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Is Risk-Based Regulation Feasible? The Case of Polybrominated Diphenyl Ethers (PBDEs)

Brian H MacGillivray, Ruth Alcock and Jerry Busby

Abstract

The polybrominated diphenyl ethers (PBDEs) are a class of brominated flame retardants used extensively in an array of textiles and plastics. Initially viewed as inert and nontoxic, in recent years an emerging body of science has cast doubt on this perception. Consequently, the compounds have drawn sustained government, media, and lobby group focus in the United States and Europe, yet have taken contrasting trajectories in different risk regulation regimes. We present a longitudinal analysis of these pathways, examining the actions of legislatures, executives, courts, scientists, and pressure groups. We show that the emergence and resolution of PBDEs as a risk issue was strongly shaped by path dependency, political entrainment (inter-institutional conflict unrelated to PBDEs), and partisan lawmaking. This raises the question of whether risk-based principles are capable of being the foundation on which managing the potential for harm can be based—even when that harm is associated with specific objects like flame-retardant chemicals. We conclude by reflecting on the difficult normative issues that are raised.

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1. INTRODUCTION

1.1. Risk Regulation and the Case of Polybrominated Diphenyl Ethers

The polybrominated diphenyl ethers (PBDEs) are a class of brominated flame retardants used extensively in an array of textiles and plastics, in order to both reduce the chance of the material igniting and slow the rate of combustion. Three PBDE mixtures have been marketed: Penta, Octa, and Deca, named after the dominant congener⁴ contained within (e.g., decabromodiphenyl ether). Initially viewed as largely inert and nontoxic, an emerging body of science has cast doubt on this perception, with particular concerns over their neurodevelopmental toxicity,⁽¹⁾ potential for endocrine disruption,⁽²⁾ and rising levels in man and the environment.⁽³⁾ Consequently, the compounds have drawn sustained government, media, and lobby group focus in the United States and Europe, yet have taken contrasting trajectories in different regulatory regimes. These complex and often chaotic pathways defy easy categorization; universal logics such as scientific or economic rationalities seem of limited utility. This makes PBDEs a classic case for comparative analysis, with the hope of better understanding what shapes regulatory responses to risk. Herein, we present the first comprehensive account of regulatory responses to PBDEs in the United States and Europe, and isolate key influences that have shaped commonalities and variations therein. Our basic thesis is that the emergence and resolution of PBDEs as a risk issue was shaped by path dependency, political entrainment, and partisan lawmaking. This raises the question of whether risk-based principles are capable of being the foundation on which managing the potential for harm can be based—even when that harm is associated with specific objects like flame-retardant chemicals. The literature to which we add is rich and wide-ranging, grouped below into the categories of skeptical and comparative accounts of regulatory responses to risk.

1.2. Skeptical Accounts of Risk Regulation

The bulk of the literature adopts a rather critical view of risk regulation.⁽⁴⁾ The general thrust is to look toward a regulatory response that seems out of kilter with technical assessments of risk or some decision rule (e.g., utility maximization), and to explain this by reference to certain pathologies, both public and governmental. One dominant branch is concerned with how psychological biases shape risk perception, and with how the law should respond. It draws principally on Tversky and Kahneman's heuristics and biases program, which focused on how intuitive rules of thumb shape people's judgments under uncertainty, and often in ways that violate the norms of the probability theory.⁽⁵⁾ Although the normative status of these heuristic influences is hotly contested in other domains,⁽⁶⁾ the focus of the risk regulation literature has been on the systematic and predictable errors in judgment that they lead to.⁽⁷⁻¹²⁾ The concern here is that biased risk perceptions may be replicated in law, policy, and regulation via democratic governments responding to the (mis)fears of the citizenry, with deleterious effect to the economy, environment, and public health. To a somewhat lesser extent, this skeptical branch draws on findings from the psychometric paradigm,⁽¹³⁾ which purported to isolate the qualitative schema or "value judgments" behind lay risk perceptions (e.g., voluntariness, novelty). Again, the focus is on how the direct translation of these lay rationalities into policy outcomes may be undesirable (e.g., giving credence to heightened concerns over novel or unfamiliar risks would, in the context of immigration policy, effectively institutionalize xenophobia). Moreover, there is some skepticism as to whether these qualitative schema can indeed be viewed as value judgments, which would afford them some legitimacy in policy-making considerations, rather than being arbitrary constructs⁽¹²⁾ or even post hoc rationalizations.⁽¹⁴⁾

The second dominant branch is concerned with failings in the democratic process.(15,16) It has its roots in public choice theory,(17,18) which views lawmaking and regulatory decisions as transactions that often depart from a deliberation of the public good toward satisfying the vested interests of the more vocal or powerful stakeholders. A particular concern is with the problem of the “omitted voice,” wherein the interests, values, and preferences of stakeholders are marginalized from the decision-making process, often with the result that they disproportionately bear the economic or even health harms of the regulatory measure.(19)

The prescriptive thrust of this work focuses on establishing institutional safeguards to ensure that risk regulation adheres to some standard of rationality, for example, in promoting risk and cost-benefit analyses as normative bases for regulatory decision making.(11,12,19,20)

1.3. Comparative Accounts of Risk Regulation

Not all scholars adopt such a critical approach to risk regulation, particularly those engaged in comparative work. The focus here is not on constraints to public interest decision making, but rather on how the norms and practices adopted by various regimes can shape decision-making outcomes. Features invoked to explain variations in regulatory outcomes include the relative strengths of political actors (whether political institutions or pressure groups); the styles of regulatory regimes (e.g., adversarial vs. cooperative, centralized vs. decentralized, openness to scientific adversarialism and advocacy groups);(21,22) the degree of precaution employed;(23,24) preferences for quantitative versus qualitative risk assessment; and political cultures.(25) Hood et al.(26) focused on the different rules, institutional arrangements, and cultures across regulatory regimes, arguing persuasively that these were shaped by the triad of market failures, interest group pressure, and public opinion. Yet this work examined variations across policy domains, rather than across regimes responding to the same issue. Other scholars have been concerned with commonalities in regulatory response, particularly with cases where actions taken or norms adopted in one jurisdiction are later borrowed or mimicked elsewhere, ranging from restrictions on a particular chemical substance, to more subtle aspects such as methods of judicial review.(27)

As this brief overview suggests, there is as yet no unified theory of risk regulation, but rather a series of perspectives that have varying degrees of explanatory power in different contexts. And so we did not enter our study with a particular hypothesis to test, but rather adopted an exploratory approach.

