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## Rulemaking in the Ages of Globalization and Information: What America Can Learn from Europe, and Vice Versa

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# ARTICLES

## RULEMAKING IN THE AGES OF GLOBALIZATION AND INFORMATION: WHAT AMERICA CAN LEARN FROM EUROPE, AND VICE VERSA

*Peter L. Strauss\**

*This Article stems from a project on European Union Administrative Law undertaken by the American Bar Association's Section on Administrative Law and Regulatory Practice. It explores the generation of normative texts by the Commission of the European Union, its executive body, from the perspective of Americans familiar with notice and comment rulemaking. Legislative drafting (an exclusive responsibility of the Commission), subordinate measures corresponding to American rules and regulations, and soft law generated by the Commission are all considered. In creating legislative proposals, the Commission uses techniques quite like American rulemaking, but with consultative practices (including electronic consultations) that seem more conducive to dialogue, and less open to simple grass-roots lobbying efforts. Soft law processes are also often highly consultative. But subsidiary legislation (rules and regulations, in American parlance) are generated following procedures considerably less transparent and open to public input, such as comitology, than one finds here.*

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## I. INTRODUCTION

Americans have, from time to time, trumpeted the virtues of the notice-and-comment rulemaking procedures their administrative agencies employ when adopting regulations, and urged other nations to imitate their practice. Perhaps noting our at least equally prominent moaning about the ossification of those procedures, those nations have seemed to resist. At the same time, the ineluctable forces of the information age are transforming politics, worldwide. The globalization of economic activity is motivating the creation of government institutions that transcend national boundaries—and for that reason also outstrip national political traditions. These institutions must find approaches to regulation that can both satisfy divergent politics and elude the frustrating grip of those whose activities require public controls. A study of the European Union's procedures for generating regulatory norms suggests possible lessons both for America, and for the Union.

On a spring day in April 2005, the *International Herald-Tribune* carried two stories that framed the project. The front page story was headlined “On the EU Battlefield: Armies of lobbyists assail Brussels,”<sup>1</sup> and opened with an account of lobbyists’ reaction to a European Commission decision that a vegetable sauce with more than twenty percent lumps was itself a “vegetable” and so subject to tariffs as much as twenty times higher than sauce as “sauce” would encounter. The American public encountered comparable silliness when President Ronald Reagan’s administration wanted to treat tomato ketchup as a vegetable, to get credit for supplying healthy foods in school lunch programs. “As the EU’s powers have extended even deeper into companies’ lives,” the *Herald-Tribune* wrote, “so the interest of businesses in defending their causes on the legislative battlefield of Brussels has intensified.” The article was about companies and the thousands of their lobbyists who now throng the EU capital, but it might as well have been about citizens or NGOs—Friends of the Earth as well as Unilever are there and fighting. Seven months later, *The Wall Street Journal* reported, to the same effect, on the travails of the Kellogg Company trying to secure uniform access for its breakfast cereals to EU markets.<sup>2</sup>

<sup>1</sup> Graham Bowley, *On the EU Battlefield*, INT’L HERALD TRIBUNE, Apr. 5, 2005, at 1.

<sup>2</sup> G. Thomas Sims, *Uncommon Market; Corn Flakes Clash Shows the Glitches in European Union*, WALL ST. J., Nov. 1, 2005, at A1.

The second story was an op-ed piece, "EU's growth triggers identity crisis,"<sup>3</sup> addressing the prospect that the stress of European enlargement imperils the European project at the very moment of an effort to adopt a European constitution, then pending ratification. Just what is Europe, and why should anyone want it? The questions were grounded in the reality of differing national ambitions and fears, ambitions and fears having rather little to do with the technical rearrangements of the draft "constitution, which few have read. By now," the *Herald-Tribune* wrote, "approval of the constitution has been turned into a referendum on issues that have little or nothing to do with the constitution, such as Turkish membership in the EU, the Stability Pact, the Bolkstein directive on liberalizing rules for the service industry, and local partisan rows."

