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The EU's New Impact on U.S. Environmental Regulation

DAVID A. WIRTH

Interactions between domestic legal regimes are occurring all the time, with the laws of one country influencing another even within the confines of state sovereignty and the limits on national jurisdiction established by public international law. Until recently, the direction of that influence in the field of the environment was largely from the United States to Europe.

Within the past several years, there has also been an emerging and discernible trend—what might be called a “back impact”—of EU policy and law on the environmental laws and policy of the United States. During this period, regulatory activity in the European Union has intensified while the United States has had more of a deregulatory orientation. As a consequence, EU legislation in the areas of environment, public health, and consumer protection has begun to have effects within the United States.

Forms of transatlantic interactions between the EU and U.S. legal systems range from the passive dissemination of good practice standards to more aggressive forms of harmonization, as through free trade agreements or upward pressures from the so-called “California effect.” One notable instance of back impact is the recent EU initiative on chemicals known as Registration, Evaluation, and Authorization of Chemicals (“REACH”).

REGULATORY INTERACTIONS

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Fluid interchanges among legal systems are ubiquitous and largely informal in nature. In the area of consumer protection, public health, and the environment, it is nonetheless possible to discern certain categories of interactions characterized by common structural features. These include the adoption of good practice standards by one jurisdiction after implementation in another. Non-binding instruments or binding treaties may serve as fora in which this form of interaction may be more actively pursued, ordinarily with the consent of the jurisdiction adopting the standard.

Less consensual, and consequently more aggressive, forms of harmonization may also be identified. These include “negative” harmonization in fora such as the World Trade Organization (WTO). In this setting, one state may object to another state’s regulation as excessively rigorous and consequently may consider it a barrier to international trade that should be removed. Alternatively, a jurisdiction adopting a strict regulatory measure may have such a large share of a particular market that industry finds it impractical or excessively costly to produce an alternative product for other markets. This phenomenon, familiar in the U.S. federal system as the “California effect,” may also operate to extend the impact of EU regulatory legislation beyond Europe.

Consensual Harmonization

One mechanism explaining interactions among legal systems resulting in the possibility of convergence, and conceptually the easiest case, is simple observation. Through straightforward exchanges of information, formal or informal, public policy in one jurisdiction may be informed by experience in another. In this manner, there may be agreement on what constitutes “good practice” standards that one jurisdiction may copy in some measure from another, with or without modifications to suit individual circumstances.

On occasion, states may find it useful to coordinate or harmonize their policies in such areas as consumer and environmental protection. Such an approach has considerable advantages, including enhancing the efficacy of individual national responses through coordinated multilateral action, minimizing distortions in competitiveness that arise from disparate national policies, and providing a mechanism for holding other states accountable for departures from agreed standards. Within the European Union, institutions such as the Commission, the Council, the European Parliament, and the Court of Justice, along with EU legislation in the form

of directives and regulations, provide a ready forum for harmonization of disparate policies among EU member states.

By contrast, there is no single institutional channel through which interactions among jurisdictions on opposite sides of the Atlantic can or must occur, and the situation is consequently much less structured. Interactions between legal systems may occur as a component of direct communications with non-EU member states, through traditional channels of diplomacy. Alternatively, international organizations may serve as fora for purposeful harmonization of policies. The Organization for Economic Cooperation and Development (OECD) has been particularly active in this field, serving as a forum for harmonization of national environmental policies and laws among its membership of industrialized, market-oriented economies through binding decisions and non-binding directives. The OECD, for example, has been actively involved for several decades in harmonizing national policies for testing chemicals.¹

Binding international agreements, whether bilateral, regional, or universal, are also channels through which national policies and laws may be harmonized and consequently are another setting in which there may be interactions among legal systems. In the fields of consumer protection, public health, and the environment, international organizations typically provide a forum for these activities on a multilateral basis. The United Nations Economic Commission for Europe (ECE), whose membership includes all states of both eastern and western Europe as well as Canada and the United States, has been working for several decades on questions of air pollution and has adopted several protocols addressing atmospheric emissions of pollutants.² Similarly, the United Nations Environment Program (UNEP) has served as a global forum for the negotiation and adoption of major multilateral agreements on protection of the stratospheric ozone layer,³ international shipments of hazardous wastes,⁴ trade in chemicals and pesticides,⁵ and regulation of persistent organic pollutants.⁶ Negotiations preceding the adoption of those agreements serve as conscious and purposeful exercises in coordinating or harmonizing national policies, in part to avoid corrosive regulatory competition and in part to solve collective action problems.

Regardless of the degree of formality of the interactions or the legal force of the resulting outcome, these efforts at harmonization are all consensual. States typically participate in drafting and negotiating non-binding instruments that apply to them, and those "soft law" good practice standards are ordinarily adopted by consensus. International agreements with binding obligations apply only to states that have affirmatively accepted them, as through ratification. The numerous opportunities for granting

or withholding consent in these settings assure that the consequences of interactions between legal systems are the result of acquiescence rather than pure coercion. That is not to say that all states have the same capacity to influence others' legal systems or to resist the exercise of international leverage. But in a consensus setting, that process is at least minimally mediated through the affirmative participation of public authorities in states that are on the receiving end of external pressures.

