

The Circuits of Regulation: Transatlantic Perspectives on Persistent Organic Pollutants and Endocrine Disrupting Chemicals

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In both Europe and the U.S., pesticide regulation has long been established as a legitimate field of public health and environmental protection. Many of the techniques and institutional frameworks of pesticide regulation are well established and shared on both sides of the Atlantic. Our preliminary research on pesticide regulation, however, pointed to two classes of chemicals that raise special problems for pesticide regulation and raise serious concerns for the protection of biodiversity and biosafety—“persistent organic pollutants” (POPs) and “endocrine disrupting chemicals” (EDCs). POPs are highly toxic chemicals that persist in the natural environment, accumulate in the food chain, and can be transported long distances (Adeola 2004). EDCs are chemicals that disrupt animal and human endocrine (hormone) systems, often with serious development consequences.

Although many pesticides are neither POPs nor EDCs (and vice versa), the chemical and environmental properties of these two chemical classes challenge traditional pesticide regulation strategies. The traditional approach establishes maximum residue levels for food and other products that ensure safe consumption. But this approach is not entirely satisfactory for POPs, because small amounts can persist in the environment and bioaccumulate, or for EDCs, which may have serious effects at very low doses. There also remains considerable uncertainty about how POPs and EDCs move through the environment and interact with other environmental pollutants. Another challenge is that standards for pesticides and toxics are set using a dose response model that assumes a linear relationship between the amount of a pesticide and its toxicological or carcinogenic health effects. However, the dose response effects of POPs and EDCs are poorly understood (Briggs 2006; Vogel 2004, 2005). That POPs may be EDCs and vice versa is of special concern (Yoder 2003).

These properties of POPs and EDCs present thorny issues for regulators on both sides of the Atlantic (Gee 2006; Solomon & Huddle 2002). As an emerging field of regulation, POPs and EDCs therefore present both a challenge to cooperative transatlantic relations and an opportunity for considerable policy learning. As one might expect, the lines of debate between Europe and the U.S. revolve partly around the advantages and disadvantages of the precautionary principle (Durodié 2003; Solomon & Huddle 2002). The possibilities for policy learning and cooperation, however, go considerably beyond this tension.

In this article, we suggest that emerging POP and EDC regulation must be understood in terms of a complex multi-level architecture of separate but interlinked regulatory sites that constitute contested arenas of cooperation, norms diffusion, and policy learning. The contestation of normative and operational principles in one arena often spills over into other arenas, encouraging multilevel action. Regulatory developments follow “circuits of regulation”—the complex patterns of influence and feedback between interlinked regulatory arenas. As a consequence, we rarely observe a linear progress toward the precautionary principle or science-based approaches, but instead a constant renegotiation of boundaries between them as well as a degree of hybridization produced by policy learning inherent in regulatory cooperation. The article analyzes the multi-level frameworks of regulation of POPs and EDCs through a focus on

federal relations within the European Union (EU) and the United States (US) as well as in multilateral and bilateral cooperation at the international level.

Circuits of Regulation

In order to understand the large and diverse universe of international chemicals management, it is useful to begin with an interpretation of regulation as an open-ended interaction between multiple parties operating across different arenas. For example, Scandinavian countries, who are quite active in international chemicals management, participate in regional forums such as the Arctic and Nordic Councils, regional multilateral environmental agreements (MEAs) such as the OSPAR Convention on the Protection of the Marine Environment of the North-East Atlantic, as well as at European Union, the United Nations, and the Organization for Economic Co-operation and Development (OECD). This article will show that even relatively narrow issue areas such as POPs and EDCs can be subject to quite a variety of regulating activity. The concept 'circuits of regulation' captures the notion that many of the most important developments in regulation take place through the interaction of separate but overlapping regulatory arenas.

These arenas afford participating actors different levels of access, are governed by different decision making procedures and different norms of interaction, and have uneven capacities to make decisions stick (Eckley & Selin 2004; Kellow & Zito 2002). The OECD, for example, requires EU member states to participate individually, which creates opportunities for member states to escape EU constraints. The capacity of these arenas to serve as 'portals' for uploading or downloading particular logics of action (in strategic terms, 'venue shopping') therefore varies considerably. Whereas many studies have focused on the regulatory dynamics of "trading up" or "races to the bottom" in regulatory standards within federal or multilevel systems, our framework also emphasizes pathways of regulatory influence across boundaries (from the EU to the U.S., from the EU to California, or from EU members to the U.S.). This approach suggests that pathways of interaction are often quite complex.

Three conceptual themes guide our reading of the circuits of POPs and EDCs regulation: institutionalization, the interaction between "mature" and "emergent" regulatory frameworks, and hybridization. Institutionalization refers to the stabilization of normative interpretations, scientific discourse, and operational principles, as well as the establishment of concrete organizations, programs, and projects. Institutionalization plays a fundamental role in circuits of regulation because once stabilized in a given site, some problem definitions, causal explanations, and courses of action come to be seen as more appropriate than others. In a world of multiple, interacting sites of regulatory activity, however, institutionalization is never a linear process. Rather, normative and behavioral practices are constantly renegotiated as a result of influence from other sites, sometimes through adjudication but more often through joint participation of particular actors.

Second, "mature" and "emergent" regulatory systems interact in complex ways. Mature systems are those that have been extensively institutionalized. However, regulatory systems face constant pressure to adapt to scientific or technological change and must constantly adapt to new risks. How "emergent" regulatory concerns interact with "mature" systems is an important issue. In mature regulatory systems, such as those that exist at the national level, we expect to see attempts to fold new areas of regulatory concern—like POPs and EDCs—into existing regulatory frameworks. Where regulatory frameworks are less mature, we expect to see more customized programs. For example, the novel quality of POP and EDC regulation is compounded at the EU

level, where regulatory programs for controlling toxics, pesticides, drugs, air and water pollution, and hazardous waste are themselves in a formative phase.