2. RESEARCH METHODS

The research objective was to chronicle and understand regulatory responses to PBDEs across a variety of jurisdictions. A qualitative research design was adopted, with the foci of analysis being the actions, decisions, and utterances of legislatures, executives (including regulatory agencies), courts, scientists, and pressure groups. The first three were those institutions vested with (often shared) formal authority to regulate PBDEs, and the last two were key providers of data, perspectives, pressure, and opinions to the regulatory process. The study examined regulation at the state and federal levels in the United States, and at national and supranational levels in Europe.

The primary data sources can be grouped into three categories. The first relates to developments in legislatures, encompassing proposed bills, records and reports of committee hearings and legislative debates, and enacted laws. The second category relates to the actions of executive bodies, mainly those of agencies charged with implementing industrial chemicals regulations (e.g., the U.S. EPA and the Toxic Substances Control Act), although also covering the exercise of veto powers and lawmaking authority of executive actors. The third category is the judicial arena, which was limited to one PBDE-related case brought before the European Court of Justice (to our knowledge, the only

directly relevant case law). These primary data were supported by four categories of secondary sources, which performed two functions. The first was to provide an account of what various actors thought about the risks posed by PBDEs, about the adequacy of regulatory responses to them, and of their role in the process. The second function was to provide cues and further data relating to those developments in risk regulation discussed above (e.g., factual accounts of legislative activity). The categories were: (a) U.K. and U.S. media coverage of the compounds via Lexis-Nexis, Newsbank, and Google News Archive; (b) interviews with regulators (3), scientists (7), NGO representatives (7), industry lobby groups (5), product users (4), and lawyers (1); (c) the websites of NGOs and lobby groups; and (d) key scientific studies and reviews of the risk posed by the compounds.

Our data analysis was inductive and grounded, drawing on mainstream approaches developed for qualitative analysis.^(28,29) The data were first assembled into a chronological account of regulatory responses to PBDEs, the rationale being that risk regulation is best understood as a process, rather than as a set of specific outcomes (e.g., risk assessments or decisions taken). This chronology was interrogated using an iterative coding approach to isolate key factors that shaped the evolution of those regulatory responses. The logic was to look at both variations and commonalities in response, to see how developments in different jurisdictions were both connected and unconnected. We first present the chronology.

3. A CHRONOLOGY

3.1. Origins of a Controversy

Our case begins in 1960 when the first patent was issued for PBDEs as flame retardants, although their manufacture as commercial products did not begin until 1965.⁽³⁰⁾ In the late 1970s they assumed a major share of the marketplace, as the manufacture of their predecessors—the polybrominated and polychlorinated biphenyls (PBBs and PCBs)—was phased out in response to several contamination incidents and concerns over their health hazards. The focus of many analytical chemists similarly shifted toward these new, but analytically compatible, compounds. As a result of their intensive and widespread use, in the coming decade PBDE congeners were detected in the environment, fish, birds, marine samples, and humans.⁽³¹⁾ Although early industry testing had suggested that PBDEs were nontoxic,⁽³²⁾ this evidence of widespread pollution, allied with growing concerns surrounding contamination of the commercial mixtures with the highly toxic dioxins and furans, brought renewed scrutiny. In 1987, the U.S. EPA issued a rule requiring PBDEs be analyzed for the presence of those contaminants,⁽³³⁾ followed by Germany's proposal for a ban on the commercial products within the European Union (1989). This was later withdrawn as it was felt to be infeasible, although that same year the German chemicals industry and plastic manufacturers voluntarily committed to cease the production and use of PBDEs.⁽³⁴⁾ Elsewhere, the locus of concern broadened beyond dioxin and furan contamination to include the PBDE congeners themselves, out of concern for their persistent and bioaccumulative nature and a recognition that the early toxicity tests were limited in scope. The Swedish chemical regulator, KEMI, convened an international conference in 1989 on brominated flame retardants (BFRs), the first of a series of initiatives launched in the Nordic countries.

These concerns reached a head in 1991, as the U.S. EPA issued a proposed test rule (Federal Register, 56, 29140) requiring manufacturers to test various PBDE congeners for a broad range of health effects (including cancer, reproductive toxicity, developmental toxicity, and mutagenicity), the Dutch government proposed a draft resolution calling for restrictions on PBDEs, and the European Commission proposed to ban the marketing of all 10 PBDE congeners (Official Journal C 46, February 22, 1991). Yet by 1994 these fears subsided, as the Organization for Economic

Cooperation and Development (OECD) and International Programme on Chemical Safety (IPCS) published reviews(35,36) concluding that the extent and toxicological significance of dioxin and furan formation during processing and combustion was lower than previously thought. Moreover, these reviews led to a growing recognition of the need to differentiate between the physical and chemical properties of the various PBDE congeners. While the IPCS concluded that the persistent and bioaccumulative nature of Penta suggested that it should not be used, together with the OECD, it observed that the presumed low exposure to Octa and Deca, allied with their relatively nontoxic profiles, meant that they posed an insignificant risk to the general population.

These developments, together with a voluntary commitment by the major manufacturers of BFRs to the OECD to reduce the threat the compounds posed (e.g., through improving the purity of commercial Octa and Deca mixtures), encouraged the Commission to withdraw its proposal for restricting PBDEs, and the Dutch government similarly softened its stance.(37) Yet not all were mollified: the Germans, Danes, Swedes, and Austrians still favored phase-outs or restrictions.(37) This culminated in the European Commission including Octa and Deca on the first priority list (1994) for risk assessment under the Existing Substances Legislation (ESL), and Penta on the second (1995).