While stunning defeats of the draft in referenda in France and the Netherlands shortly consigned the draft constitution to oblivion, the EU continues to function under its present treaty regimes. And that still has remarkable implications for Europe's national governments. As one author recently wrote, "up to 90% of all environmental legal acts within the national legal systems [of the European Union] are of EU origin and national parliaments sometimes . . . have nothing to do other than simply transform European directives into national legislation."<sup>4</sup> This decline in national parliaments gives the question how EU laws are formed particular interest; to what extent are EU institutions under democratic control, to what extent corporativist, etc.?

This Article is associated with a larger project carried out under the auspices of the American Bar Association's Section of Administrative Law and Regulatory Practice. The project as a whole is intended to help Americans understand the administrative law of the European Union. This particular element of it is nominally concerned with activities parallel to what American administrative lawyers know as "rulemaking." It reports some observations on how the European Commission (the EU executive) works to shape legal texts—statutes, regulations, even influential advice—in comparison to American approaches, and in a context in which access, transparency, influence, and accountability are increasingly important.

It seems useful to warn the reader at the outset that the comparison project is imperfect in a variety of respects. To be wholly successful, any project in comparative law had better aspire to understand the whole of the societies and institutions being compared, not just pieces of them; and the very complexity of the EU framework defeats that hope. The study draws on several studies of particular sectors of the EU by experienced Brussels practitioners, undertaken with the helpful advice of high-level Commission staff; and those reports reveal significant variation in practice from sector to sector—despite the Commission's efforts to assure uniformity. Beyond this, the study addresses *only* activities taking place at the European level—in general, although not exclusively, within the EU itself. But lawmaking in Europe is an intermixture of EU and Member State activity,

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<sup>3</sup> William Pfaff, *EU's Growth Triggers Identity Crisis*, INT'L HERALD TRIBUNE, Apr. 5, 2005, at 7.

<sup>4</sup> Christoph Demmke, *Comitology in the Environmental Sector*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC 279, 279 (Mads Andenas & Alexander Turk, eds., 2000). A footnote adds details: 35% in Denmark, 50% in Netherlands and Germany, 80% in the United Kingdom, and up to 95% in Portugal, Greece, Italy, and Spain. *Id.* n.2.

particularly when it comes to the adoption of measures to implement EU legislation—the activity American lawyers would most readily identify as rulemaking. While American analogies are available—for example, the EPA oversees State Implementation Plans (that may involve *state* rulemaking activities) as well as engaging in its own rulemaking—these analogies are not so well developed in the American literature of administrative law, and the extent of interpenetration in Europe is considerably greater. Any study would be complicated, as well, by the variety of languages and political systems one would encounter among the Member States.

The presentation following looks at European-level procedures for generating abstract norms. It does so at three or perhaps four levels of decreasing formality, proceeding from the more to the less formal; diversity increases as one descends. European Union law can be framed within a nesting hierarchy that would be familiar to Americans—or, for that matter, to the citizens of any modern, developed legal order. At the highest levels of the legal order, one finds limited foundational documents—a constitution, or treaties—that are the product of extraordinary procedures rarely invoked and requiring demanding procedures for ratification as well as adoption. At the next level, one finds laws, statutes, directly enacted by a Congress or parliament, no more than a few hundred yearly. Beneath that, subsidiary legislation or regulations adopted by executive authority—departments, agencies, ministries—under legislative authorization; typically, at this level of detail, thousands annually. Enabling legislation may authorize others than the executive—subordinate political units (states in the United States, Member States in the EU), even private organizations—to adopt norms under conditions of supervision and, perhaps, required procedure. These norms interact. Then one may find in still greater profusion documents offering guidance or other forms of “soft law,” not in itself binding on citizens although still influential. And this distribution of normative instruments holds true for Europe. In 1996, for example, the European Parliament and Council adopted 484 “legislative” acts; in the same year, following very different processes and under rather light supervision, the European Commission adopted 5147 “regulations,” with a great deal of Member State implementing measures, standards, organization measures, and uncounted “soft law” below that.<sup>5</sup>

Any normative text embodies both a view of the realities with which it deals, we could say technical or factual propositions about the real world to which it relates, and a set of political or social propositions about desired, hopefully just, outcomes. The tension between the idea of norms as the expression of a political judgment, and norms as the product of an expert technical judgment, is felt differently at each level of this hierarchy. Here’s a concrete example in the American context.