Finally, hybridization is the juxtaposition or integration of different regulatory logics within the same arenas. Hybridization occurs through various mechanisms, but particularly through the interpenetration of horizontal and vertical levels or regulatory cooperation (Weiner 2003). Policy cleavages at subnational and federal levels are ported to the international level, where different international institutions serve the interests of different federal and subnational interests. In the case of POPs and EDCs, actors promoting stricter chemicals regulation in general, and the precautionary principle in particular, have sought support in MEAs (Stockholm, Rotterdam, Basel), whereas actors primarily concerned with economic competitiveness have aligned themselves with the efforts of such organizations as the OECD. Negotiation within any one arena, however, tends to produce complex juxtapositions of regulatory principles rather than pure forms.

Analyzing international chemicals management through the lens of ‘circuits of regulation’ helps explain the sometimes contradictory results in the comparative regulation literature, particularly regarding divergence between EU and US views of the precautionary principle. Whereas several authors have challenged the conventional wisdom that EU and US risk regimes are diverging, their arguments are often based on different cases or types of risk or the difference between risk assessment and risk management (Eckley & Selin 2004; Vogel 2003; Weiner 2003). In European chemicals reform, Pesendorfer (2006) suggests that the precautionary principle started giving way to “no data - no problem” approaches, whereas Andersen and Liefferink (1997) argue that the OECD has aided the development of the precautionary principle in international law.

POP and EDC Regulation in the United States and Europe

It would be difficult to canvas the full range of POP and EDC regulatory activity in the United States and Europe. For the U.S., we first focus on programs administered by the Environmental Protection Agency. Then, to capture the important federal dimension of environmental regulation in the U.S., we examine the case of California, which is regarded as an environmental vanguard within the federal context. We then turn to the Europe, where we focus on regulatory developments in the European Union.

United States

POPs and EDCs may be pesticides, industrial chemicals, by-products of industrial processes, or drug residues. As such, they are regulated through any number of laws and regulatory programs. In the U.S., the basic legal frameworks are the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Clean Water Act (CWA), the Clean Air Act (CAA), the Federal Food, Drug, and Cosmetics Act, and the Resource Conservation and Recovery Act (RCRA). These laws have spawned relatively mature (though not necessarily effective) programs for regulating toxics, pesticides, water and air pollution, consumer products, and recycling. Of the “dirty dozen” of POPs regulated under the Stockholm Convention on Persistent Organic Pollutants, nine are pesticides prohibited under FIFRA (aldrin,

dieldrin, chlordane, DDT, endrin, mirex, heptachlor, hexachlorobenzene, toxaphene), three are regulated as hazardous air pollutants under the CAA (chlordane, PCBs, toxaphene, dioxins, furans), five are regulated as priority toxic pollutants under the CWA (DDT, endrin, hexachlorobenzene, PCBs, dioxins), and one is prohibited under TSCA (PCBs) (EPA 2002).

To understand how the emerging concern with POPs and EDCs is handled within the context of these mature regulatory systems, it is useful to begin by examining the limitations of the Toxic Substances Control Act (TSCA). TSCA is the major regulatory framework for regulating chemicals in the U.S. The fact that only one of the current “dirty dozen” (PCBs) is regulated under TSCA is indicative of the limitations of this law as mechanism for regulating POPs and EDCs. One of TSCA’s major drawbacks as a chemical regulation framework is the huge backlog of chemicals to be tested, with new chemicals being constantly added to the backlog (Center for Occupational and Environmental Health 2008; Easthope & Valeriano 2007; Tickner et al 2005; Daub 2004). Tickner, Geiser and Coffin (2005) suggest that TSCA has been a relatively effective screening program for new chemicals (as opposed to existing chemicals). However, Easthope and Valeriano argue that TSCA has proved “essentially powerless” in regulating POPs (2007:201).

Under TSCA, industry does not have to test for environmental or health effects of new or existing chemicals, although the U.S. Environmental Protection Agency (U.S. EPA) can specifically require such tests through rule-making procedures and existing effects data must be submitted (GAO 2007; Phillips 2006). Requiring testing is generally a cumbersome process and the EPA has done this for only around 200 chemicals since 1979 (GAO 2007:9). As the General Accountability Office writes: “Partly because of the resources and difficulties the agency faces in order to require testing to develop information on existing chemicals, EPA has moved toward using voluntary programs as an alternative means of gathering information from chemical companies in order to assess and control the chemicals under TSCA” (GAO 2007:“highlights”). Tickner, Geiser, and Coffin (2005) point out that the EPA often lacks the basic data that would allow them to justify further industry testing.

The burden of proof for regulating or banning a chemical under TSCA is quite high. Section 6 of TSCA allows the EPA to regulate chemicals that pose an “unreasonable risk to health or the environment.” Since the passage of TSCA, however, the EPA has only restricted the use of five existing chemicals or chemical classes (polychlorinated biphenyls (PCBs), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium; GAO 2007:18). To meet this burden of proof and survive court scrutiny, the EPA must develop substantial evidence. It must also demonstrate that a ban on the chemical is the least burdensome alternative, which is difficult to demonstrate (as illustrated by the court’s rejection of the EPA’s asbestos rule).