Until recently, most exchanges of this sort in the fields of consumer protection, public health, and environmental protection ran primarily from west to east, that is from the United States to Europe, especially during the flowering of U.S. environmental legislation during the 1970s. EU legislation on air and water pollution, management of hazardous wastes, and environmental assessment, to name but a few substantive areas, was largely influenced by the U.S. experience.⁷ Even today it would be difficult to say that as activity in these areas intensifies in Europe, American policymakers at the federal level have shown much interest in absorbing lessons from the European experience, at least on a national scale. Most of the interest in EU regulation has, by contrast, arisen out of the potential for excessive stringency in European regulation.

Negative Harmonization

Situations not characterized by consensus may involve unilateral exercise of influence, whether intentional or not, which tends to result in relaxation of the rigor of regulatory standards. Structured negative harmonization of this kind in the context of free trade agreements, such as those adopted under the auspices of the World Trade Organization (WTO), is one of the principal drivers of globalization.

Differences in national regulatory approaches can lead to trade disputes, the resolution of which is one of the principal purposes of the WTO. If exporters from one country claim that another's higher standards are impeding market access, the question is then whether the higher standard is a non-tariff barrier to trade whose principal purpose is to protect domestic industry from foreign competition or, alternatively, a legitimate exercise of a state's sovereign police power to protect consumer welfare and the environment. Assuming a dispute reaches a sufficiently high level, the state with the lower standard may seek recourse through litigation initiated through a trade agreement's dispute settlement mechanism, typically among the more efficacious in the international system.

The tension between liberalized trade on the one hand and policies to

promote consumer protection, public health, and environmental quality on the other is, indeed, an inherent structural attribute of a negative approach to harmonization. Free trade agreements achieve their goal of enhancing human welfare by limiting governmental interventions into what otherwise would be a free market. International obligations relating to trade are consequently almost exclusively “negative” in the sense that they place constraints on governmental action. From an environmental, public health, or consumer protection point of view, this phenomenon is the equivalent of deregulation—in the sense of reducing the level of governmental intrusion in the market—and trade agreements by virtue of their negative obligations are inherently deregulatory.

Environmental protection, by contrast, anticipates affirmative governmental interventions in the marketplace to offset market failures. Obligations in trade agreements *proscribe* certain governmental behaviors that impede trade, while domestic environmental regulations and international environmental agreements *prescribe* governmental actions to protect public health and ecosystems. It is important to note that international trade agreements, by their terms, do not mandate any minimum standards for protection of the environment or human health. Rather, these instruments establish constraints on how states may act if they choose to regulate in these areas.

At a more specific level, trade agreements focus on environmental, public health, and consumer protection measures as potential impediments to international trade. The task from the point of view of trade policy is consequently to distinguish between those unilateral measures ostensibly intended to promote environmental, consumer protection, or public health goals that are legitimate exercises of governmental regulatory powers and those that are, by contrast, pretexts for protectionism. This is a very different posture from a multilateral negotiation on an issue such as control of shipments of toxic waste, which is designed to overcome collective action problems by reference to at least some minimal level of international agreement about the nature of the underlying threats.

Transatlantic disputes between the United States and Europe over EU-level environmental and consumer protection measures of precisely this kind have featured prominently in the agenda of the dispute settlement apparatus of the WTO. These include an EU prohibition on the sale of imported and domestically manufactured meat and meat products derived from cattle treated with growth-promoting hormones,⁸ as well as a recently decided challenge initiated by the United States, Canada, and Argentina in 2003 to the EU's de facto moratorium maintained at that time on the ap-

proval of biotech products.⁹ The mere threat of a conflict, as opposed to an actual dispute, may also act to dampen national regulatory efforts—a “raised eyebrow,” biased toward inaction and against regulatory intervention.

Upward Harmonization

In contrast to consensual harmonization, negative harmonization is unilateral in nature, with one state’s policy or law exerting downward pressure on another’s. A counterpart phenomenon may also occur, in which higher standards buoy up those of others, creating—in contrast to negative harmonization—momentum in the direction of greater rigor.

This kind of upward harmonization can occur when a jurisdiction with high standards and that commands a very large market makes a unilateral regulatory decision, even one that ostensibly applies only internally. If that jurisdiction’s market share is sufficiently large, regulatory requirements can affect an even larger area, including those under the control of other sovereign authorities. Whether states or private entities, the trading partners of a jurisdiction adopting demanding regulatory standards may find it disadvantageous to produce products or services that do not meet

The mere threat of a conflict, as opposed to an actual dispute, may also act to dampen national regulatory efforts—a “raised eyebrow,” biased toward inaction and against regulatory intervention.

the higher requirements, even if other markets have less rigorous regulatory standards. The net effect is an upward pressure on standards even outside the jurisdiction that established them.