- The American Constitution, in sweeping terms, authorizes Congress to legislate

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<sup>5</sup> Georg Haibach, *Separation and Delegation of Legislative Powers: A Comparative Analysis*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC, *supra* note 4, at 53. To similar effect, for different years and making comparisons to similar European national experience, see Gunther Schafer, *Linking Member State and European Administrations—the Role of Committees and Comitology*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC, *supra* note 4, at 3, 6, 9; Josef Falke, *Comitology, From Small Councils to Complex Networks*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC, *supra* note 4, at 331, 336.

on matters affecting national commerce, in support of public safety and welfare. We don't expect expert knowledge to have much if anything to do at the constitutional level. Albeit premised on views of human nature that might or might not be valid, the Constitution is expressed only as high politics; at most we sometimes ground its interpretation in propositions about the real world that draw on expert judgment.<sup>6</sup>

- For the American Congress, whether and under what conditions to permit nuclear generation of electric energy are judgments fundamentally controlled by its members' assessments of nuclear power's risks, in itself and in relation to other possible power sources (oil, for example). The legislature's work is the exercise of ordinary politics, albeit that work is sometimes framed by views of the facts-on-the-ground that might be thought technical. Little Congress does is framed or credible as the exercise of expert judgment; we commonly think of "legislative facts" as facts that are acceptable to be determined by a vote. Any judicial check on such legislative judgments rests either on sheer, demonstrable irrationality ("the world is flat") or on inconsistency with the higher norms of the Constitution. The Constitution might not permit legislative judgments based on propositions about racial difference, for example, even if in some technical sense the propositions were true. Ordinarily, however, we accept that legislation is proper if a majority in the legislature supports it—that is, what the majority believes the facts to be suffices.

- Once we get to the level of regulations, expert judgment about the facts begins to count for a lot—although politics may still have a role to play.<sup>7</sup> Congress has established a Nuclear Regulatory Commission to oversee nuclear power generation. When its commissioners adopt a regulation about necessary levels of radiation protection, their political authority as immediate delegates of Congress and appointees of the American President may carry some weight for Americans aware of the inevitable imprecision of human factual judgment about such matters. Still, at this level, accuracy in assessing reality becomes much more important as a test of legitimacy. We teeter between regarding regulators as persons whose authority and actions are warranted by their apolitical expertise, and taking them as political agents (in this case, of the chief executive) whose authority and actions are to be derived not from facts they are uniquely positioned to assess, but from their relationship to that principal. We are uncertain whether the process for creating regulations is one designed for gathering and assessing facts, or one in which it is important that all points of view can be expressed. American judges have created regimes of review, "hard looks," that place a high value on factual accuracy and afford much less room for politics than legislators enjoy.<sup>8</sup>

- "Soft law"—say, policy advice—emerging from the Commission may be just as political as regulations; but in technical agencies, at least, "soft law" is primarily the product of subordinate bureaus, not the political leadership of the agency. And when it is, with policy thus made at the greatest remove from political controls, we really

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<sup>6</sup> For example, that African-American school children are psychologically, developmentally disadvantaged by segregated education. *Brown v. Board of Educ.*, 347 U.S. 483, 494 (1954).

<sup>7</sup> On the interrelation of expert and political rationales of legitimacy, see Matthew Adler, *Justification, Legitimacy, and Administrative Governance*, ISSUES IN LEGAL SCHOLARSHIP: THE REFORMATION OF ADMINISTRATIVE LAW art. 3 (John F. Manning ed., 2005).

<sup>8</sup> See *Sierra Club v. Costle*, 657 F.2d 298 (D.C.Cir. 1981); *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87 (1983).

expect/hope that expert judgment will prevail. When the Nuclear Regulatory Commission's Bureau of Standards has issued a guidance document stating that a containment four feet thick, built of concrete in a specified way, will provide a required level of radiation protection for a nuclear power plant of a certain design, we expect that document to stand or fall entirely on the basis of expert judgment. The deeper one moves into the bureaucracy of administrative government, then, the more important is the model of fact-finding expertise.