As the result of these regulatory limitations, TSCA plays a limited role as a framework within which to regulate POPs or EDCs. In the case of POPs, the EPA has sought to create a special “cross-media” (e.g., air, water, land, etc.) program to address this group of chemicals. Building on the Canada-U.S. Binational Toxics Strategy, the EPA established a strategy to regulate “Priority Persistent, Bioaccumulative and Toxic” (PBT) pollutants in 1998 (Hagen & Walls 2005; US EPA 2001, 1998). One of the main purposes of the strategy is to coordinate EPA activities on particular priority pollutants that are regulated under a range of different laws and programs, which it does through the develop of national plans for priority PBTs. Although the EPA’s PBT strategy conceives of a process to identify additional priority PBTs, it has initially focused on the 12 Stockholm Convention pollutants and has initiated national planning for only three chemicals beyond the 12 Stockholm POPs: mercury, alkyl-lead, and octochlorostyrene

(EPA 2008). Under RCRA, however, the EPA has developed a list of 31 (from a draft list of 53) high priority pollutants and recommended a 50% reduction in hazardous waste of these pollutants by 2005. The 31 pollutants include 28 organic compounds (27 of which were identified as PBTs) and 3 metals (cadmium, lead, and mercury). This waste minimization program is voluntary. Under the EPA's "Chemical Right to Know Initiative" the EPA has also developed a "PBT Chemical Reporting" program (Tickner et al 2005). Thus, beyond the limited regulation of POPs within the framework of TSCA, the EPA's role is mostly coordinative rather than regulatory.

FIFRA is generally regarded as a stronger regulatory framework than TSCA and has become the basis for regulating EDCs (Easthope & Valeriano 2007). An amendment to FIFRA, the Food Quality Protection Act of 1996 established an Endocrine Disruptor Screening Program (EDSP) for pesticides and non-pesticide chemicals. The EDSP uses a scientific testing paradigm similar to that used by TSCA, and thus faces many of the same criticisms. Vogel argues that the scientific testing program is particularly inappropriate for EDCs. Endocrine disrupters, he writes, break "...all the rules and assumptions that have guided toxicology through the era of modern chemical regulation" (Vogel 2005:1; see also Briggs 2006). He argues that the complexity of endocrine disruption is not well-suited for a scientific testing paradigm because their effects may manifest over longer time periods and at different stages in the life cycle of an organism. Classical toxicology may also be inappropriate because assumptions about 1) monotonic dose response, 2) uniformity of effect; and 3) thresholds effects do not necessarily hold with endocrine disrupters (the bottom line is that the complexity of endocrine disrupter cause-effect relationships foils the ability to have a straightforward testing program). The EDSP, he argues, has also become bogged down in validating special testing procedures for endocrine disrupters and the testing program is simply overwhelmed by the number of potential endocrine disrupters that would have to be tested (87,000 chemicals).

In 1998 the EPA launched a priority setting process to identify high priority chemicals for screening and testing. Priority-setting, however, is itself a difficult process because it means making informed judgments about priorities in a state of fairly high uncertainty and scarce information (Mariorowski & Timm 1999). Vogel argues that there is a "catch-22" in setting screening priorities, because the lack of basic information even makes it difficult to set priorities for further information collection (Vogel 2005). The EPA has developed two technologies to assist in screening. The first is called high-throughput pre-screening (HTPS). It is a high volume testing strategies to identify interactions between chemicals and estrogen, androgen, and thyroid receptors. The second approach uses computer modeling to simulate chemical behavior. Both of these approaches are useful, but limited, according to Vogel, because they test only for "receptor binding" (Vogel 2005:5). The U.S has also created an endocrine disrupter research inventory to track research and focus intergovernmental research efforts (Maciorowski & Timm 1999). A peer review of the EPA's endocrine disrupter research program argues that it is a generally well-conceived and organized research program (Harding et al. 2006). The EPA, however, has not really entered the stage of regulating endocrine disrupters, because it is still in the stage of developing screening and testing procedures (Vogel 2005). EPA announced it was ready to start testing dozens of suspected EDCs in 2007, but critics charged that the entire process had been compromised by chemical industry interference.

To conclude this section, POPs and EDCs are an emerging concern in the U.S., but programs to regulate these two chemical groups remain closely tied to mature regulatory programs.

California

California has a strong environmental tradition and often leads the U.S. on a range of environmental concerns, including chemicals regulation. The most famous—and some would say infamous—example is the “Safe Drinking Water and Toxic Enforcement Act of 1986,” better known as Proposition 65. California’s Proposition 65 is often seen as a powerful tool for protecting consumers against toxic chemicals. Under this law, the state must create a list of carcinogenic and reproductive toxics and inform consumers when they are potentially coming into contact with them. Prop 65 is often seen as a mechanism that has allowed California to act on toxic chemicals when the federal government has been slow to act (Rechtschaffen & Williams 2005). However, the National Resources Defense Council (NRDC) notes that many potential endocrine disruptors are not listed on the Prop 65 list (NRDC 2008).

In addition to regulation under Prop 65, POPs and EDCs could also be regulated by California’s pesticide regulatory program, which must be understood within the context of the structure of U.S. federal pesticide programs. Under FIFRA, the U.S. EPA has responsibility for regulating the registration, sale, and use of pesticides in the U.S. FIFRA, however, has a long history of policy turmoil and ineffectiveness that stem from the structure of the program, political conflict between agricultural and environmental interests, and the magnitude of the problem (Bosso 1987; Hoberg 1990). In this policy context, state pesticide programs often complement and extend federal regulation, sometimes creating more stringent programs for the registration, manufacture, and use of pesticides. California claims to have the strictest pesticide laws and regulations in the U.S and has a long history of enacting tougher pesticide regulatory standards than the federal government. After the revision of FIFRA in 1972, California created more stringent reporting requirements for registration of pesticides. The state was sued by the National Agricultural Chemical Association in 1980, which claimed that the federal law prevented states from imposing their own registration requirements. A federal district court ruled in favor of California.