3.2. The Calm Ends and the NGOs Enter the Fray

PBDEs reemerged as a significant political, regulatory, media, and NGO concern in 1998 following reports that levels of Penta had been rising exponentially in human breast milk,(3) evidence of neurological deficits in laboratory animals exposed to relatively low levels of certain congeners,(38) and research indicating PBDEs had reached deep ocean waters.(39) In that year the World Health Organization, under the auspices of the IPCS, responded by suggesting that the use of BFRs be avoided wherever possible,(40) while the OSPAR (Oslo-Paris) convention set a (nonbinding) target of cessation of emissions, discharges, and losses within a generation.(41) At the same time, members of the European Parliament began petitioning the Commission as to whether they were willing to consider restricting BFRs and PBDEs in particular, highlighting their status as global contaminants, the breast milk findings, and their alleged similar behavior and toxicities to PCBs (e.g., Official Journal C 142, May 21, 1999). The Commission responded by citing the industry's voluntary commitment to the OECD and the ongoing risk assessments as reasons for deferring action (ibid.). Similarly, concerns over the health effects of flame retardants as a class prompted the U.S. Congress in 1999 to delay the Consumer Product Safety Commission (CPSC) from issuing flammability standards (which would have led to an increased use of PBDEs), pending a National Research Council toxicity study. Yet this study(42) subsequently concluded that Deca posed an insignificant risk to consumers in textile applications, and so PBDEs were to lie somewhat dormant as an issue in the United States for a number of years.

Meanwhile, a variety of NGOs, notably Greenpeace, Friends of the Earth, and the World Wildlife Fund, became increasingly concerned with PBDEs as part of their broader focus on what they perceived to be the failures of industrial chemicals regulation, producing literature reviews,(43) press releases, commissioning and conducting scientific research,(44) and more generally seeking to influence political and regulatory outcomes. In 1997, the major manufacturers of BFRs formed the Bromine Science and Environmental Forum (BSEF) in response to what one industry interviewee called the “globalisation of regulatory threats,” and the coming decade saw these two sides fight various battles in public and government arenas. One significant public victory for the NGOs arose from their sustained pressure on retailers of products containing PBDEs, which culminated in commitments from a number of major companies (e.g., Apple, IKEA) to phase out their use.

3.3. The Demise of Penta and Octa, and Shift in Focus Toward Deca

In January 2001, following completion of the Penta risk assessment,(45) the European Commission forwarded a proposal to Parliament for restricting Penta. Parliament sought to amend the measure by extending it to include the Octa and Deca mixtures, efforts initially blocked by the Commission and Council. Ultimately, the draft Octa assessment(46) substantiated Parliament's concerns, whereas the "final" Deca evaluation(47) failed to identify a significant risk and derived high margins of safety for humans and the environment. Compromise was reached in the form of a Directive restricting only Penta and Octa, which entered into force in February 2003 (Official Journal L 42, February 15, 2003).

Yet this by no means represented an all-clear for Deca in the EU. The risk assessment was more ambivalent than appeared at first glance, acknowledging uncertainties surrounding: the validity of the methodology applied; the high levels found in predatory birds (implying a potential for biomagnification); and the extent and toxicological significance of debromination of the parent compound. Equally crucially, the seemingly reassuring margins of safety for humans took no account of a then-recent study(48) that saw neurodevelopmental deficits arising from doses substantially lower than previously reported. A number of technical experts from member states considered this uncertainty sufficient to warrant precautionary action, and the assessment stated that "consideration should be given at a policy level about the need to investigate risk management options now in the absence of adequate scientific knowledge." Moreover, the EU's Scientific Committee on Toxicity, Ecotoxicity, and the Environment was sharply critical of the Deca assessment, finding fault in both the methodology and assumptions adopted.(49) Specifically, they criticized the assessment for using outdated toxic equivalency factors for dioxins and furans, and went on to derive workplace exposures to these byproducts that exceeded the acceptable daily intake by a factor of 50. All of this meant that the risk assessment was not closed in any meaningful sense, and updates would continue alongside additional scientific and monitoring investigations in an effort to resolve the remaining uncertainties.

While no restrictions on Deca were adopted under the ESL, the Restriction of Hazardous Substances Directive (RoHS; Official Journal L 37, February 13, 2003) included a ban of all PBDEs in electrical and electronic equipment—albeit with the proviso that the case for exempting Deca be revisited as a matter of urgency. In response to fears of impending regulatory action (RoHS had not yet entered into force), the industry collective VECAP (Voluntary Emission Control Action Programme) was formed, with the goal of reducing Deca emissions in manufacture, formulation, application, and coating in both textiles and plastics.(50) This program, and the significant reductions in emissions that appeared to result from it, was crucial to the broadly favorable 2004 update of the Deca risk assessment.(51) Although this assessment and its conclusions were criticized by the EU's Scientific Committee on Health and Environmental Risks,(52) it provided the rationale for the Commission to set in motion efforts to exempt the compound from RoHS. This marked the transition toward a political and ultimately legal dispute in Europe, which we return to later.

3.4. State-Level Action in the United States

To now, the regulation of PBDEs in the United States had proceeded along a relatively smooth path, with various initiatives ongoing at the federal level, particularly at the EPA, to better characterize the risks that they posed (e.g., updates of their toxicological profiles under the Integrated Risk Information System (IRIS)). This was dramatically altered in 2003, as reports emerged that levels of Penta in U.S. human breast milk exceeded those in Europe by one to two orders of magnitude, and were growing exponentially.(53) This was seized upon by media outlets(54,55) and NGOs, and in the face of perceived federal inaction a series of bills were introduced in California, Michigan, and New York calling for wide-ranging restrictions of Penta, Octa, and Deca, and in the case of Maine seeking

restrictions of BFRs as a class. Beyond the rising breast milk levels, bill proponents pointed to PBDEs' neurodevelopmental toxicity, structural and toxicological similarities to PCBs, and the precedent of measures taken elsewhere to eliminate or restrict their use. Opposition was rooted in concerns that the restriction of Deca was not scientifically justifiable (being putatively less toxic and bioaccumulative than Penta and Octa), and fears that fire safety may be undermined. Ultimately, those early bills were watered down in committee, being enacted as restrictions of Octa and Penta, typically calling on the relevant state agency to report back with recommendations on Deca.

The years 2004–2005 saw similar bills introduced to the Maryland, Hawaii, Oregon, Illinois, Montana, Minnesota, and Connecticut legislatures (joined in 2006 by Rhode Island, 2007 by Washington, and 2008 by Vermont and Alaska), and renewed efforts in California and Maine to restrict Deca (for a summary of these bills, see <http://www.ewg.org/node/26976>). Proponents were emboldened by emerging evidence that Deca was perhaps the dominant PBDE congener in dust,⁽⁵⁶⁾ had a higher than previously thought potential for bioaccumulation,⁽⁵⁷⁾ and debrominates to form potentially more toxic and bioaccumulative compounds.⁽⁵⁸⁾ Typically, those groups signed on and providing testimony in support of PBDE restrictions included environmental and health NGOs, medical groups (e.g., nurses' associations), and independent scientists. Fire-fighter associations and regulatory agencies had shifting allegiances throughout, while those in opposition were often restricted to a range of industry bodies and scientists. Events in Oregon are a good illustration of the cut and thrust in the legislative process, and the argumentation employed.