An American lawyer also approaches the creation of these differing normative texts—constitutions, statutes, regulations, guidance documents—with a set of institutional expectations that shape his understandings.

- Each of these levels—constitution, statute, regulation, soft law—is the product of a distinct institution. The people, acting complexly through a variety of institutions/agents, make constitutions; the legislature makes statutes; the political leadership of an executive agency (or the courts) makes rules; the staff of a subordinate bureau creates guidance documents. Different individuals and different procedures are responsible for the wording of statutes, of regulations, and of advice.
- “Separation of powers” considerations, in the American perspective, sharply differentiate legislative from executive authority and activity. Statutes are the work of the legislature. The President can recommend legislation and can attempt to block (veto) entire enactments of which he disapproves; but he cannot force consideration of any measure and he scarcely participates in the work of its drafting and detailed consideration. Regulations and soft law are the product of processes in which neither the Congress as a whole nor any of its individual members are entitled formally to exercise decisional authority, save for the possibility of enacting statutes in disapproval.<sup>9</sup> (It is a matter in vigorous dispute whether the President, as distinct from the government body the Congress has explicitly made responsible to act, is so entitled.)
- There is the expectation, too, that the constitutionally established institutions and their authority are quite fixed, not contingent. Since the Civil War at least there has been no sense that the authority of Congress depends from day to day on the continued acquiescence of states in a problematic union. When the President and the executive branch act, they have at best a weak obligation to engage in consensual dealings among executive authorities with equivalent responsibilities in the states.
- Within the executive itself, as remarked, the exact nature of presidential authority over agency choices is unsettled. Do the agencies possess their own authority, whose exercise the President merely oversees; or is their authority necessarily derivative of his own, so that he may not only see to their faithful execution of the laws but substitute his own judgment for theirs on disputable matters? Whichever choice one makes between these contending views, to Americans it is clear that the President is a popularly elected, and thus politically accountable figure—essentially the only such figure in the executive.<sup>10</sup>

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<sup>9</sup> This is hardly to deny the possibilities of informal influence, as by oversight hearings, appropriations measures, casework, and the like.

<sup>10</sup> No one knows quite how to regard the Vice President, whose election follows from the President's and whose constitutionally described functions are at least as much legislative (presiding in the Senate, with a tie-breaking vote) as executive (substituting during periods of presidential incapacity).

Consequently they understand his exercise of authority to be hierarchical, not democratic; Americans do not imagine the executive as a collective.

The tension between superior expertise and politics as the coin of bureaucratic legitimacy, as well as the hierarchy of normative instruments will be familiar enough to any citizen of a parliamentary democracy, but many of the forgoing propositions will nonetheless seem strange. She may be used to governmental institutions in which a principal (if not the dominating) executive figure, the prime minister, must be a member of the legislature and is in a position to control both the introduction and the ultimate passage of statutes. Ministers, what Americans would regard as cabinet Secretaries, may also sit in Parliament; and in any event they are directly answerable to it for the regulations adopted in their administrations. And the parliamentary cabinet is much more a collective body — ministers often sharing electoral responsibility with their Prime Minister; the duration of their government depending both on its continuing success in parliament, and on the ministers' continuing collective willingness to constitute a government. Much less likely is any idea that the prime minister has a particular, unique, and electorally grounded authority to dictate the proper outcome of any disputed matter within the executive.

For the European Union, in particular, the institutional context is quite different to that of the United States. American expectations are out of place.