In 1991, the pesticide program was given departmental status within the Cal Environmental Protection Agency (Cal EPA). The California Department of Pesticide Regulation (DPR) is a large and sophisticated regulatory agency that claims to be distinctive among American States: “California is the only pesticide regulatory program in the country with a large and highly regarded scientific and technical staff that evaluates toxicology, environmental and other data required for pesticide registration, and conducts comprehensive risk assessments, including assessment of dietary risk” (California Department of Pesticide Regulation 2001:11). The reason, DPR claims, is the scale and complexity of agriculture in California: “The agricultural chemical problems in California are more numerous and more complex than in most other states. Farmers of California produce more than 200 different commercial crops in a terrain that includes the highest and the lowest altitude in the United States” (California Department of Pesticide Regulation 2001:70). The State also uses a lot of pesticides, though use has stabilized at around 200 million pounds of active ingredients per year (PAN California Pesticide Use Data Base).

California’s regulations are “far more comprehensive” than EPA’s (California Department of Pesticide Regulation 2001, 45). “DPR requires efficacy data be submitted as part of an application for registration. U.S. EPA requires manufacturers to develop such data but waives its

submission, except for products with public health issues, such as disinfectants. DPR also sometimes denies registration to products approved by U.S. EPA. The Department may base such decisions on toxicology or environmental studies judged to be inappropriate or inadequate, label instructions that fail to mitigate possible hazards, or inadequate margins of safety.

Beyond pesticide regulation, the weakness of TSCA has encouraged California to consider regulations for EDCs in urban waste water recycling and to embark on a more precautionary “green chemistry” initiative (Center for Occupation and Environmental Health 2008; Wilson et al 2006). This initiative has looked to the EU’s REACH program for inspiration. In September 2008, Governor Schwarzenegger signed AB 1879, which gives the Department of Toxic Substances Control authority to create a process of identifying priority chemicals. The Department then has the authority to take a range of regulatory actions, including restrictions or a ban. In 2006, California also passed a bill (SB 1379) to establish the nation’s first bio-monitoring program to measure and catalogue human exposure to chemicals. The law is specifically concerned with the bioaccumulation of certain types of chemicals and requires Cal EPA to monitor the presence and concentration of designated chemicals in Californians. California also passed the first cosmetics safety law at the state level in 2005, which requires manufacturers to inform consumers of the use of potentially carcinogenic or reproductive toxins (Washam 2006). The law relies on Proposition 65’s list of toxic chemicals. Beyond its more assertive stance on toxics regulation, California has begun to show interest in adopting a more explicitly precautionary approach to regulation. The Cal EPA currently has a project on “Cumulative Impacts and Precautionary Approaches,” which is designed to make recommendations for how Cal EPA should utilize precautionary approaches.

California’s adoption of a more precautionary approach must be understood in terms of an interaction with the federal government’s “scientific testing” approach. The EPA’s slow testing regime has encouraged California to take the lead. A good example of this interaction is California’s recent ban of brominated flame retardants (BFRs), a class of chemicals known as PBDEs, a suspected endocrine disrupter (Hooper and She 2003). The EPA has often implicitly supported California’s actions and supported the BFR ban (Daub 2004). Daub suggests, in fact, that California’s ban on BFRs may have established a precedent for unilateral state action when the federal government is slow to act on POPs and EDCs. Daub speculates as follows: “Because the California legislation passed with no independent, validated, peer-reviewed scientific findings, and no impediment by the EPA or Congress, it may be an indication that the United States is beginning to lean towards a more precautionary model of risk management that more closely resembles that of its European counterparts” (Daub 2004:L347). He notes that because of the size of the California market, the California ban essentially becomes a national ban. He cautions, however, that with respect to POPs and EDCs “...there is a need for national uniformity, accountability, and authority to act internationally.” Easthope and Valeriano (2007) argue that EU efforts on PBDEs provided support for bans on PBDEs in California and other states.

In addition to the ban on brominated flame retardants, California was also the first state in the nation to ban several phthalates (DINP, DIDP, and DNOP) in toys and child care products (signed October 2007; takes affect January 2009). Several other phthalates are listed as Proposition 65 chemicals (DEHP, BBP, DBP, and DnHP). This is another case where California followed the European lead (Schapiro 2007). Since 1999, the European Union has imposed a temporary ban on phthalates in toys and child care products and since January 2007, the EU

banned three phthalates (DEHP, DBP, and BBP) in all toys and child care articles and three others (DINP, DIDP, and DNOP) in toys and child care articles that can be put in the mouth.

To conclude this section, chemical regulation in California reveals an interesting “circuitry” of influence. In the context of relatively weak U.S. federal programs, California has undertaken its own initiatives, and in doing so it has sometimes followed the lead of the EU.

European Union

A significant and increasingly differentiated literature attests to the fact that the European Union’s regulatory portfolio for environmental issues has experienced phenomenal growth during the last twenty years (Jordan 2005). The EU has also aspired to be a global environmental leader, although many have noted a growing mismatch between the EU’s pronouncements and its limited capacity to deliver (Chaban et al 2006; Holzinger et al 2006). Using the distinction introduced by Andresen and Agrawala (2002), the question is whether the EU is in fact a leader or a ‘pusher’ characterized by persistent but largely ineffectual negotiating efforts and public declarations.

Conceiving of the EU as a unified actor is an inadequate approach to understanding its engagement in today’s complex, multi-level regulatory architecture. The EU is a federal system consisting of a very diverse membership of 27 countries, each with different environmental priorities, capabilities, and internal divisions. The EU is also a party to most multilateral environmental agreements alongside its members, requiring a high degree of coordination. European Union institutions are subject to multiple cleavages, not only between Commission, Council, and Parliament, but also between Commission Directorates, between Parliamentary Committees, and between different Councils (Hey 2000). Finally, Europe’s chemicals industry has a strong influence on decision-makers and is highly involved in policy making, partly because it often possesses greater knowledge than public authorities about chemicals, products, and possible substitutes (Pesendorfer 2006; for a cautious view of industry impact, see Hough 2003). The complex decision-making procedures at the European level thus produce a veritable circuit board of regulatory possibilities.