In the United States, this phenomenon is sometimes called the “California effect,” named for a sub-national jurisdiction that has been a leader in environmental and consumer protection. Although home to only about 12 percent of the nation’s population, California is the single most

populous state. It is also the state with the highest gross domestic product (GDP), accounting for about 13 percent of the country’s total. California is itself one of the ten largest markets in the world, with a total GDP greater than that of Canada, Spain, or South Korea. When California regulates a particular product or activity, a firm doing business there has a number of choices: it may decide (1) to undertake special modifications to its business practices just for the California market; (2) to forego sales in California; or, as is frequently the case, (3) to alter its products or services offered for sale

in *all* markets to conform to the California standards, especially if creating two product streams would be impracticable or excessively costly.

One good example of this latter alternative is California's Proposition 65,¹⁰ approved by statewide voter referendum in 1986. The statute prohibits exposing the public without warning to carcinogens or reproductive toxins, as in consumer products or food, unless the risk of a lifetime of exposure is insignificant. This requirement states a presumption that labels are required unless demonstrated to be unnecessary. Because of the "California effect" resulting from the size of the market in that state, Proposition 65 has had a nationwide impact on manufacturers that have had an incentive to reformulate all their products to avoid the labeling requirements in California. More recently, in the absence of a coordinated federal policy and after the Bush administration gave notice of its intention not to ratify the Kyoto Protocol, California has recently adopted its own legislation to reduce industrial carbon dioxide emissions by 25 percent by 2020.¹¹ This action, the first of its kind undertaken by a constituent state of the United States, is also expected to have a nationwide effect.

A similar phenomenon can operate on the international level.¹² Historically, in the fields of environment, public health, and consumer protection, it has been U.S. standards that have exerted upward pressure on public policy in Europe. So, for instance, in the mid-1980s, the United States was the first country to adopt requirements for a regime of "prior informed consent" (PIC), prohibiting exports of hazardous wastes unless the government of the state of import has expressly agreed to accept those shipments. This in turn led to the Basel Convention,¹³ which extends a PIC regime potentially universally.

The United States continues to regulate in ways that have impacts on public policy in other jurisdictions, as in post-Enron securities legislation.¹⁴ In environmental, public health, and consumer protection regulation, however, the past two decades or so have seen a slowing of U.S. regulatory activity, with an emphasis on outright deregulation in some situations. Meanwhile, polls in the EU demonstrate that the public considers the environment a top public policy priority, and there is substantial and increasing support for action at the European level.¹⁵ At the same time that the U.S. has tended to rely on existing policies or to roll back some environmental protections, the European Union has taken the lead in a number of areas, such as climate change.¹⁶

With its recent expansion to 27 member states, the EU now has a population more than one and one half times as large as that of the United States and an economy of roughly equivalent size. Consequently, there is

at least some potential for legislation and other policy actions taken at the EU level to create a back impact across the Atlantic in a manner that would have been unlikely as recently as five years ago. This possibility suggests that the EU is in the process of becoming an alternative power center in the area of social welfare regulation, a development that may not necessarily be entirely welcome among certain constituencies in America.

TRANSATLANTIC INTERACTIONS ON CHEMICALS

Regulation of chemicals draws on each of these forms of interaction and illustrates the tensions that can result. In particular, the EU's REACH initiative demonstrates the extent to which European regulation can affect the behavior of governments and private parties in other jurisdictions.

Existing Policies

Of the tens of millions of different chemical substances known, about 30,000 are utilized in industrial processes. Of those, very few have been thoroughly tested for human toxicity or adverse environmental impacts. Section 4 of the U.S. Toxic Substances Control Act (TSCA),¹⁷ enacted in 1976, is representative of attempts to respond to this lack of information surrounding the health and environmental effects of existing and new chemicals. The legislation was intended to create a regulatory structure systematically designed to address data gaps with respect to the toxicity of existing substances that “may present an unreasonable risk of injury to health or the environment.”

Under the legislation, a high-level committee of governmental officials identifies priority chemicals for testing based on such factors as production data, likely human exposures, and the extent to which existing toxicity data suggest cause for concern. After receiving the committee's recommendation, the Environmental Protection Agency (EPA) has 12 months in which to require testing of the chemical, and if so, to determine what tests must be performed—a regulatory strategy intended to initiate systematic action on the part of governmental authorities. If testing is called for, the tests are performed by industry under governmental supervision. Implementation of the TSCA testing program was uneven at first and the subject of several lawsuits in its early stages. As of this writing, the EPA has focused the program on a Master Testing List (MTL) that is intended to identify existing chemicals that present the greatest need for testing.¹⁸

Besides testing existing chemicals, a related public policy strategy is

to anticipate and prevent risks from the large number of newly introduced chemicals that may harm public health or the environment. Section 5 of the TSCA¹⁹ sets out a system of pre-manufacture notification (PMN) intended to address the problem of the entry of new chemical substances with unknown risks into the stream of commerce. That provision requires the proposed manufacturer or processor of any new chemical substance to notify the EPA at least 90 days in advance of either activity. The EPA may then prohibit the manufacture, distribution, use, or disposal of that chemical pending further inquiry by the agency. Section 5 also authorizes the EPA to promulgate regulations governing significant new uses of existing chemicals. This provision of the statute provides only for notification of new chemicals and does not require a prior governmental evaluation before a notified chemical may enter commerce. Testing requirements are minimal, and there is no requirement that the manufacturer demonstrate safety before a new chemical may enter commerce. The burden consequently is on the governmental authority to intervene in cases of concern, often based on minimal information.