- Both as the child of treaties, and as a reflection of the content of those treaties, the Union and its institutions are contingent on the continued interaction of states in a way Americans may find hard to appreciate. Its primary laws are the product of international concord, not popular will.<sup>11</sup> Its institutional arrangements, and its civil servants, need to be sensitive to the proposition that the Member States are nations, and the EU is not. Those nations have linguistic identities (reflected in the obligation to translate governing documents into all official languages of Member States), unshared (and often long) histories and characters, and differing legal and governmental institutions and orientations. Rivalries reflected in both diplomatic and martial history stretch far into the past. Collective action at the European level is far from instinctual, and almost invariably requires a level of integration of supranational and national effort Americans would find difficult to appreciate.
- One can construct its other normative documents in a hierarchy outwardly similar to American expectations: "legislative acts" that are the product of what might seem a bicameral legislature acting in coordination with an executive authority; "rules" produced by the executive authority; and guidance emerging from its bureaus. Yet strikingly, the European Commission, the Union executive, unambiguously holds important responsibilities in the creation of *all* these documents: the EU legislature can act *only* on proposals that come from it; the Commission is the source of most pan-European "rules" or implementing measures having the force of law; and soft-law guidance, as well, generally requires its approval. And, on the other hand, this unity is undercut by the EU's sharply limited direct authority to command; the bulk of implementation of EU legislative measures is left to Member State initiative, under constrained circumstances of supervision.

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<sup>11</sup> The Draft European Constitution, had it been ratified, would not have been a "constitution" in the usual national sense. Although titled a constitution, its text consistently presents itself as a treaty—as a "We the States," not a "We the People" document.



- The Commission's makeup reflects parliamentary rather than republican expectations about executive structure: Its President is chosen by the legislature, not by the people, and it acts collegially. Those in charge of its directorate generals (the equivalent of ministers in a parliamentary system) hold an independent authority on which in some sense the President depends.

- A number of elements make the Commission's ostensibly independent policymaking responsibilities for implementation more an element of collective responsibility, contingent both on national and international bureaucratic consensus, than a node of independent institutional power. Comitology, a practice internal to the EU that engages national representatives in discussions with responsible Commission staff, is the most directly relevant of these for a discussion of EU procedures.<sup>12</sup> But framework legislation is often designated for implementation at the national level under Commission guidance, making this interdependence even more clear. Other measures frequently recognize significant standard-setting authority in transnational standard-setting bodies outside the Council-Commission-Parliament trilogy—international organizations like the Codex Alimentarius Commission of the FAO and WHO,<sup>13</sup> dealing with food safety issues, independent agencies such as the European Food Safety Authority,<sup>14</sup> and quasi-private standards organizations such as CEN, the European Committee for Standardization.<sup>15</sup> Save perhaps for comitology committees, analogous institutions are not lacking in American experience. State implementation measures adopted under federal supervision are characteristic of many spending (education, welfare) and regulatory (environment, workplace safety) regimes; and at the state level, organizations like ANSI (the American National Standards Institute) are often entrusted to a significant degree to develop the technical standards underlying public regulation. Yet we are used to thinking of administrative law in simpler ways, not in these terms.

- Finally, and quite strikingly from the perspective of the tension between expertise and politics as the coin of legitimacy, the literature about the Commission's actions consistently imagines Commission bodies to be expert as well as consensual—their authority grounded in technocratic rather than political judgment. Popular will is in some sense feared, while judicial checking of sums is thought unnecessary, an invitation to unwonted legalism.

The contrasts with the American system, then, are striking—and in many respects self-conscious.

What has already been said, particularly about the many diversities of the Member States of the European Union, should suggest that considerations of participation and transparency have great importance to any such undertaking. That importance is heightened, in my judgment, by the proposition that we stand on the cusp of an identity crisis in our relations to government generally, as the information age transforms the relationships we can have with it, and it with us. Internet resources may permit us to access and share governmental information more widely,

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<sup>12</sup> See *supra* Part III(a).

<sup>13</sup> Codex Alimentarius Home Page, [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp).

<sup>14</sup> European Food Safety Authority Home Page, <http://www.efsa.eu.int>.

