Un Regard Extérieur: Back Impact of European Union Legislation on American Environmental Regulations

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LES ÉCHANGES ENTRE LES DROITS, L’EXPÉRIENCE COMMUNAUTAIRE

Une lecture des phénomènes de régionalisation et de mondialisation du droit

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EXTRAIT

BRUYLANT
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UN REGARD EXTERIEUR :  
BACK IMPACT OF EUROPEAN UNION  
LEGISLATION ON AMERICAN  
ENVIRONMENTAL REGULATIONS

PAR

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Résumé :

Si l'influence du droit des Etats-Unis en Europe ne peut être niée, il faut aussi admettre en retour, que le droit européen, à travers sa législation en faveur de l'environnement et du consommateur, influence de manière partielle mais remarquable le droit américain («Back impact»).

Les origines de ce rayonnement européen tiennent, entre autres, à l'élaboration et à la diffusion de guides de bonnes pratiques et à l'existence d'une volonté ferme de parvenir à un certain degré d'harmonisation des droits nationaux. Ce constat est illustré, dans la présente note, par le projet REACH (Registration, Evaluation and Authorisation of Chemicals) qui concrétise un véritable compromis européen et, par extension, constitue un parfait exemple des effets bénéfiques du droit européen sur la réglementation américaine relative à l'environnement.

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Legal interactions may occur not only among member states of the European Union, but also between Community law and the law of non-Member States. The law of other states may influence Community law, or Community legislation may have an impact abroad. In transatlantic relations, until recently the direction of that influence has been largely from the United States to Europe.

Within the past several years, there has been an additional discernible trend — what might be called a «back impact» — of EU policy and law in the United States. During that period regulatory activity in the European Union has intensified, simultaneous with an expansion to 27 Member States, at the same time that the United States has had more of a deregulatory orientation. This development is perhaps only to be expected, and is probably most evident in the field of competition law. It is not uncommon for major mergers now to require the approval not only of the U.S. Department of Justice, but also of the European Commission. Less obviously, but just as importantly, EU law in the areas of environmental and consumer protection has begun to have effects within the United States.

This paper first identifies forms of transatlantic interactions between the EU and U.S. legal systems. These 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». The paper then examines one notable instance of back impact, the recent EU initiative on chemicals known as «REACH».

II. — FORMS OF INTERACTIONS BETWEEN REGULATORY REGIMES

Interactions among legal systems are occurring all the time and are largely informal in nature. In the area of consumer protection 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 discerned. These include «negative» harmonization in fora such as the World Trade Organization (WTO). In this setting, one state may object to another's regulation as excessively rigorous and consequently a barrier to international trade which should be removed. Alternatively, a jurisdiction adopting a strict regulatory measure may have a sufficiently 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 regulation beyond Europe.

A. – 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, whether formal or not, 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 which 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, Community institutions such as the Commission, the Council, the European Parliament, and the Court of Justice, along with Community 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 structural channel through which interactions among jurisdictions lying on opposite sides of the Atlantic can or must occur, and the situation is consequently much more fluid. 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. For example, the OECD 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 a setting in which national policies and laws may be harmonized, and consequently in which there may be interactions among legal systems. In the fields of consumer protection and the environment, international organizations typically provide a forum for these activities as well. 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 toxic substances (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), interna-

(1) E.g., Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals, OECD Doc. C(81)30, as amended by OECD Doc. C(97)186; Decision-Recommendation on Compliance with Principles of Good Laboratory Practice, OECD Doc. C(89)87, as amended by OECD Doc. C(95)8; Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals, OECD Doc. C(90)163; 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.


tional shipments of hazardous wastes (4), trade in chemicals and pesticides (5), and regulation of persistent organic pollutants (6).

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 containing binding obligations apply only to states that have affirmatively accepted them, as through ratification following signature of the instrument. 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.

It is probably fair to say that exchanges of this sort in the fields of consumer and environmental protection ran primarily from west to east, that is from the United States to Europe, 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 policy makers at the federal level have shown much interest in absorbing lessons from the European experience,


at least on a national scale (8). Most of the interest in EU regulation has, by contrast, arisen out of the potential for excessive stringency in European regulation (section II.B).

B. - Negative harmonization

Situations not characterized by consensus may involve the unilateral exercise of influence, whether purposefully or not, that tends to result in relaxation of the rigor of regulatory standards. For example, one jurisdiction may try to attract business or industry in the form of lower standards or attenuated regulatory requirements. This concept is well understood in the federal structure of the United States, where it is known as «regulatory competition» (9). A similar phenomenon can operate internationally, resulting in a downward spiral or a «race to the bottom». As jurisdictions compete with each other to be more attractive to business and industry, there is the possibility in extreme cases for the creation of «pollution havens» in countries that – whether by policy design, lack of political will, economic necessity, or insufficient regulatory capabilities – attract industries that pollute the environment.