Pending entry into force of REACH, four principal legislative enactments²⁰ and a variety of other subsidiary instruments establish public policy for chemicals policy in the EU. As with the TSCA, current EU legislation distinguishes between new and existing chemicals based on a dividing line of 1981, when there were approximately 100,000 existing chemicals that were then in use. The present EU legislation establishes testing requirements only for new chemicals, defined as those introduced on the market after 1981, and the burden is on public authorities to intervene to regulate risks from chemicals. The distinction between new and existing chemicals has consequently favored the latter, reducing incentives for the development of less hazardous substitutes for existing chemicals.

International efforts at harmonization of comprehensive policies for chemicals have been modest. The OECD, as noted above, has undertaken some efforts in the area of mutual recognition of test data. However, an OECD initiative to establish a minimum pre-market set of data in the early 1980s failed when the United States did not accept the plan, largely because the proposal exceeded the requirements of existing domestic legislation, principally the TSCA. Under United Nations auspices, an ambitious Strategic Approach to International Chemicals Management (SAICM) culminated in an International Conference on Chemicals Management held in Dubai in February 2006. But the outputs from this effort, like most OECD undertakings, are voluntary and directed largely at capacity building in developing countries rather than regulatory innovation.

Major multilateral agreements regulate trade in hazardous wastes²¹

and chemicals and pesticides,²² but those agreements are intended primarily to protect developing countries from unwitting or illegal dumping or shipments of chemicals that have been prohibited in industrialized countries. Another binding agreement establishes strict, comprehensive regulatory limits for persistent organic pollutants,²³ but that agreement at present covers fewer than 20 chemicals, most or all of which have already been banned or severely restricted in the United States and the EU.

REACH

Against this regulatory background, the European Commission in 2003 proposed legislation to the European Council and the European Parliament consisting of a comprehensive new regulatory framework for Registration, Evaluation, and Authorization of Chemicals (REACH), which would systematize and strengthen chemical regulation by requiring registration of existing and new chemicals.²⁴ REACH has been approved in a final vote in the European Parliament and a decision at the Environment Council and will enter into force on June 1, 2007.²⁵

REACH, which contains the most rigorous testing requirements of any regulatory regime in the world, requires registration of all existing and new chemicals produced or imported in volumes of a ton or more per year per manufacturer or importer. Failure to register means that the substance or chemical will not be allowed on the European market. The proposal covers approximately 30,000 chemicals and is designed to identify those that might be carcinogenic (causing cancer), mutagenic (causing genetic mutations), or teratogenic (causing adverse reproductive effects), that are persistent and bioaccumulate (such as polychlorinated biphenyls (PCBs)), and at least in certain cases chemicals that might be endocrine (hormone) disrupters. The registration process will require the production of basic toxicological data, including studies of environmental toxicity, if they are not already available. It will also require chemical safety reports that describe exposures and measures to reduce risks.

The testing regime is graduated by volume, with progressively more rigorous requirements for higher-volume chemicals. In response to concerns about the potential impact on small businesses, the final compromise version of REACH imposes only very modest demands on chemicals produced in amounts of less than 100 tons per year. More information is required for chemicals produced in amounts above 100 tons per year. Firms are encouraged to form consortia and to collaborate, reducing costs in registration and testing, when they are registering the same chemical.

The use of information on tests already performed is encouraged. One of the chief issues in the final stages of negotiation on the proposal concerned the “substitution principle,” addressing the conditions under which the most toxic substances are to be replaced.

A new European Chemicals Agency to be located in Helsinki will grant the required registration. A preliminary evaluation of the registration dossier will be performed by this agency, which can request more information or enforce testing requirements. A more comprehensive evaluation procedure can be initiated if it is suspected that a substance may present a risk to human health or to the environment. The requirement for registration will be phased in, with the chemicals of greatest toxicological concern produced in or imported into the EU in the greatest quantities subject first to the registration process. For substances of very high concern—and that will be identified through a decision-making procedure involving the Agency, the member states, and the Commission following entry into force of REACH—prior approval in the form of authorization by the Commission will be required. The proposal also provides for public access to basic toxicological information, a public policy strategy that complements the remainder of the proposal.