3.4.1. Oregon

In February 2005, Senate Bill 962 was introduced to the legislature, seeking restrictions on Octa, Penta, and Deca. In March, the bill was heard in the Senate Committee on Health Policy, where discussions focused on Deca. The hearing opened with BSEF representatives:

- raising concerns that the measure would undermine fire safety;
- highlighting a range of studies that they portrayed as finding little cause for concern over Deca;^(42,51,59)
- arguing that Deca was neither bioaccumulative, nor toxic, nor subject to significant debromination, and that the levels reported in breast milk were negligible;
- drawing attention to the uncertainty surrounding the toxicological and environmental profile of alternative flame retardants; and
- claiming that the bill went further than any other piece of U.S. legislation.

In short, they argued that Deca was a safe, proven, effective flame retardant, and so not only was there no scientific basis for restricting it, but that doing so would likely threaten fire safety and environmental and human health.

Testimony in support of the bill (from a research scientist, physicians, and a pediatrician) questioned the scientific merits of those claims, arguing:

- that the potential for debromination had been known for decades;
- that the focus on low levels in breast milk was misleading as Deca was thought to preferentially bind to proteins in blood (and hence blood levels were the best measure of exposure);
- that Deca exhibits both developmental neurotoxicity and endocrine disruption;

- that levels of total PBDEs in the most exposed humans were approaching those that caused harm in laboratory animals; and
- that the young were particularly vulnerable to the compound (due to higher rates of tissue absorption, relatively slow metabolism, and greater exposure due to breast-feeding).

A member of the Oregon Nurses Association drew supporting testimony to a close by chronicling the history of public health failures in dealing with neurodevelopmental toxics, wherein early warnings had been overlooked in the face of misleading industry assurances of safety, and by pleading that the same mistake not be repeated with Deca. The hearing ended with Senator Kruse striking a note of caution, drawing attention to what he portrayed as the excessive regulation of environmental contaminants following the publication of *Silent Spring*, and questioning the utility of animal toxicity studies in general.

In the following months a further hearing took place in the same committee, wherein something of a consensus was reached that the science was insufficiently clear to support banning Deca, and the bill was amended to require further study of Deca prior to any restriction. Yet industry still had concerns that this reflected a presumptive ban, and two further hearings were held in the House Committee on Environment in May 2005. The by-now-familiar arguments were again on display, with some new twists. Expert testimony emphasized the structural and toxicological similarity between PBDEs and PCBs, and the implications to society of decreasing IQ levels that may arise from exposure to these types of compounds. The logic was that a narrow focus on individual compounds (i.e., Deca) was ill-advised owing to the inferences that can be made within and across chemical classes, and the reality that humans were exposed to chemicals as mixtures not discrete substances. Some committee members were unimpressed by this reasoning, with one claiming that linking Deca with decreasing IQ levels represented a “quantum leap” beyond the evidence. Ultimately, the language was altered to reflect the industry's position, amid concerns, voiced by a senator giving testimony to the House Committee, that the case for restricting Deca was based on “political science masquerading as real science.”

3.4.2. Elsewhere

Those arguments forwarded in Oregon were largely mirrored in other states considering restrictions, with some key distinctions. One was a greater emphasis by bill opponents on fears that Deca restrictions may lead to job losses or even whole industries moving elsewhere (especially in Connecticut, where Chemtura were located). Another was that by 2007 agency reviews from Maine(60) and Illinois(61) had concluded that safer, effective, and technically feasible alternatives to Deca were broadly available, undercutting opposition claims that restrictions would undermine fire safety. Finally, there was greater focus elsewhere on the threats posed to fire-fighters by the formation of dioxins, furans, and a dense black smoke upon burning PBDEs, and a deep skepticism held by many legislators toward industry science and testimony. These latter two elements were particularly prominent in Maine, Washington, and Minnesota, where partial restrictions on Deca eventually passed both Houses, becoming law in the former two states in 2007 (codified as Chapter 70.76 RCW, and Chapter 296, respectively), although the Minnesota governor used his veto powers in 2008 against the bill. Meanwhile, of those states that had considered PBDE restrictions, only Vermont, Alaska, Connecticut, and Montana failed to restrict Penta and Octa.

3.5. Deca and the RoHS Directive

Our account of European developments ended with the Commission setting out to exempt Deca from the RoHS Directive. It pursued this via the comitology rather than codecision procedure.⁵ This

began with the Commission forwarding its draft proposal to the technical waste committee. Although a plurality voted in favor of the proposal (April 2005), it was not a qualified majority, leading the Commission to forward the proposal to the European Council (June 2005). Sweden, Belgium, Denmark, Finland, and Portugal vehemently objected to this course of action in a letter to the environment ministers and the Commission that same month. They argued that the technical committee had no mandate to decide on a matter of such importance and political nature, and voiced concerns that by pursuing the exemption via the comitology procedure, the Commission had “set aside democratic principles involving codecision within the European Parliament.” Critically, under comitology the Parliament's role was restricted to issuing nonbinding resolutions on the proposal, as it did in July, which called upon the Council to reject it. Yet the result of the technical committee was mirrored in the Council in late August (i.e., plurality support), entitling the Commission to exempt Deca, which it did in October 2005 (Official Journal L 271, October 15, 2005).

This was by no means an isolated conflict between the institutions, as in response to an earlier (April 2005) parliamentary resolution drawing attention to the Commission's alleged systematic misuse of the comitology procedure, the latter body replied (August 2005) acknowledging 37 cases in the areas of public health and the environment where it had failed to respect the legislature's rights between December 2003 and February 2005.⁽⁶²⁾ This dramatically illustrated the scale of the problems with both the existing comitology arrangements and the balance of power between the two institutions,⁽⁶³⁾ and provides the context in which to interpret the Parliament's subsequent actions.