<sup>15</sup> European Committee for Standardization Home Page, <http://www.cenorm.be/cenorm/index.htm>.  
See *supra* Part II(c).

and also to participate in policy formation by bringing our views to bear in a pointed and timely fashion. Yet at the same time, these resources may magnify both the possibilities for internal manipulation and control, and the possibilities for distorting or at least obfuscating the public's will. To take two simple examples, looking in opposite directions:

- Fifteen years ago, when government files were made of paper, discovering their content even assuming they were public would have required me to go (or more likely to hire an attorney to go) to them, sort through them hoping to find what I wanted, and take notes or make physical copies. Today, sitting at a computer, I can immediately access not only the proposals government agencies may have made for rulemaking and a portal through which to comment on them, but also the comments others have already filed, supporting studies, and (for rules already in place) interpretations or guidance the responsible agency may have issued. The added transparency, and its effect in freeing citizens from having to secure the services of possibly expensive intermediaries, is stunning.
- Fifteen years ago, it would also have cost me physical effort and the price of a postage stamp for each letter I wrote to Congress or an administrative agency, and there would have been a postmark to tell the recipient where the letter came from. None of this is true any longer. We have all learned to distrust the reality of ostensible electronic return addresses; and profitable commercial ventures compete to provide NGOs and others with the electronic wherewithal to make the most of this essentially costless possibility for communication. What to make of an apparent outpouring of public sentiment has become much more problematic.

This project seeks to effect a comparison between rulemaking procedures of the EU and the United States at the second, third, and fourth levels of the hierarchy of norms suggested above, limited to the EU itself (with minor attention to pan-European standards organizations) and with particular attention to the use and impact of internet resources.

## II. FRAMING LEGISLATION

We start, then, with the framing of legislation—"statutes," in the American context; "regulations" and "directives" under the current EU treaties.<sup>16</sup> Like statutes, "regulations" and "directives" have the force of law; but in a treaty-grounded institution, they speak primarily to the membership of nation-states. "Regulations," a form less interesting to our study, may have direct legal effect permitting enforcement by individuals.<sup>17</sup> Directives, by contrast, are legislative acts that "shall

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<sup>16</sup> Treaty Establishing the European Community, Nov. 10, 1997, 1997 O.J. (C 340) 3, art. 249 (ex 189) [hereinafter EC Treaty]. "Regulations" would have been denominated "European laws" and "directives," "European framework laws" had the draft EU constitution been ratified—a usage less confusing from the American perspective. Article 249 also refers to "decisions," binding in [their] entirety upon those to whom [they are] addressed." Because they are addressed to named individuals, "decisions" seem best characterized as executive, perhaps adjudicatory, acts rather than measures of general applicability. They will not be further considered here. See PAUL CRAIG & GRAINNE DE BURCA, *EU LAW—TEXT, CASES AND MATERIALS* 115 (3d ed. 2003); KOEN LENHAERTS & PIET VANNUFFEL, *CONSTITUTIONAL LAW OF THE EUROPEAN UNION* 780–81 (Robert Bray ed., 2d ed. 2005).

<sup>17</sup> A "regulation" is a Community legislative act described in the EC Treaty as being "binding in its entirety and directly applicable in all Member States." EC Treaty art. 249 (ex 189). "[I]f they are

be binding as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.”<sup>18</sup> This formulation self-evidently creates opportunities for delegation to Member States, the principal source of implementing measures. Yet it also is the source of delegations to EU authorities to set technical parameters within which the Member States are to act. An example would be a directive requiring Member States to prevent or limit pollution of water and air by ships;<sup>19</sup> this directive entails attention to, and parameters for, discharge provisions, construction requirements, equipment requirements, and requirements for operational procedures; even if such a directive itself set the initial parameters that state implementation must meet, it will frequently authorize EU authorities to revise those parameters as developing technology makes possible. As they “leave to the national authorities the choice of form and methods,” it would appear that directives create obligations that, at least in formal terms, only the Commission can directly enforce.<sup>20</sup> But the European Court has found numerous respects in which directives may be given legal effect in private litigation, even litigation between two private parties, leading to the observation that “the distinction between directives and regulations remains salient in political terms even while the legal consequences of their use are complex and confused.”<sup>21</sup>

The discussion here will be limited to the framing of proposals for legislation, treating debate and enactment as matters outside the purview of this Article. Respecting the latter, it seems sufficient to remark that enactment procedures are themselves set by the relevant treaty provisions. For binding legislative instruments of general validity (i.e., regulations and directives), there are at present essentially two types of legislative procedure—the consultation procedure and the co-decision procedure. Of those, the more important is the co-decision procedure, a complex process that generally allows the Council to act by “qualified majority” voting, allows the Parliament to interact directly with the Council in the development of the ultimate legislation, and gives it a veto over the terms of that legislation. Under consultation procedure, much less frequently used as Parliament has gained in stature, the Council must act unanimously, and while the Parliament must be consulted, it has no direct right to participate in the development of the legislation and no veto power.