The EU’s approach to POPs and EDCs illustrates this complexity. As EU law is only effective indirectly, its strength depends on enforcement by member states. Member states thus retain significant regulatory authority, including the right to adopt trade-distorting measures “on the grounds of the protection of health and life of humans, animals or plants” (EC Treaty Article 36). Since EU law has to be transposed into domestic law, there is also considerable variation in the precise means of implementation. This variation reinforces member states’ environmental priorities and thereby compounds the difficulties of reaching common EU positions in international negotiations. It also encourages member states to forge their own regulatory paths. Sweden, for instance, has traditionally sought to upload its pioneering chemicals policies via third party arenas, including the Nordic Council or the POPs-related conventions (Kellow & Zito 2002); the same Nordic states have sometimes used international institutions to influence EU policy, illustrated by the late 1990s discussions surrounding the establishment of an “Eco-Schengen” (McCormick 1998). Countries concerned with the competitiveness of their chemicals industries, on the other hand, may align themselves with DG Enterprise rather than DG Environment (Pesendorfer 2006).

The precautionary principle is often advanced as the common ground that unites EU member states. Although the EU’s POPs and EDC strategies bear the mark of the principle, the

preceding discussion suggests a more differentiated interpretation. What emerges through the lens of circuits of regulation is a rich tapestry of interaction potentials that offers considerable leeway for individual actors to influence chemical regulation up, down, and across their own boundaries.

EU strategy on POPs

The European Community participates in both the United Nation's Economic Commission on Europe (UNECE) POPs Protocol and the Stockholm Convention on POPs as a Regional Economical Integration Organization (REIO), for which the two agreements make provisions. According to senior UNEP officials, however, the European Commission has been attempting to change this designation (Personal interview, November 25, 2008). One of the reasons behind the move is that the voting rules under the Stockholm Convention allows REIO's to vote with a number of votes equal to the number of member states that are parties, but it cannot exercise that right if a member state chooses to exercise its right to vote.

The EU has deployed a series of legal instruments to implement the provisions of the Stockholm Convention and the UNECE POPs Protocol and the Rotterdam Convention that regulates international trade in hazardous chemicals. Directive 96/59/EC seeks to gradually phase out PCBs; another set of instruments aims at the reduction of direct and indirect releases of unintentionally produced POPs into soils, water, and air. Each of these regulations is directly applicable in all member states, including those not yet parties to the respective international agreements. While additional regulations address the prevention of marketing and use of POP-like chemicals, the classification, packaging and labeling of dangerous substances, and the placing of plant protection and biocidal products on the market, they cannot prevent the production of new substances with POP characteristics, a task covered under the REACH program (CEC 2007).

All intentionally produced pesticides listed in the Stockholm Convention and the UNECE POPs Protocol have long been phased out in the EU, the exception being lindane, which was used until 2007 as public health and veterinary topical insecticide and has been proposed by Mexico for addition to the Stockholm Convention (CEC 2007). However, one of the most infamous Stockholm POPs, DDT, continues to be produced as an intermediate for another pesticide. Despite substantial progress, POPs continue to be released into the environment, where they join the constant cycling of historical releases (CEC 2007).

In March 2007, the European Commission released the Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants (POPCIP), which also covers substances included in the 1998 UNECE Protocol on POPs. The strategy expresses the EU's intent to have further substances listed under the Stockholm Convention in order to meet the 2020 chemicals target adopted at the World Summit on Sustainable Development (CEC 2007). According to Stockholm Convention Secretariat documents, the addition of up to nine substances at the May 2009 Conference of Parties (COP 4) is highly likely (Personal interview, November 6, 2008). The twelve POPs formally recommended for addition to the Stockholm Convention include a group of substances that still are, or have until recently been produced and widely used in the EU, as well as ones not known to have been produced or used within the EU for decades. The former group includes the widely used brominated flame retardant (c-PentaBDE), which was banned for marketing and use in the EU in 2003 and recently banned in California, and

PFOS, which the EU banned in 2006 and the main U.S. manufacturer has voluntarily phased out (CEC 2007).

Consideration of the multi-level circuits of regulation offers new insights into the relationships concerning POPs regulation between the EU, its member states, and international institutions. The EU's intent to expand the list of substances covered under the Stockholm Convention and the UNECE POPs protocol is one dimension of its so far unsuccessful attempts to promote a global chemicals umbrella convention. The EU's efforts can be seen as a strategy for uploading federal legislation to the international level, a prospect vigorously blocked by other international actors. The EU's race to the top does not explain the full picture, however, since EU negotiating positions, which are reached through extensive coordination meetings, cannot always prevent its members from either pursuing their goals through other fora or from unilaterally forging ahead on a particular issue, as in the case of Sweden's unilateral proposal to add PFOS to the Stockholm Convention's Annexes A and B (Personal interview, November 6, 2008).

EU strategy on EDCs

In contrast to the cluster of international regulations governing POPs, EDC initiatives have mostly focused on research and monitoring, both internationally and in the EU. A number of reasons explain this difference, including relatively weaker scientific consensus and the sheer breadth of substances with potential endocrine disrupting effects. From the perspective of international circuits of regulation, several additional reasons help explain the dynamics of the EU's approach to EDCs. First, many of the most well known EDCs are already regulated under existing domestic and/or supranational law. Each intentionally produced POP, for instance, is also a suspected EDC. Second, awareness of the importance of EDCs emerged at the same time as international agreements on POPs were being negotiated, offering alternative circuits for addressing EDCs.

