avoiding these chemicals.
- Phase-outs of harmful chemicals. Some national governments have set a series of political goals to phase out problematic chemicals and those that are unstudied.

- Development and adoption of safer products through clean technologies and substitution. These countries are providing technical support and initiating demonstration projects on alternatives as a critical step in developing safer alternatives.

Following several years of debate, in 2001 the European Commission issued its “White Paper on a Future Chemicals Strategy”, outlining the Commission’s intentions for a fundamentally new integrated chemicals policy. The overarching goals of the policy are the protection of health and promotion of a non-toxic environment, while preventing fragmentation of the internal European market, avoiding barriers to trade, and enhancing the innovation and competitiveness of European industry.⁴

The White Paper emphasizes both increased testing of all chemicals and management of particular high hazard chemicals. It aims to bridge the knowledge and management gap between new (usually more thoroughly tested and managed) and existing chemicals by eliminating this distinction. Specific objectives include:

- Making industry responsible for generating knowledge on chemicals and maintaining safety;
- Extending responsibility for testing and management along the manufacturing chain;
- Substitution of substances of very high concern and innovation in safer chemicals; and
- Minimization of animal testing.

The centerpiece of the White Paper is the establishment of a new integrated chemicals management scheme for the European Union called the REACH (Registration, Evaluation and Authorization of Chemicals) process. The REACH process contains the following elements:

- Registration – All chemicals in commerce produced over one ton per year (some 30,000 substances) must be registered or risk being prohibited from the market. Manufacturers and importers of chemicals will be required to submit a registration dossier including data on identity and properties of substances; intended uses and exposures; preliminary risk assessment for intended uses and disposal; and proposed risk management measures. The registration will require basic ecological and human toxicity testing, which will be tiered based on production volume. Registration exemptions will be allowed for some chemical intermediates and research and development. The testing requirements are to be flexible in nature, designed to obtain key hazard and exposure information, allowing companies to enter into consortia to prepare data
- Evaluation – Chemicals produced over 100 tons per year and those of particular concern will undergo an evaluation process. The evaluation will include the development of substance-tailored testing programs and, if necessary, accelerated risk reduction measures.
- Authorization – Chemicals of greatest concern based on their inherent hazardous characteristics will have to undergo an authorization process to continue their use much like regulations on pharmaceuticals. Authorization will be made on a case-by-case basis considering risk, socio-economic impact, necessity, and economic and technical feasibility of alternatives. Authorization will initially apply to approximately 1,400 chemicals that are known or highly suspected carcinogens, reproductive toxicants or mutagens, as well as persistent organic pollutants (POPs). This list has been expended to include substances that are persistent, bioaccumulative and toxic (PBTs) or highly persistent and bioaccumulative (vPvBs), and other substances of high concern once criteria are developed (such as sensitizers and chemicals that disrupt the endocrine system)

The fundamental restructuring of chemicals regulation in the European Union is a monumental task many complex questions have come up during its drafting, including inclusion of downstream users and product manufacturers, access to information, and coordination of the program. The European Union is likely to finish draft legislation to implement REACH by summer 2003 with implementation following parliamentary and Council of Ministers debate for 2006. In the interim period the European Union is developing a strategy for addressing risks of PBTs and vPvB substances as well as working on the implementation of a key piece of legislation designed to reduce emissions of persistent chemicals into aquatic environments: the 2000 Water Framework Directive.

The new European chemicals policy proposals have to a great degree been shaped by obligations resulting from regional and global international treaties, agreements, and programs. The European Union has used these international venues as a means to support and strengthen their new policies; to harmonize international standards upwards; to “pull along” less advanced or more reactive European countries; and to protect the European Union from potential trade-related disputes as a result of chemicals restrictions. Some of the most important international treaties and programs influencing current European approaches to chemicals management, include: the Oslo and Paris Convention for Protection of the Marine Environment of the North-East Atlantic, the Stockholm Convention on Persistent Organic Pollutants, the Rotterdam Convention on Prior Informed Consent, and other United Nations sponsored programs such as the Global Mercury Assessment and the Intergovernmental Forum on Chemical Safety.^{8,9}

A sweeping change in chemicals management policies in Europe is inevitable. This new policy will require basic data on all chemicals in commerce, information on risks throughout chemical lifecycles, rapid evaluation of chemical risks, and substitution of those substances of highest concern, including persistent and bioaccumulative substances. There are some limitations in the proposed European policy, however, with regards to addressing substances in products, using a variety of regulatory and non-regulatory tools in implementation and providing support to stimulate development of safer chemicals and chemical processes. These limits as well as technical assistance to small and medium sized enterprises and support to developing countries to implement similar policies will need to be addressed if the emerging European policies are to have global impacts in reducing exposure to POPs and other persistent toxic chemicals.

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