Transatlantic Interactions

Within the EU, REACH is the product of affirmative, consensual efforts at harmonization among member states. More to the point from the perspective of the present analysis, REACH has been the subject of transatlantic interactions that illustrate the dynamics of both negative and upward harmonization as products of exchanges between legal systems.

The TSCA, the most closely analogous federal legislation in the United States, is considerably less rigorous in its requirements than REACH. The TSCA contains no requirement for registration or authorization, and in general creates no impediments to manufacture and marketing unless the EPA affirmatively acts to regulate a chemical or substance. Although notice to the EPA is necessary for new chemicals prior to manufacture, there is no requirement for a standard battery of tests, or any tests at all for that matter. Much of the information submitted to the EPA about new chemicals in particular is identified as proprietary and therefore confidential. The statute contains a provision designed to create a program for testing existing chemicals, but that has not been particularly systematic.

The result is that very few chemicals have been regulated under the authority of the statute, which relies on a cost-benefit test requiring a

finding of “unreasonable” risk. TSCA grandfathered 95 percent of then-existing chemicals, and even today 95 percent of chemicals on the market have never undergone even minimal toxicity testing.²⁶ One of the EPA’s major initiatives under the law, a virtually total ban on asbestos, was invalidated by a court despite ten years of agency work on the regulation and hundreds of studies on the effects of asbestos.²⁷ The judicial opinion set a very high threshold for meeting the standard for an “unreasonable risk,” effectively dampening subsequent regulatory initiatives under the TSCA.

After REACH, Europe and America consequently present two very different regulatory milieus. As a result of these regulatory disparities, the executive branch of the United States government undertook a concerted effort to block or weaken the proposal after the release of the EU’s white paper in 2001. These activities are documented in communications from various departments and agencies, including the Departments of State and Commerce, the U.S. Trade Representative, and the EPA. Those communications are collected in reports of the U.S. House of Representatives²⁸ and the Freie Universität Berlin,²⁹ documenting that the executive branch in effect adopted as U.S. government policy the position of the American chemicals industry on REACH.

As might be expected, those reports and other anecdotal accounts describe typical activities associated with a negative harmonization approach. Those include lobbying EU institutions in Brussels and elsewhere, démarches in EU member state capitals, and appeals to weaken REACH in non-EU countries including South Africa and Asian countries like Malaysia, Korea, Thailand, and the Philippines. In a more structured setting for encouraging negative harmonization, the United States in a June 2004 submission to the WTO Committee on Technical Barriers to Trade identified 59 points of objection by reference to GATT/WTO disciplines. Just recently, as the process for adopting REACH was in its final stages, the U.S. Mission to the EU sent an electronic message lobbying members of the European Parliament with the subject line “REACH Second Reading: US Views.” The message concludes, “Attached is our ‘voting’ list on some of the amendments you will be voting on tomorrow.”³⁰

REACH is also an international case study in upward harmonization of the “California effect” variety, but with the unfamiliar twist that the European Union is the source of the upward pressure. While opposing the proposal and attempting to weaken it through the U.S. Government and its own efforts, U.S. industry also realizes that it is going to have to adapt to those aspects that cannot be changed. U.S. exports subject to REACH amount to \$14 billion per year and are responsible for 54,000 jobs in the

United States.³¹ Many firms that operate in the United States that would be affected by REACH are, moreover, multinationals whose activities in Europe will be directly regulated. REACH's requirements consequently apply to every major consumer product manufacturer in the world.

There are also less obvious back impacts of REACH in the United States. The studies required by REACH, and made public pursuant to its requirements, may document previously unknown health effects. According to at least one informed observer, that new information will force a thorough reevaluation or replacement of the TSCA, the principal U.S. statutory authority, within the next three to five years.³² Given relatively vigorous toxic tort litigation activity in the U.S., information generated or released in Europe is likely to fuel lawsuits brought in America. The United States also may well become a repository for harmful chemicals that are not allowed into the European market, in effect transforming the U.S. into a "pollution haven."

At the sub-national level, states in the United States are beginning to respond to legislation originating from Brussels. California's Electronic Waste Recycling Act of 2003³³ references the EU's Restriction of Hazardous Substances Directive by name, incorporating its standards by reference for the purpose of establishing regulatory requirements for electronic devices containing certain heavy metals. In a multiple-tiered "California effect," this state-level statute relying on an EU directive could have the practical effect of leveraging the application of European standards for the entire U.S. market, all without any formal policy input from the U.S. government.

Effects on Governmental Processes in the United States

A "California effect" driven by public policies adopted not by a constituent sub-national unit within the United States, but from Europe, is a new phenomenon in American political and legal life. A "California effect" emanating from abroad creates dynamics that may well be familiar to a European looking west across the Atlantic, but which have rarely been encountered—and to date are grossly underappreciated—by Americans casting an eye in the opposite direction.

The closest precedent to the simultaneous operation of pressures for both negative and upward harmonization is the case of genetically modified (GM) foods and crops. The United States has few regulatory impediments to marketing GM products, but the EU requires prior governmental authorization. As a result of EU-level legislation and member state action, many new product approvals were blocked after 1998, as a consequence of

which a number of products allowed in the United States were prohibited in the European market. This situation triggered a successful challenge initiated in the WTO by the U.S., Canada, and Argentina,³⁴ an example of negative harmonization.