In January 2006 the European Parliament (and Denmark) took legal action seeking to annul the Deca exemption, on the grounds that the Commission had:

- not satisfied the conditions explicitly required under RoHS (instead relying upon the “unlawful criterion” of the risk assessment outcome) and thereby misused its powers;
- breached its duty to provide a proper rationale in the proposal;
- failed to respect the precautionary principle and erred in assessing scientific evidence; and
- breached the principle of proportionality. ⁽⁶⁴⁾

Following the hearing in December 2007 before the ECJ,^(64,65) the judges ultimately determined that the Commission had infringed Article 5(1) of the RoHS Directive, which set out the criteria for exempting substances (i.e., it had failed to follow the requirements explicitly set out in the Directive). In view of this, they found it unnecessary to rule on the other issues raised, such as the scientific or technical merit of the exemption, or the question of precaution. And so the Deca exemption was annulled, effective in July 2008.

3.6. Federal Developments in the United States

We rejoin events at the federal level in the United States in October 2003, when congressmen contacted the EPA to express concerns over delays in the Agency's risk assessments of PBDEs, citing the now familiar worries over their toxic effects and growing levels in breast milk. These concerns, along with the knowledge of the troublesome history and common structure and toxicology of many flame retardants (e.g., TRIS, PBBs), led to the failure of various congressional bills calling for comprehensive fire safety standards in the wake of the tragic nightclub fire in Rhode Island (e.g., S 1798, “American Home Fire Safety Act”). Moreover, they were instrumental in weakening the fire safety regulations ultimately issued by the responsible agency, the CPSC.^(66,67)

February 2004 saw the introduction of the “Toxic Flame Retardant Prohibition Act” (HR 4076) to the House of Representatives, which sought to restrict Octa and Penta and called on the EPA to consider phasing out precursors to these compounds (i.e., Deca). Yet it never left committee, leaving the regulatory burden with the EPA. Notably, the EPA had already negotiated a “voluntary” phase out of Octa and Penta manufacture with Great Lakes Corporation, to take effect by the end of 2004. Although this did not prevent import of products containing those mixtures, it signaled a shift in the Agency’s focus toward Deca, whose revised toxicological assessment under the IRIS program was taking longer than expected.

It emerged that one reason for the delay was that the study was being deliberated upon as part of the interagency peer-review process, coordinated by the Office of Management and Budget.(68) This process was roundly critiqued by the Government Accountability Office(69) and later at a Senate hearing (“Oversight on EPA Toxic Chemical Policies,” U.S. Senate Committee on Environment and Public Works, April 29, 2008). The principal concerns were that it slowed the regulatory process, and provided opportunity for political interference given that it lacked transparency and gave powers to other federal agencies that had potential conflicts of interest. Adding fuel to this, in March 2008 it was revealed(70) that the American Chemistry Council (ACC) had successfully pressured the EPA to remove toxicologist Deborah Rice from her position as the head of the expert panel reviewing the Deca toxicology assessment under IRIS, and to strike her comments from the record. The ACC had argued that she had been a “fervent advocate” for banning the substance in her role as regulatory scientist in Maine, and therefore had a conflict of interest. This led to scathing criticism from academic and political circles,(71) prompting Congressmen Stupak and Dingell to write to the EPA demanding an explanation (letter available at <http://www.ewg.org/node/26175>). This critique culminated in a hearing in September that year dealing with what the congressional majority perceived to be industry’s undue influence over these review panels and the consequent corruption of science at the EPA (“Science Under Siege: Scientific Integrity at the Environmental Protection Agency,” Subcommittee on Oversight and Investigations, September 18, 2008).

In the midst of this controversy, the EPA released the Deca toxicological assessment,(72) which lowered the substance’s RfD based on the Viberg et al.(73) study on developmental neurotoxicity, much to the chagrin of the substance’s producers who had roundly critiqued what they claimed was its fundamentally flawed methodology. Ironically, a panel source informed us that Rice herself had drawn attention to some of these methodological limitations in her role as panel chief.

4. UNDERSTANDING PATTERNS IN REGULATORY RESPONSE

We now turn to the question of what shaped regulatory responses to PBDEs? Clearly, scientific and economic rationalities were important; for example, the growing evidence questioning PBDEs’ supposedly benign environmental and toxicological profiles, allied with the rising availability of alternatives for achieving flame retardancy, played their part. Yet equally, our chronology reveals that these factors are not the sole explanation. The following discussion begins by invoking the concept of path dependency to understand, in part, commonalities in responses to PBDEs across different jurisdictions. We then turn to traditional capture theories, for which we find little concrete support, and introduce the related yet distinct concept of political entrainment, before reflecting on the partisan judgments and voting patterns of lawmakers.

4.1. Path Dependency

4.1.1. Self-Reinforcing Institutional Practices

“Environmental scientists are flock animals...and I think that's based on competence, instruments and funding.”

Analytical chemist, interview.

The PBDEs are but one in a long line of similar flame retardants that were viewed initially as largely benign, before subsequently attracting sustained regulatory attention.(74) This Sisyphean pattern is in part due to self-reinforcing practices in chemical manufacturing and research laboratories. Taking manufacturing first, these chemical and structural similarities are due to certain shared properties being intrinsic to flame retardants' effective functioning, such as persistence and, for polymer additive flame retardants, lipophilicity.(75) Yet, as several of our interviewees noted, this pattern also relates to manufacturers' desires to exploit their existing expertise, knowhow, equipment, and patents. Turning to laboratories, it is well established that the research focus of environmental chemists tends to shift from one compound to another based in large part on structural similarities.(76,77) Known as the analogue approach, it is explained by the fact that it takes a significant investment of resources (instruments, funds, time) to develop the capacity to reliably and accurately detect a particular compound at trace levels in various media. As structurally similar molecules often require largely similar methods and instrumentation for sample preparation and detection, the analogue approach best exploits the prior investments in capacity building of a particular research team or laboratory. In our case, the measurement of PBDEs utilizes existing methodologies for PCBs, and many laboratories shifted their focus toward the former as PCBs were phased out. In sum, the emergence of PBDEs as commercial products, the now thriving research program focused on them, and the regulatory attention that it continues to spur, owe their origins as much to commercial and technical practicalities, as to risk-based logic.

4.1.2. The Troublesome History of Flame Retardants

“I really don't want us to make the same mistakes that we made with PCBs and have this take 40 years before we finally, after seeing the damage to our children, decide to phase it out.”

Senator Pappas, Minnesota Senate Environment and Natural Resources Committee hearing on proposed PBDE restrictions, March 12, 2007.