Growing concern about EDCs at the European level prompted a number of parliamentary questions starting in the mid-1990s, but particularly following the 1996 Weybridge workshop on EDCs. In response, the European Parliament called on the Commission to prepare measures for improving the legislative framework, promoting research, and fostering public awareness, which led to the adoption of the Community Strategy on Endocrine Disrupters in December 1999 (CEC 1999). At the time, several member states had already launched national research programs or adopted specific measures to limit or phase out the use of certain suspected EDCs.

The Community Strategy embraced the precautionary principle and set out a series of short-, medium-, and long-term actions. Chief among these was the establishment of a priority list of substances to be flagged for testing and assessment. The Strategy also called on further research, international cooperation (particularly with OECD's Task Force on Endocrine Disrupter Testing and Assessment; EDTA), and adaptation of existing, rather than new, legislation (CEC 1999). By the time priority listing was completed, however, seven years had passed since the EDC Strategy was adopted and the EU was in the midst of adapting to REACH, under which endocrine disrupting chemicals can now be designated as "substances of very high concern." Commenting on this progress, a member of OECD's EDTA argued that the EU's EDC activities have narrowly focused on the development of priority lists and failed to generate adequate follow-up (Personal interview, November 14, 2008). Lack of regulatory progress and

international cooperation on the part of the EU was also noted in a 2003 report to the European Commission on information exchange and international coordination on EDCs (MRC-IEH 2003). While the EU made considerable efforts in the context of its EDC Strategy, most of the actual EDC research, testing and assessment has been carried out in the US, and to a lesser degree Japan, and in contrast to the EU, both the US and Japan already cooperated closely with the OECD EDTA (MRC-IEH 2003). The report also argued that international agreement on the objectives and mechanisms for prioritizing chemicals had yet to be reached. This in turn echoes UNEP's assessment that the development of an EDC convention today would raise considerable controversy (Personal interview, November 24, 2008).

While regulatory activity has not progressed, the EU has invested significant resources into EDC research under the Framework Programmes for Research & Development. Due to the potentially far-reaching impact of EDC testing and regulation on the chemical industry, especially under REACH, the European chemical industry established the Endocrine Modulators Steering Group (EMSG) as a special task force under the Long-range Research Initiative of the European chemical industry association, which collaborates with OECD's EDTA Task Force.

The EU's approach to EDCs has broadly embraced the precautionary principle through a lengthy process of priority listing, the usefulness of which remains to be seen in the context of REACH. Among the first substances of very high concern, five of fifteen are designated toxic to reproduction, even though 60 EDCs of high exposure concern had been identified eight years earlier. Critics consider the list a "drop in the ocean" (EEB 2008a). Restrictions on phthalates (DINP, DiDP and DNOP) similar to those now on the candidate list already exist under the EU Toys directive, but so far no member state has suggested these substances be included in the REACH list. Bisphenol-A, a well-known EDC, has also been left out of the list.

The Dynamics of International POP and EDC Regulation

The last decade has witnessed unprecedented activity toward the establishment of an international regime for the regulation of chemicals, although more progress has been made regarding POPs than EDCs. Here, we contextualize this activity within the larger international chemicals arena and provide more details on the principal POP and EDC agreements and initiatives. This *ensemble* unfolds at different levels and multiple sites to reveal the multifaceted circuits of regulation characterizing this domain of regulatory cooperation.

Since the 1972 United Nations Conference on the Human Environment, several major international chemicals initiatives have been established. In 1980, the WHO, the ILO and UNEP jointly created the International Programme on Chemical Safety (IPCS). Following UNCED, representatives of government, intergovernmental organizations, NGOs and the private sector established the Intergovernmental Forum on Chemical Safety (IFCS) in 1994, while ten intergovernmental bodies formed the Inter-Organization Programme for the Sound Management of Chemicals (IOMC: UNEP, ILO, FAO, WHO, UNIDO, UNITAR, OECD, UNDP, World Bank, and GEF) in 1995. Each of these initiatives has served as an important conduit for the exchange of information, the coordination of activities, and the consolidation of a recognized international 'chemicals cluster' at the intersection of various circuits of regulation.

Although this cluster is highly diverse, three general trends mark its recent development. First, the EU's increasingly active role has manifested itself in part in an expansionary advocacy. The EU has promoted the creation of a global umbrella convention for chemicals and sought to

increase the number of substances listed in the Stockholm and other conventions. Kelemen (2007) has argued that the EU's global push results from a "race to the top" on environmental standards within the EU, which incentivized Europe to "internationalize" its standards at the global level. Kellow and Zito (2002) further suggest that the attractiveness of linking EU regulation to international policy-making results from EU members' desire to ensure compatibility and delegate technical matters, particularly when international institutions have access to a wider range of information than that available to individual EU members.

The second trend is a reflection of the recent expansionary dynamic, which led to the elaboration of the Strategic Approach for International Chemicals Management (SAICM) as a global policy framework for chemicals management. SAICM became the fall-back option after the EU failed to gain support for a global umbrella convention (Personal interview, November 24, 2008). SAICM, which was adopted in 2006, complements existing instruments, including conventions and previously launched initiatives but seeks to provide overarching policy guidance and serve as an interface for hitherto uncoordinated public, private, and non-governmental chemicals activities (SAICM 2008). In contrast to many previous efforts of this kind, SAICM has strong governmental backing, intergovernmental enforcement, and a funding mechanism. The United States, a strong opponent of the EU's umbrella framework idea, is one of the strongest SAICM supporters (Personal interview, November 24, 2008). Finally, the international chemicals landscape has become subject to consolidation and mainstreaming. Notwithstanding SAICM's intent to complement active processes, for instance, parties to the IFCS have already decided to integrate with SAICM. Parties to international chemicals conventions have started an active process of enhancing coordination and cooperation. Important functions of the Stockholm, Rotterdam, Basel Conventions, for instance, may be merged into one common arrangement (UNEP 2008).