At the same time, new requirements for labeling and traceability that were not the subject of the WTO challenge were having a back impact in the United States, requiring U.S. producers to segment their products into two distinct streams, GM and non-GM, to meet the needs of the European market³⁵—an example of upward harmonization emanating from abroad. The result has been a virtual collapse of the market for U.S. exports of corn, and American rice and wheat producers have resisted adopting GM varieties for fear of risking a similar fate.³⁶

In short, American public policy is now, at least under some circumstances, the product of debates occurring in Brussels. U.S. laws are, in a sense, being drafted overseas. While this may be a fact of life in a globalized world, and in substance perhaps helpful by tending to encourage

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progressive development of regulatory policy in North America, this phenomenon has serious long-term implications for the process of crafting U.S. public policy.

First, and perhaps most obviously, not every U.S. constituency has the resources or the political leverage to effectively represent its interests in Brussels. As noted in the Waxman report,³⁷ the U.S. government's position on REACH has been informed almost exclusively by the preferences of the U.S. chemical industry. U.S. non-governmental organizations (NGOs) that might have an interest in more rigorous requirements have had a negligible impact on the executive branch's position. Nor is this constituency, representing the interests of non-EU nationals, likely to have much influence directly in Brussels. Moreover, many chemical companies which have been active in influencing the U.S. government in the U.S. are multinationals, with a simultaneous presence on both sides of the Atlantic. That means that they have direct input as domestic constituencies in *both* Washington and Brussels, whereas at least under some circumstances, the representatives of competing interests may have neither.

Second, and perhaps even more notably, the process for policy input by the United States government in Brussels is radically different from that

domestically. The U.S. government exerts an influence in the EU-level process in the form of diplomatic representations, which are the product of a deliberative process for crafting foreign policy. As such, U.S. public policy vis-à-vis the EU on chemicals legislation is established through procedures very different from that for an analogous domestic regulatory issue, such as the adoption and implementation of the Toxic Substances Control Act.

As “the sole organ of the nation in its external relations, and its sole representative with foreign nations,”³⁸ the President and the Executive can and do conduct foreign policy with little, if any, involvement from the Congress. The process of formulating foreign policy is typically undertaken in governmental departments, such as the Department of State, that have responsibilities for external relations, and with considerably less involvement with regulatory powers by agencies like the EPA than would be encountered on a purely domestic issue. Unlike the process of developing domestic regulations, foreign policy is typically elaborated in secret, often within security agencies, without notice to the public.

The process of communicating with foreign governments—the conduct of diplomacy—is similarly conducted out of the public eye and under a cloak of secrecy and confidentiality between governments. There is, moreover, virtually no opportunity for judicial review of foreign policy positions taken by the executive branch.³⁹ The result is that there has been no requirement for the United States government to explain or account for its position to the Congress or the American public. As demonstrated by the Waxman and Freie Universität Berlin reports, such a situation is fertile ground for capture by special interests, such as the chemical industry, and for the exclusion of other constituencies such as public interest advocates.

CONCLUSION

As the European Union continues not only to expand its membership, but also to harmonize its regulatory policies at an ever higher level of coordination, EU legislation is likely to have an increasing effect on the domestic legal regimes of other jurisdictions— and most particularly on the United States. As with REACH, the nature of those interactions is unlikely to fit into any one mold. Differences in regulatory approaches will most likely continue to give rise to trade-related tensions, with a corresponding pressure for negative harmonization. At the same time, as the EU is increasingly able to resist such pressures, it is likely to become a more effective driver for upward harmonization, as affected constituencies such as U.S. industry have little choice but to comply with EU legislation.

Simultaneously with each of these considerations, and entirely consistently with both, a de facto convergence in real-world practice even without formal harmonization may very well create a climate of greater receptivity to interchanges between legal systems in a "best practices" mode. As the effects of REACH are felt in the United States and the motivation for a regulatory rapprochement increases, one might expect to see some receptivity both in Europe and America to proposals for more vigorous harmonization in multilateral fora such as the OECD or UNEP.

As demonstrated by the example of REACH, regulatory initiatives undertaken by our large trading partners can exert pressure on public policy within the United States and catalyze responses by private parties even in the absence of domestic law and regulations. To the extent that the states build on this momentum, as in the case of California's adoption of EU legislation as its own, this effect is intensified. Because these dynamics can help overcome policy gridlock in Washington in areas such as chemicals policy, advocates for more vigorous regulatory interventions in areas such

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As demonstrated by the example of REACH, this twentieth-century model is wholly inadequate to address twenty-first century realities.

as the environment, consumer protection, and public health might see these developments as helpful. While that may be the case in the near term, the long-range implications are more troubling.