Structured negative harmonization 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. That is, exporters from one country may claim that another's higher standards are impeding market access. The question then is whether the higher standard is a non-tariff barrier to trade whose principal purpose is to protect domestic industry and 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 set-

(8) But see section II.C infra (state-level legislation in the United States modeled on EU law and policy).

(9) See, e.g., Regulatory Competition and Economic Integration: Comparative Perspectives (Daniel C. Esty & Damien Geradin, eds. 2001); Joel P. Trachtman, «Regulatory Competition and Regulatory Jurisdiction», 3 J. Int'l Econ. L. 331 (2000).
tlement mechanism, typically among the more efficacious in the international system.

The tension between liberalized trade on the one hand and environmental and consumer protection on the other is, indeed, an inherent structural attribute of a negative approach to harmonization. Trade liberalization, like policies which promote environmental or consumer protection, enhances human welfare. Free trade agreements, however, achieve this goal in a manner that is structurally different from the international environmental instruments identified in the previous section. Trade agreements encourage liberalized or free trade by limiting governmental intrusion 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 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 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 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. Free trade agreements accomplish this goal by articulating rules designed to clarify the line dividing these two categories. The dispute settlement process then operates as an adversarial, quasi-
adjudicatory setting in which to apply those rules, requiring the respondent state to justify its exercise of governmental authority in response to an assertion of inconsistency with GATT/WTO rules by the challenging state. This is a very different posture from a multilateral negotiation on an issue such as protection of the stratospheric ozone layer, 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.

This kind of problem is familiar within the EU thanks to the famous case of Cassis de Dijon (10), in which the European Court of Justice held that a German ban on a French liqueur, ostensibly imposed because its low alcohol content could deceive consumers into overconsumption and intoxication, was inconsistent with the Treaty of Rome. Such disputes between the United States and Europe over EU-level environmental and consumer protection measures 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 (11) and 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 approval of biotech products (12).

The mere threat of a conflict, as opposed to an actual dispute, may also act to dampen national regulatory efforts. Employing an approach that might be called the «raised eyebrow», a state skeptical of another’s need for a regulatory intervention may influence the other state’s policy, whether for trade reasons or otherwise. External representations asserting that a proposed national environmental or consumer protection measure is inconsistent with

(12) European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WTO. Doc. No. WT/DS291/R, WT/DS292/R & WT/DS293/R (Sept. 29, 2006) (panel report). See 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 Pallemaerts, 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.
international trade rules may enhance the leverage of domestic constituencies opposed to that action, regardless of the motivation for objection.

C. – Upwards 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 which 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, as a practical—although not necessary legal—matter its regulatory requirements can affect an even larger area, including those under the control of other sovereign authorities. Trading partners of a jurisdiction adopting demanding regulatory standards, whether states or private entities, may find it disadvantageous to produce products or services that do not meet 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 which has been a leader in environmental and consumer protection. Although home to only about 12% of the nation's population, California is the single most populous state. It is also the state with the highest gross domestic product, accounting for about 13% 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. After 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 (13), approved by voter referendum in that state in 1986. The statute prohibits exposing the public to carcinogens or reproductive toxins, as in consumer products or food, without warning 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 decided not to seek ratification of the Kyoto Protocol, California has recently adopted its own legislation to reduce industrial carbon dioxide emissions by 25 percent by 2020 (14). 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 (15). Historically, in the field of environment 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 (16), 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 (17). In environmental and consumer protection regulation, however, the past two decades or so have seen a

(16) Basel Convention, supra note 4.
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 environment a top public policy priority, and there is substantial and increasing support for acting at the European level (18). 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 (19).

With the recent expansion to 27 Member States, the EU now has a population more than half again as large as that of the United States and an economy of roughly equivalent size. Consequently, there is at least some potential for Community 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.

III. TRANSLANTIC INTERACTIONS ON CHEMICALS REGULATION

Regulation of chemicals is an area that illustrates each of these forms of interaction and the tensions that can result. In particular, the EU’s initiative on Registration, Evaluation, and Authorization of Chemicals (REACH) demonstrates the extent to which European regulation can affect the behavior of governments and private parties in other jurisdictions.

A. 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 environ-


mental impacts. Section 4 of the U.S. Toxic Substances Control Act (TSCA) (20), 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 federal 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, 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 (21).

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 TSCA (22) sets out a system of premanufacture 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 EPA at least 90 days in advance of either activity. EPA may then prohibit the manufacture, distribution, use, or disposal of that chemical pending further inquiry by the agency. Section 5 also authorizes

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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 enactments (23) and a variety of other subsidiary instruments currently establish existing chemicals policy in the EU. As with the U.S. Toxic Substances Control Act, current EU legislation distinguishes between new and existing chemicals based on a dividing line of 1981, when there were approximately 100,000 existing chemicals recognized. 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 (section II.A), 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 TSCA. Under United Nations auspices an ambitious Strategic Approach to International Chemicals Management (SAICM) culminated in an International Conference on Chemicals Management

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held in Dubai in February 2006. But the outputs from this effort, like most of the OECD undertakings, are voluntary and directed largely at capacity-building in developing countries rather than regulatory innovation.