POPs

Several international agreements relate to POPs, including the 2001 Stockholm Convention (in effect since May 2004), the 1998 Aarhus Protocol on Persistent Organic Pollutants (in effect since October 2003), the 1979 UNECE Convention on Long-range Trans-boundary Air Pollution, the 1998 Rotterdam Protocol on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (in effect since February 2004), the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (in effect since 1992), and the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic (in effect since 1998).

The most important regulatory framework for persistent organic pollutants is the Stockholm Convention, which is the first global treaty that seeks to ban an entire class of chemicals because of their effect on human health. The Stockholm Convention covers an initial list of 12 substances ("the dirty dozen"), including 9 pesticides (aldrin, endrin, dieldrin, chlordane, DDT, heptachlor, mirex, and toxaphene) and 3 industrial products or byproducts (PCBs, dioxins, furans), but observers note that most of these have long been banned (and their patents have run out) (Yoder 2003). The Convention prohibits and/or urges elimination of the production, use, import, and export of substances contained in Annex A (intentionally produced POPs); restricts the production and use of chemicals in Annex B (DDT); and obligates governments to reduce releases of Annex C substances (unintentionally produced byproducts). While the Convention provides for the incorporation of additional chemicals, the US first

rejected the idea of an interim review committee to evaluate additional chemicals (Schafer 2002), then pushed for a stringent scientific review process and a political process with high barriers (CIEL 2006). As of this writing, up to nine additional substances are expected to be added.

The Stockholm Convention broadly incorporates the precautionary principle, yet explicit reference is made to the 'precautionary approach' instead. The degree to which the precautionary principle would be enshrined in the Convention was the most controversial element in the negotiation process, which is sometimes characterized as having pitted the EU and NGOs on the side of precaution against the US and industry on the side of sound science (Schafer 2002). Maguire and Hardy (2006), however, argue that whereas the convention text evokes both precaution and science, it does so in a way that co-opts and subordinates (but does not merely displace) 'sound science' discourse.

The Stockholm Convention is closely related to the Rotterdam and Basel Conventions. The Basel Convention seeks to minimize the generation of hazardous waste, including those containing POPs, localize their disposal, reduce transboundary movement, and channel assistance to poor countries. The Rotterdam Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure and covers banned or restricted pesticides and industrial chemicals, including 9 of the 12 POPs addressed in the Stockholm Convention. The links between the Stockholm, Rotterdam, and Basel conventions are so close that a 'tripartite synergies' was initiated in 2007 to enhance cooperation and coordination in administration, programming, decision-making and oversight (UNEP 2008). Lastly, pesticides, industrial chemicals, and unintentional by-products are addressed under the CLRTAP POPs Protocol, which covers all substances regulated by the Stockholm Convention. The Protocols's ultimate objective is to eliminate any discharges, emissions and losses of these POPs.

The regulatory circuits concept seems to bear the most fruit at the international level, where feedback effects between separate but interlinked regulatory arenas are quite visible. For example, numerous parties to the Stockholm Convention, which refers to the "precautionary approach," are also contracting parties to the OSPAR Convention, which not only makes explicit reference to the "precautionary principle" but has broadened its application from marine pollution to encompass all human activities. This strong manifestation of the precautionary principle combines with more comprehensive criteria for defining harmful substances, which the Nordic countries and the EU can use in other POPs venues. Similarly, since the CLRTAP POPs Protocol covers a larger set of substances than the Stockholm Convention, parties to both may use the former as a precedent to expand coverage of the latter, a course of action the EU has pursued with respect to the pesticide chlordecone and the flame retardant hexabromobiphenyl (Personal interview, November 24, 2008).

EDCs

In contrast to POPs, EDCs are not subject to any international convention. From a legal perspective, POPs are a relatively established issue area, whereas international concern about EDCs is much more emergent. From a scientific perspective, however, the difference is not so clear, since the growth of international concern with POPs was in part due to research into endocrine disrupting effects of POPs (Yoder 2003). Despite, or perhaps because of the lack of a global EDC treaty, different aspects of endocrine disrupters have been addressed in a number of

international arenas. These arenas intersect with the circuits of regulation for POPs: substantively, because most POPs are proven or suspected EDCs, and institutionally, because many actors use the same venues for addressing the two

Aside from the European Union's EDC strategy, the OECD is the principal international forum for continuous work on EDCs, even though UN agencies such as WHO and regional bodies such as OSPARCOM have periodically shown some interest in EDCs, and organizations as diverse as the North Atlantic Treaty Organization and World Wildlife Fund have organized research conferences and/or published position papers on the subject (MRC-IEH 2003). As a consequence, the complexity of the issue and the cost of research have been widely recognized and the need for cooperation at the global level emphasized.

In the broader international context, OECD co-ordinates its work with other international organizations and, together with IPCS, is working to address concerns about EDCs expressed at the second Intergovernmental Forum on Chemical Safety. IPCS and OECD provided a secretariat for follow-up activities and a Steering Group, co-chaired by the European Commission and the US Environmental Protection Agency, was established.

Current international unwillingness to translate concerns with endocrine disrupting chemicals into a binding agreement attests to the emerging nature of EDCs.

Transatlantic Policy Cooperation

The multi-level character of POPs and EDCs regulation has clearly created complex pathways of regulatory influence and interaction. Our survey of regulatory activity for these two classes of chemicals suggests that POPs regulation is more developed than EDCs regulation, particularly at the international level. The effects of EDCs also appear to be less well understood scientifically and to present especially difficult regulatory challenges. Nevertheless, when taken together, the increasing attention to POPs and EDCs suggests that perspectives on chemical regulation in both the Europe and the U.S. are shifting. Although the EU has more actively advanced the precautionary principle in chemicals management, the U.S. has also taken significant steps towards regulating POPs and EDCs, even under an administration hostile to many environmental issues. In concluding this paper, we note several areas of existing or possible regulatory cooperation on POPs and EDCs.