.....
 U.S. administrative law rests on the implicit assumption that American public policy is primarily domestic in nature. The prevailing model assumes that Congress adopts legislative directives, which sketch in the broad outlines of public policy, and that the particulars will be elaborated by the executive branch in subsequent regulations. Guarantees of transparency, accountability, and rationality in governmental decisionmaking accompany this process at every step, in both the Congress and in executive branch agencies. ■

ENDNOTES

- 1 As demonstrated by the example of REACH, this twentieth-century model is wholly inadequate to address twenty-first century realities. To the extent that the United States is on the receiving end of international pressures for upward harmonization, as in the case of REACH, there will always be domestic special interests that will be adversely affected. The executive branch, in turn, can expect appeals to intervene to eliminate or relax the rigor of the foreign action. The Congress may be totally unaware of these developments, and the U.S. legal system provides few if any entry points for the public or the courts to intrude into what is, in effect, the conduct of diplomacy. As a result, the executive branch is likely to experience

asymmetric pressures, with its response subject to little or no external scrutiny. Situations such as REACH, in which U.S. public policy in effect is being negotiated in diplomatic circles rather than debated in public institutions, are already numerous and will only increase in number over time. Due to the fact that our governmental structure is characterized by a separation of powers, in which the President is diplomat-in-chief for the Nation, there are legitimate and potentially serious constitutional considerations to be addressed in circumstances such as the REACH example. We nonetheless have no choice but to respond to these new but underappreciated challenges, accepting that we live in a globalized world and adapting our domestic institutional and legal structures accordingly.

E.g., Organization for Economic Co-operation and Development [OECD], *Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, OECD Doc. C(81)30 (May 12, 1981), *as amended by* OECD Doc. C(97)186 (Nov. 27, 1997); OECD, *Decision-Recommendation on Compliance with Principles of Good Laboratory Practice*, OECD Doc. C(89)87 (Oct. 2, 1989), *as amended by* OECD Doc. C(95)8 (Mar. 9, 1995); OECD, *Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals*, OECD Doc. C(90)163 (Jan. 31, 1991); OECD, *Decision Concerning the Adherence of Non-Member Countries to the Council Acts Related to the Mutual Acceptance of Data in the Assessment of Chemicals*, OECD Doc. C(97)114 (Nov. 26, 1997).

- 2 *E.g.*, Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, June 24, 1998, 37 I.L.M. 505 (1998); Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Heavy Metals, June 24, 1998, www.unep.org/env/lrtap/full%20text/1998.Heavy.Metals.e.pdf.
- 3 Montreal Protocol on Substances That Deplete the Ozone Layer, Sept. 16, 1987, 26 I.L.M. 1550 (1987). For the Secretariat of the Protocol and developments subsequent to the conclusion of the agreement, *see* ozone.unep.org/index.asp.
- 4 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Mar. 22, 1989, 28 I.L.M. 657 (1989) [hereinafter Basel Convention]. For the Secretariat of the Convention and developments subsequent to the conclusion of the agreement, *see* www.basel.int/.
- 5 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Sept. 10, 1998, 38 I.L.M. 1 (1999) [hereinafter PIC Convention]. For the Secretariat of the Convention and developments subsequent to the conclusion of the agreement, *see* www.pic.int/.
- 6 Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532 (2001) [hereinafter POPs Convention]. For the Secretariat of the Convention and developments subsequent to the conclusion of the agreement, *see* www.pops.int/.
- 7 *See, e.g.*, David A. Wirth, *Hazardous Substances and Activities*, in OXFORD HANDBOOK OF INTERNATIONAL ENVIRONMENTAL LAW (Daniel Bodansky, Jutta Brunée, Ellen Hey eds., 2007), 394.
- 8 Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products*, WT/DS26/AB/R & WT/DS48/AB/R (Jan. 16, 1998).
- 9 Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R & WT/DS293/R (Sept. 29, 2006) [hereinafter Panel Report]. *See also* David A. Wirth, *The Transatlantic GMO Dispute Against the European Communities: Some Preliminary Thoughts*, in EU AND WTO LAW: HOW TIGHT IS THE LEGAL STRAITJACKET FOR ENVIRONMENTAL PRODUCT REGULATION? 175 (Marc Pallemmaerts ed. 2006). In November 2006 the Commission decided not to appeal the panel's report to the WTO Appellate Body because the moratorium was terminated in 2004 and the regulatory provisions at issue in the dispute are not affected by the panel's report.
- 10 Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25249.5-25249.13.
- 11 Global Warming Solutions Act, Cal. Health & Safety Code §§ 38500-38599.
- 12 *See, e.g.*, DAVID VOGEL, TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY (1995).