Major multilateral agreements regulate trade in hazardous wastes (24) and chemicals and pesticides (25), 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 (26), 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.

B. – Reach

Against this regulatory background, the European Commission in 2003 proposed legislation to the 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 (27). As of this writing, 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 (28).

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 reg-

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(24) Basel Convention, supra note 4.
(25) PIC Convention, supra note 5.
(26) POPs Convention, supra note 6.
ister means that the substance or chemical will not be allowed on the market. The proposal covers approximately 30,000 chemicals and is designed to identify those which might be carcinogenic (causing cancer), mutagenic (causing genetic mutations), or teratogenic (causing adverse reproductive effects), which are persistent and bio-accumulate (such as polychlorinated biphenyls (PCBs)), and at least in certain cases chemicals which 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. Chemical safety reports will be required which describe exposure 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 testing 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 the 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 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 to the registration process first. For substances of very high concern – and which 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.

C. - 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 Toxic Substances Control Act (TSCA), the most closely analogous federal legislation in the United States, is considerably less rigorous in its requirements than REACH. TSCA contains no requirement for registration or authorization, and in general creates no impediments to manufacture and marketing unless the federal Environmental Protection Agency (EPA) affirmatively acts to regulate a chemical or substance. Although notice to 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 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% of then-existing chemicals, and even today 95% of chemicals on the market have never undergone even minimal toxicity testing (29). One of 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 (30). The judicial opinion set a very high thresh-

old for meeting the standard for an «unreasonable risk», effectively dampening subsequent regulatory initiatives under 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 after the release of the EU’s white paper in 2001 to block or weaken the proposal. These activities are documented in communications from various Executive Branch departments and agencies, including the Departments of State and Commerce, the U.S. Trade Representative, and the Environmental Protection Agency. Those communications are collected in reports of the U.S. House of Representatives (31) and the Freie Universität Berlin (32), documenting that the Executive Branch in effect adopted the position of the American chemicals industry on REACH as U.S. Government policy.

As might be expected, those reports and other anecdotal accounts describe the typical sort of activities associated with a negative harmonization approach. Those include lobbying EU institutions in Brussels and elsewhere, démarches in EU Member State capitals, and appeals for support in non-EU countries including South Africa and Asian countries like Malaysia, Korea, Thailand, and the Philippines to weaken REACH. 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, the U.S. Mission to the EU sent an electronic message lobbying members of the European Parliament before its second reading of the proposal 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» (33).

(33) Message from Michele Dastin-van Rijn, Trade and Regulatory Affairs Officer, United States Mission to the European Union (Oct. 9, 2006).
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 (34). 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 TSCA, the principal U.S. statutory authority, within the next 3 to 5 years (35). Given the 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 2003 (36) references the EU’s RoHS Directive (37) by name, incorporating its standards by reference for the purpose of establishing regulatory requirements for electronic devices containing certain heavy metals. In a multiple-

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(35) See SCHAPIRO, supra note 29.
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. federal government.

D. – 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 from point of view of 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. 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 on the European market. This situation triggered a successful challenge initiated in the WTO by the U.S., Canada, and Argentina (38), 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, so as to meet the needs of the European market (39) – 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 (40).

(38) Supra note 12.
(40) For more examples, see Ackerman, Stanton & Massey, supra note 34.
In short American public policy is now, at least under some circumstances, the product of debates occurring in Brussels. U.S. laws are, at least in a sense, being written overseas. While perhaps a fact of life in a globalized world, and in substance maybe helpful by tending to encourage progressive development of public policy in North America, this phenomenon has serious 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 effectively to represent its interests in Brussels. As noted in the Waxman report (41), 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» (42), the President and the Executive can and do conduct foreign policy with little if any

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(41) *Supra* note 31.
involvement from the Congress, the national legislature. The process of formulating foreign policy is typically undertaken in governmental settings, such as the Department of State, with responsibilities for external relations, and with a considerably lesser involvement of agencies like EPA with regulatory powers than would be encountered on a purely domestic issue. Unlike the process of developing domestic regulations, foreign policy is adopted in secret without notice to the public, often within security agencies.

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 (43). 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 the exclusion of other constituencies such as public interest advocates.

IV. — 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, Community legislation is likely to have an increasing effect on the domestic legal regimes of other jurisdictions—and most particularly 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 dynamics, and

(43) See, e.g., Thomas M. Franck, «Courts and Foreign Policy», Foreign Pol'y, Summer 1991, at 66.
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. One indication that such a maturation is occurring might initiatives for more vigorous harmonization in multilateral fora such as the OECD or UNEP.