Before PBDEs, there was asbestos, PCBs, and PBBs. The troublesome history of these and other flame retardants loomed large in the media, in legislative hearings, in scientific debates, and in NGO briefings. What this meant is that PBDEs came to the scene in the context of widespread health and environmental concerns about their predecessors. This formed a schema through which the environmental and toxicological significance of their emergence as contaminants was viewed, and was a critical influence on policy making. For example, EU parliamentary concern over PBDEs was shaped by this history; U.S. congressional action on flammability standards was delayed on account of it; and PBDE bills and committee hearings at the U.S. state level were peppered with references to their predecessors, at times arguing that this troublesome history justified blanket restrictions on brominated and chlorinated flame retardants (e.g., California AB 706). Moreover, our interviews with toxicologists and NGO representatives revealed that their interest in PBDEs was in no small measure driven by this history. The lessons of this troublesome history of flame retardants, and of chemicals regulation more generally, was portrayed by many as being one where early warnings should be acted upon in a precautionary manner:

“For heaven's sake, didn't we learn anything from the issues of DDT and PCBs? It's really time to act.”

Analytical chemist, Ake Bergman, quoted by Raloff.(78)

"I want you to remember the ... true suffering that's existing today and continuing into the future based on public health policy decisions we've made in the past, I've said that history doesn't repeat itself, [but] it rhymes...[and] it will take tremendous political will to create a new verse."

Kathleen Drum, Oregon Nurses Association, testimony before Oregon Senate Committee on Health Policy hearing on proposed PBDE restrictions, March 23, 2005.

Of course, the historical schema through which people view current events, and the lessons that it offers, is rarely uniform. Those opposing PBDE restrictions at times drew attention to examples of what they perceived to be overzealous regulation:

"I harken back to a book...called Silent Spring, which was based on somewhat dubious science, the result of that book was that there was a groundswell in the nation and we banned DDT, looking back DDT was a rather benign substance...we now have 30,000 deaths worldwide due to malaria because we cannot combat the mosquitoes...we just need to proceed with caution."

Senator Kruse, Oregon Senate Committee on Health Policy hearing on proposed PBDE restrictions, March 23, 2005.

Yet the troublesome history of flame retardants was by some distance the dominant schema, perhaps because their similarities in chemical structure, physical properties, and toxicological endpoints and mechanisms of action made the association almost unavoidable. And so the question often seemed not so much what should we do about PBDEs, but what should we have done about their predecessors?

4.1.3. Precedent

"Maine will be the only state, the only jurisdiction in the world, that will have statutorily banned Deca...let's not lead Maine off the cliff."

Senator Smith, Maine Senate debate on proposed PBDE restrictions, May 17, 2007.

In the environmental and health regulation literature, it is well established that the influence of regulatory practices and decisions can extend well beyond their formal jurisdictional boundaries. Some scholars, focusing on the United States, argue that federal inaction can lead to a "race to the bottom," wherein individual states compete with each other to achieve the laxest regulatory controls in order to attract industry.(79) This theory has fallen out of fashion owing to a lack of empirical support,(80) and the more recent focus is on hybridization,(27,81) to which our study lends support. For example, several of the bills introduced to state legislatures in the United States were largely carbon copies of those introduced in Maine. Moreover, many legislative hearings and debates on these bills focused in no small part on the status of regulatory efforts elsewhere, particularly on the growing movement toward restricting Penta and Octa (and concerns about becoming "dumping grounds" for these), and on the status of Deca within Europe's ESL and RoHS Directive. Finally, agency reports typically featured extensive discussions of developments elsewhere.(60,61) In short, states and nations learnt from the regulatory innovations of one another. Enactment in a given jurisdiction: (1) highlighted the political, commercial, and technical feasibility of regulating; (2) made available a body of knowledge supportive of restrictions (e.g., risk assessments, cost-benefit appraisals); and (3) encouraged many jurisdictions to take measures of their own out of fear of becoming a "dumping ground" for the restricted compounds. In a sense, the difficult question

of what should we do about PBDEs was often substituted by the simpler one of what have other jurisdictions done about PBDEs?

4.2. Regulatory Capture, Political Entrainment, and Partisan Lawmaking

4.2.1. Traditional Capture Theories

Public choice theory, a dominant perspective of how government functions,(10) is organized around the concept that legislative and agency decisions are not based upon a deliberative balancing of the public good, but instead are slanted toward protecting the narrow and typically economic interests of the more vocal and powerful interest groups. In the United States, a recent but by no means unique concern of NGOs and academics has been the perceived coopting of environmental policy by industrial interests within the Bush Administration's EPA, neatly articulated below:

"The Bush Administration...you've read all the stuff about EPA senior political appointees changing scientific documents on global warming...all that kind of stuff, [they're not isolated issues]...it's just been seven years of just kind of hell."

Former EPA scientist, interview.

What's interesting for us is not testing this broad ranging claim, but rather the question of whether the regulation of PBDEs had been subject to capture, and, if so, through what mechanisms? The first set of material evidence we uncovered, which speaks to this question, came from a Government Accountability Office (GAO) investigation(69) and two congressional hearings. These focused upon the Bush Administration's reforms to the EPA's chemical risk assessment program IRIS, within which various PBDE congeners were undergoing reassessment. The GAO surmised that these reforms increased the influence of industry and other federal agencies that hold a potential interest in weakening chemicals regulation, lacked transparency, and markedly slowed the process. At the hearings, the congressional majority was less measured in its criticism:

"The [Bush] Administration has...tainted and corrupted, and I use my words advisedly, they have corrupted the process of [chemical] risk assessment...We now have a circumstance where we're going to see a formalisation of a process that puts politics in the centre of regulating chemicals...instead of pure science; this is a travesty...we're not going to stand for it [in Congress]"

Senator Barbara Boxer, U.S. Senate Committee on Environment and Public Works hearing "Oversight on EPA Toxic Chemical Policies," April 29, 2008.

Strong words, yet as the GAO report and testimony made clear, while there was certainly a case to be made that the reforms were unwise, there was no concrete evidence that industry or any agency had unduly influenced the assessments of PBDEs under IRIS. The second set of material evidence relates to the EPA's removal of Deborah Rice from the expert panel reviewing the Deca toxicology profile. Here, a fairly unambiguous case has been made that the EPA were overly deferential to industrial interests—specifically, the ACC who requested her removal.(70) Yet as a source from the panel informed us, Rice's removal did not materially influence the review's outcome.