- 13 Basel Convention, *supra* note 4.
- 14 *E.g.*, Public Company Accounting Reform and Investor Protection Act of 2002 (Sarbanes-Oxley Act), Pub. L. No. 107-204, 2002 U.S.C.C.A.N. (116 Stat.) 745.
- 15 *See, e.g.*, *Special Environment Eurobarometer "Attitudes of Europeans Towards the Environment,"* ec.europa.eu/environment/barometer/index.htm.
- 16 *See, e.g.*, Ragnar E. Lofstedt & David Vogel, *The Changing Character of Consumer and Environmental Regulation: A Comparison of Europe and the United States*, 21 *Risk Analysis* 399 (2001) (hypothesizing "flip-flop" in positions of U.S. and EU with respect to regulatory rigor between 1970s and present).
- 17 15 U.S.C. § 2603.
- 18 *See* U.S. Environmental Protection Agency, *TSCA Chemical Testing Program Objectives*, www.epa.gov/opptintr/chemtest/pubs/vision.htm.
- 19 15 U.S.C. § 2604. *See generally* U.S. Environmental Protection Agency, *New Chemicals Program*, www.epa.gov/oppt/newchems/index.htm.
- 20 Council Directive 67/548, 1967 O.J. (L 196) 1 (EEC), *as amended* (on the Approximation of Laws, Regulations and Administrative Provisions relating to the Classification, Packaging and Labelling of Dangerous Substances); Council Directive 88/379, 1988 O.J. (L 187) 14 (EEC) (on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States relating to the Classification, Packaging and Labelling of Dangerous Preparations); Council Regulation 793/93, 1993 O.J. (L 84) 1 (EEC) (on the Evaluation and Control of the Risks of Existing Substances); Council Directive 76/769 (on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations), 1976 O.J. (L 262) 201 (EEC) (on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations).
- 21 Basel Convention, *supra* note 4.
- 22 PIC Convention, *supra* note 5.
- 23 POPs Convention, *supra* note 6.
- 24 *See* European Commission, *Proposal for a Regulation of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency and Amending Directive 1999/45/EC and Regulation (EC); and Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals*, COM (2003) 644 final. The formal proposal was preceded by a Commission white paper released in 2001. European Commission, *White Paper on the Strategy for a Future Chemicals Policy* (Feb. 27, 2001), available at europa.eu.int/comm/environment/chemicals/pdf/0188_en.pdf.
- 25 Regulation 1907/2006 of the European Parliament and of the Council; and Directive 2006/12 of the European Parliament and of the Council, 2006 O.J. (L 396) 1 (EC) (concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, and repealing or amending the relevant Council and Commission Directives).
- 26 *See* MARK SCHAPIRO, *THE DIRECTIVES: THE UNTOLD STORY OF GLOBAL MARKETS, TESTING EVERYDAY PRODUCTS, AND THE CHEMICALS THAT BIND THEM* (White River Junction, Vermont: Chelsea Green Publishing forthcoming 2007).
- 27 *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).
- 28 H.R. Comm. on Government Reform (Minority Staff), *A Special Interest Case Study: The Chemical Industry, the Bush Administration, and European Efforts to Regulate Chemicals* (Apr. 1, 2004), available at www.democrats.reform.house.gov/Documents/20040817125807-75305.pdf [hereinafter Waxman report].

- 29 Francis R. Pickering, Jason Dorn, Alant Jost, Mehmet Yilmazata & Felix Mann, *Treading Softly: Europe, Chemicals, and the Bush Administration* (John F. Kennedy Institute, Freie Universität Berlin Jan. 25, 2006), www.dipa-berlin.org/w/files/fallstudien/usreach.pdf [hereinafter Freie Universität Berlin report].
- 30 Email from Michele Dastin-van Rijn, Trade and Regulatory Affairs Officer, United States Mission to the European Union (Oct. 9, 2006) (on file with author).
- 31 See generally Frank Ackerman, Liz Stanton, and Rachel Massey, *European Chemical Policy and the United States: The Impacts of REACH* (Tufts University, Global Development and Environment Institute Working Paper 06-06, Sept. 2006), <www.ase.tufts.edu/gdae/Pubs/wp/06-06USREACH.pdf>.
- 32 See Schapiro, *supra* note 26.
- 33 Cal. Pub. Res. Code §§ 42460-42486. See generally Noah Sachs, *Planning the Funeral at the Birth: Extended Producer Responsibility in the European Union and the United States*, 30 HARV. ENVTL. L. REV. 51 (2006).
- 34 See Panel Report, *supra* note 9.
- 35 See, e.g., U.S. Dept. of Agric., Advisory Comm. on Biotechnology and 21st Century Agric., *Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States* (2005), w3.usda.gov/agencies/biotech/ac21/reports/tlpaperv37final.pdf.
- 36 For more examples, see Ackerman, Stanton & Massey, *supra* note 31. See also Rick Weiss, *Rice Industry Troubled by Genetic Contamination*, WASH. POST, Mar. 11, 2007, at A3.
- 37 Waxman Report, *supra* note 28.
- 38 *United States v. Curtiss-Wright Export Corp.*, 299 U.S. 304, 319 (1936).
- 39 See, e.g., Thomas M. Franck, *Courts and Foreign Policy*, FOREIGN POL'Y, Summer 1991, at 66.