Continue and deepen international cooperation on POPs. Several international agreements are now in place to encourage countries to phase out persistent organic pollutants. They structure actor participation on the basis of traditional models of multilateral agreements, with clear divisions of privileges and responsibilities between parties and observers, states and regional organizations, and governmental and non-governmental actors. Both the EU and the US have contributed to the creation of these international agreements, but the U.S. has not ratified any of the Conventions. Its formal influence as an observer is limited, yet its scientific and financial contributions make it a powerful participant in both the Rotterdam and Stockholm Conventions (Falkner 2005).

Solidify international cooperation within the context of the OECD for an expanded EDC screening and testing program: Neither the EU or the US have made significant progress in scientifically screening and testing EDCs. As our review of the EU and US programs makes

clear, the number of possible EDCs is immense and the process of screening and testing is exceedingly slow. Given the magnitude of the problem, a cooperative program of testing could be of great benefit to both the EU and the US. Some degree of cooperation has already begun. In 2000, the European Commission and U.S. EPA agreed to share on a regular basis EDC information on priority setting, screening and testing as well as on research activities. In addition, endocrine disruption was identified as one of four priority research topics under the EC-US Science and Technology Co-operation Agreement.

Given that the OECD has already established a program to harmonize testing and validation methods and tools for EDCs, it is the appropriate arena in which to expand international cooperation on screening and testing. The Special Activity on Endocrine Disrupter Testing and Assessment (SAEDTA) was established in 1996 - before Stockholm negotiations commenced! - to ensure that testing and assessment approaches for endocrine disrupters would not substantially differ among OECD countries. OECD played a leading role in test guideline development, but nobody had a clear view on which national or international organization should be responsible for what area.

The EDTA Task Force has since worked to provide information on national and regional activities, develop appropriate OECD Test Guidelines, and harmonize hazard characterization and testing strategy approaches. The Task Force is part of the OECD's Test Guidelines Programme, an internationally recognized standard setting process whose guidelines become mandatory for member countries (most EU regulations refer to them). Its work is carried out through validation management groups (VMGs) for mammals, ecotoxicity, and non-animal tests, respectively; while the first Test Guideline was approved in 2007, none of the VMGs has completed its work. Gelbke et al (2004) suggest that while OECD's endocrine disrupter validation program has been very successful, there is widespread recognition that more is to be done. Work has also not touched on several big issues, including the development of a classification system, very low dose impact, and EDCs contained in mixtures (Personal interview, November 14, 2008).

For a number of reasons, there is great reluctance on the part of several OECD members to work towards the harmonization of testing strategies, let alone discuss regulatory initiatives (Personal interview, November 14, 2008). OECD's EDC work is blocked by member countries' reluctance to proceed with the harmonization of testing requirements, even though industry has indicated a strong interest in that direction. Tentative steps are being made to advance discussions on assessment (evaluating how test results are used). Moreover, the US and Japan have been the most active supporters of the EDTA Task Force, in large part by carrying out much of the test validation, while the EU has largely remained absorbed with its reform of chemicals policy.

Expand international cooperation on specific POPs or EDCs: One implication of our regulatory circuits argument is that the timing of similar regulatory activities in different arenas is important for understanding new regulatory developments. From this perspective, opportunities for harmonization and upgrading of international standards for POPs and EDCs will depend on the convergence of public and NGO concern, scientific findings, regulatory program developments, and of course, political opportunity, across regulatory arenas. Convergence of opinion and activity across different regulatory arenas is partly fortuitous and depends on many arena-specific factors. However, a second implication of our regulatory circuits argument is that convergence is also partly the result of strategic alignment across regulatory arenas. One

possibility is therefore to explore opportunities for strategic alignment between the EU and California for the purpose of upgrading of international standards. To some degree, strategic alignment between the EU and California on POPs and EDCs is already visible. California's "green chemistry" initiative is inspired, in part, by the EU's REACH initiative and California's ban on brominated flame retardants and phthalates in toys gained momentum from a similar EU ban.

Endosulfan is an example of where the timing might be right for an international upgrading of standards and where a strategic alignment between the EU and California might support this upgrading. Endosulfan is a POP and possible EDC for which there is evidence of bioaccumulation. It is currently banned in the EU and the European Commission has proposed to include it on the list of banned POPs under the Stockholm Convention. In 2002, the U.S. Fish and Wildlife Service recommended that the EPA ban it and 2007 EPA memo found that endosulfan underwent long-range transport, is persistent, and can bioaccumulate (U.S. EPA 2007). In California, endosulfan use has dropped significantly and the California Department of Pesticide Regulation sent a draft Endosulfan risk assessment to the scientific review committee in February 2008. The draft risk assessment advises that endosulfan be listed as a California "toxic air contaminant" under the State's Toxic Air Contaminant Act.

Regulatory developments for controlling persistent organic pollutants and endocrine disrupting chemicals are clearly taking place in many interlinked regulatory arenas within and across Europe, the US, and internationally. While we have not fully traced the pathways of influence between these arenas, it seems fairly clear that the circuitry of influence is quite complex. New programs for regulating these chemicals are being created and institutionalized at the subnational, national, regional, and international level and these developments are clearly occurring in an interactive fashion. Some of these programs build on or conform with existing regulatory programs and frameworks, while others are being developed *de novo*. This pattern of institutionalization has rarely been a straightforward process. Instead, venue shopping and political negotiation have created complex regulatory logics that often combine precautionary and scientific testing paradigms in the same institutions (especially at the international level). Since the regulation of POPs and EDCs is still in its infancy, we expect this pattern of complex interaction to continue for the near term.

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