What we can say from our study is that claims of capture were far from uncommon, being voiced within legislatures, NGOs, industry lobby groups, and the scientific community. Moreover, although they tended to relate to regulatory policy being captured in a way that sacrificed health for profit, some argued that NGOs had excessive influence on policy making leading to unwarranted burdens on industry, and others that industry factions producing alternatives or substitutes for PBDEs had sought regulation of those compounds:

“We have a bill which seeks to ban a product [commercial PBDEs] in the State of Maine, which provides an automatic competitive advantage to other products of a similar nature. I have heard rumours to the effect that a competing manufacturer may be financing this particular legislative effort...I have no evidence that this is the case.”

Representative Daigle, Maine House debate on proposed PBDE restrictions, March 31, 2004.

As the congressman's last words hint, claims of capture rarely surpassed the standard of plausibility. If we use plausibility as an evidentiary standard, we would be flirting with a conspiracy theory approach to social science, finding “vested interests” as the explanation for every decision. Yet claims and perceptions of capture matter because they can shift debates over risk issues away from considerations of science, values, and economics. These claims and perceptions, unless substantiated by evidence, are in our view not conducive to reasoned discussion. The House Speaker, in responding to the congressman's concerns, deserves the last word:

“Interests bring bills before this institution. Probably every bill that we have had has interests in that. If the Representative would confine his remarks to the merits of this bill rather than the other concerns, it would be helpful.”

Speaker, Maine House debate on proposed PBDE restrictions, March 31, 2004.

4.2.2. Political Entrainment

In contrast to the mixed evidence of regulatory capture, we found clearer evidence of what we term political entrainment: where a particular risk object is caught up in a broader political conflict, and is ultimately regulated according to a set of criteria largely unrelated to the risk at hand. We are referring to the political and ultimately legal conflict over Deca's exemption from the RoHS Directive in the EU. As discussed earlier, Parliament's decision to challenge the legality of the Commission's exemption was not based solely upon concern for the merits of the decision from a risk-based perspective, but rather was the culmination of a long-standing conflict between the two institutions over the Commission's neglect of Parliament's oversight rights within the comitology process. Allied with this, Parliament was frustrated that the Commission was often using the comitology process (under which the former had little powers) when codecision was a more appropriate instrument:

“The case must also be seen as [part of]...a long row of cases which revolve around the issue of the Commission exceeding its implementing powers; the Parliament think that the Commission should, instead of using comitology for so many different issues, they should to a large degree use the codecision instrument [to change existing Community law].”

Lawyer close to case, interview.

The case was resolved along relatively narrow procedural lines, with the court ruling that the Commission had failed to comply with the exemption process outlined in the Directive itself; no ruling was issued on the scientific or technical merit of the exemption. This is not to question the normative status of the judgment, nor to cast aspersions on the motivations of those who brought the case. To the contrary, potential misuses of executive powers must be investigated and, if substantiated, ultimately checked by the courts in any society that values the rule of law and democracy. Nevertheless, Deca was ultimately restricted in Europe (in electrical and electronic applications) on the basis of a legal action that was motivated in large part by concerns that went beyond the scientific or technical merits of doing so, and a court judgment that did not rule on those merits. Risk-based regulation, this was not. Of course, it is true that all decisions on risk are to some degree political, in the sense that they are the outcome of a mixture of analysis, deliberation, value

judgments, and the consideration of broad and sectional interests. But here, the regulation of Deca was almost entirely untethered to questions about the risks that it posed, and the benefits that it supplied. That is, the politics of the risk issue had become entrained in the politics of a quite separate and broader dispute. If these kinds of inter-institutional conflicts begin to influence the playing out and resolution of a broader array of risk issues in Europe, then the endeavor of risk-based regulation may be in danger of losing its legitimacy.

4.2.3. Partisan Lawmaking

"I have maintained that, for me at least, the science of this matter should be determinative."

Senator Smith, Maine Senate debate on proposed PBDE restrictions, May 17, 2007.

An interesting distinction between American and European responses to PBDEs is the patchwork quilt of regulatory measures in the former, compared to Europe's more uniform responses. At root, this stems from the distinction between federalized and unitary approaches to governance. In the area of industrial chemicals regulation, the U.S. states are relatively free to enact laws and regulations in the absence of federal direction, in contrast to their European counterparts. For example, although some EU member states planned unilateral measures on PBDEs and, in the case of Sweden, even enacted a restriction on Deca, these were ultimately withdrawn in the face of the Commission's opposition and threats of legal action. More interesting, however, is the particular pattern of the U.S. quilt, and its roots in the balance of partisan power within state legislatures.

The clear majority of states that enacted PBDE restrictions were dominated by the Democratic Party in both Houses at the time of passage (8 of 11). Moreover, within these, the positions and votes of lawmakers toward proposed restrictions—specifically of the Deca mixture—were highly correlated with party membership. To illustrate, Minnesota's House (85 Democrats, 48 Republicans) split 93–39 on the final vote on proposed restrictions of Deca, with only four Democrats dissenting. The Senate (44 Democrats, 23 Republicans) similarly split 45–20 in their final vote, with one Democrat dissenting. And it was their Republican governor who ultimately vetoed the bill. In Washington, the House (62 Democrats, 36 Republicans) split 71–24 on the final vote of proposed Deca restrictions, with one Democrat in opposition. The Senate (32 Democrats, 17 Republicans) split 41–8 in favor, with no Democrats dissenting. Maine is an interesting outlier, as its restriction of Deca passed both houses nearly unanimously. This is not due to an absence of partisanship within its legislature (as we shall see later), but rather because the authority to restrict Deca had been placed in the hands of the Department of Environmental Protection. Specifically, the earlier law restricting Octa and Penta contained a provision stating that it was the intent of the legislature to restrict Deca if the agency identified a safer, nationally available alternative, which by this stage it purported to have done.

Moreover, the examination of the legislative debates and committee hearings reveals that these partisan divides extended beyond policy issues (e.g., how to deal with scientific uncertainty) to cover disagreements over whether Deca exhibited delayed developmental neurotoxicity, over the extent and toxicological significance of its debromination, over whether its combustion byproducts posed a hazard to fire-fighters, and over what constituted valid evidence in making such judgments. Reports of legislative committees on the scientific merits of proposed bills often broke along similarly partisan lines. For example, on April 25, 2007, Maine's Joint Standing Committee on Natural Resources issued a divided report on whether the proposed Deca restriction (LD 1658, later enacted as Chapter 70.76 RCW) should pass. Of those nine legislators voting in support of the bill's passage, eight were Democrats. All three dissenters were Republican. This suggests that partisan affiliation played a significant role in shaping lawmakers' interpretations of the scientific evidence, rather than

simply shaping how they proceeded from an agreed upon level of risk to determining the optimal policy response.

5. CONCLUSIONS

We have shown that the emergence and resolution of particular risk issues—in this case PBDEs—is shaped by path dependency, political entrainment, and partisan lawmaking. The findings challenge the idea that risks are regulated on their individual merits. They raise the question of whether risk-based principles are capable of being the foundation on which managing the potential for harm can be based—even when that harm is associated with specific objects like flame-retardant chemicals. We conclude by summarizing our theoretical contribution, before reflecting on the difficult normative questions that are raised.

Path dependency is the phenomenon that regulatory outcomes are strongly shaped by potentially arbitrary starting conditions. In our study, it had three distinct manifestations (although conceivably they may interact to form a cascade of sorts). First, analytical chemists were drawn toward PBDEs from older, analytically compatible compounds, largely out of a desire to exploit their laboratories' existing instrumentation, expertise, and methodological protocols. Claiming that this tendency is widespread in analytical chemistry, scholars have argued that by picking-off “low hanging fruits,” laboratories may be neglecting chemicals that pose significant risks simply because they are incompatible with existing instrumentation and methodologies.⁽⁷⁶⁾ Second, we observed that debates about the threats posed by PBDEs, and about the ideal policy response to those threats, drew heavily on past experiences with “similar” chemicals, particularly the PCBs and PBBs (i.e., on reasoning by analogy). We also saw that the selection of particular historical analogues is contested rather than preordained (e.g., consider the attempts to establish experience with DDT as the relevant analogue). This is because there is no unproblematic criterion that guides the selection of analogues (e.g., there are often many properties on which one might generalize and construct classes); similarity is, to a large extent, in the eye of the beholder. The final aspect of path dependence is that early regulatory actions taken by even relatively small and economically weak states such as Maine can create powerful incentives and pressure for other jurisdictions to mimic their actions. While learning from other states is no bad thing, mimicking has its limitations. One is that the evolution of regulatory responses over time and space may depend on the relatively arbitrary question of which jurisdiction gets to set the precedent. A second is that in cases where different jurisdictions have adopted different stances on a risk issue, then who should be mimicked (e.g., the majority, the most expert, or those of a certain political leaning)?

Traditional capture theories are relatively well-worn territory, and we are skeptical of their explanatory power in this case. Indeed, we suggest that capture theories may themselves be problematic, in the sense that a preoccupation with vested interests can lead policy debates to depart from norms of reasoned deliberation. A distinct but related phenomenon we identified was political entrainment. Here, the regulation of a given risk was caught up in a broader political conflict—the struggle between the European Commission and Parliament over lawmaking and implementing powers—and ultimately resolved according to criteria largely unrelated to the risk at hand—relatively narrow procedural concerns. This phenomenon, if widespread, casts serious doubt on the very concept of risk-based regulation. Finally, our study highlighted the substantial role that partisanship played in the regulation of PBDEs within the U.S. state legislatures. The issue of whether or not to restrict a particular class of flame retardants does not on its face seem an ideologically salient one—it is hardly gun control or abortion—so sharp partisan divides on this question seem to cast doubt on the capacity of legislatures to handle the nuts and bolts of risk regulation. If these divides stemmed from reasoned ideological disagreements about how to proceed from an agreed

upon level of risk to the optimal policy position, that would be one thing. Yet they encompassed both ends of the science-policy continuum, including relatively esoteric disputes about the validity of neurodevelopmental toxicity testing protocols.

So what does all this mean for risk-based regulation? After all, its fundamental premise is that regulatory decisions should flow from balancing the risks and benefits of particular risk objects.⁽⁸²⁾ Of course, there is now widespread acceptance that social and moral judgments will inevitably and quite properly underlie this balancing, for example, through the consideration of distributional concerns. Nevertheless, the logic of risk-based regulation is that regulatory decisions should be driven by the merits (or lack thereof) of the individual risk object, not by the object's compatibility with existing laboratory practices and instrumentation, or by considerations of which class of historic compounds it putatively belongs to, or by broader institutional disputes, or, finally, by partisan considerations. Proponents of risk-based regulation might thus seek reforms in light of our study, with the goal of stripping away these extraneous dimensions of regulation. But the problem is that the multidimensionality of risk regulation is not necessarily pathological. That is, factors such as path dependency and political entrainment can be justified by separate logics or rationalities. We illustrate this point below.

For example, reformers might seek to counteract political entrainment by calling on courts to refrain from overturning regulatory decisions on procedural grounds. But this is not entirely consistent with a separate rationality, that of securing good governance, of holding the various branches of government accountable to their own laws. Similarly, reformers might argue that policy making should focus principally on evidence derived from the risk object itself (e.g., evidence directly pertaining to a chemical's toxicity and exposure), rather than drawing heavily on historical analogues. But this would involve turning a blind eye to the lessons of the past (however they might be construed), and would thus be incompatible with norms of precautionary governance. As a final example, reformers might call for legislatures to make greater use of ad hoc or standing expert advisory panels⁽⁸³⁾ to compile, analyze, and legitimize the state of knowledge on risk issues under consideration, as a way of reducing the role that partisanship plays in interpreting regulatory science. But perhaps this would simply involve recasting what are fundamentally ethical disagreements as merely technical disputes.

That is not to say that these ideas are not worthy of consideration. Rather, our basic point is that it is not self-evident that the logic of risk-based regulation represents a normative ideal. Instead, it requires justification relative to alternative logics of governance, in terms of whether it is likely to lead to a superior body of laws, regulations, and outcomes for society. This is a challenge that requires broad empirical sampling, and elaboration of normative commitments, rather than case-study research. Our contribution lies in showing that risk-based regulation may be something of a mirage, and one that does little justice to the far more complex, messy, and multidimensional character of governance as practiced.

Footnotes

4 The class of PBDEs include 209 possible substances, each of which is known as a congener.

5 The former is the process by which the Commission, aided by various committees, implements legislation, while the latter is the process by which the Parliament, Council, and Commission write legislation.

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