The limitation of this study to the *framing* of legislative proposals may immediately strike American readers as nonsensical. In the American context, the drafting of legislation is not an important, and certainly not a public, procedural

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immediately part of the domestic law of Member States [without requiring implementing legislation] there is no reason why—so long as their provisions are sufficiently clear, precise and relevant to the situation of an individual litigant—they should not be capable of being relied upon and enforced by individuals before their national courts.” CRAIG & DE BURCA, *supra* note 16, at 190.

<sup>18</sup> EC Treaty art. 249 (ex 189).

<sup>19</sup> See, e.g., Protocol of 1978 Relating to the International Convention for the Prevention of Pollution from Ships, 1973 (MARPOL 73/78).

<sup>20</sup> EC Treaty arts. 226, 228.

<sup>21</sup> CRAIG & DE BURCA, *supra* note 16, at 227. See generally *id.* at 202. “The Legal Effects of Directives”; SACHA PRECHAL, *DIRECTIVES IN EU LAW* (2d ed. 2005). For example, a directive will often set a time by which compliance is required; after the expiration of that time, private parties may be able to avail themselves of national non-compliance with the directive defensively in litigation with the non-complying nation or its agencies.

context. In formal terms legislative proposals come only from legislators. The members of Congress are under no procedural obligations whatever to the outside world in what they may choose to introduce as legislative business. One searches congressional websites in vain—both the general website,<sup>22</sup> and individual committee websites—for signs of engagement with the public in the framing of legislation. Each chamber has offices responsible for drafting desired legislation on members' behalf; their use is not obligatory, however, and they deal only with the members requesting their drafting help. Private citizens, more likely lobbyists or NGOs, may draft proposed legislation, but they must persuade members to introduce it.<sup>23</sup>

The American Constitution empowers the President to suggest legislation to Congress, but the power to make suggestions is not uniquely his, and the fact that he has made a suggestion does not create legislative business. His suggestion must be introduced by a member of Congress, who is formally, if not always politically, free to decline to do so, or to change its wording in any manner she chooses before doing so. To be sure, the President has put in place internal procedures for controlling the development of legislative recommendations; agencies must secure clearance from the Office of Management and Budget before seeking congressional action, and that obligation is used to effect a very useful coordination across the whole face of the executive branch. But while it is always possible that the administration's friends are engaged in this process, or that for some particular initiative—health care reform, or the creation of an energy policy—the White House will establish a consultative framework to shape its recommendations, none of this is commanded by law. There are no equivalents in statutory development for the internet notices and consultations that mark American rulemaking, now broadly exposed and engageable on the internet. Neither are there American legislative equivalents of the public analytic regimes agencies are required to follow in developing their rulemaking proposals. True, Congress has instructed itself to engage in environmental, economic, and other forms of analysis in connection with legislative work; and one can note in legislative histories assertions that this required analytic work has been done. But participation in and enforcement of these obligations are wholly internal matters; the public, including in this respect the President and executive branch, are not involved.

The European Union, in contrast, operates within a regularized procedural framework for the development of legislative proposals, as established by the EU and EC Treaties. Under the treaties, as would have been continued by the draft European Constitution, essentially all legislative business—that is, all proposals considered by the Council and Parliament for actions that will have the force of law on Member States and/or their citizens—*must* originate with the Commission. The rationale behind entrusting the Commission with such a monopoly is to prevent the submission of legislative proposals inspired by nationalistic interests that would lead to the backsliding of Community legislation. The Parliament and the Council have authority to amend and adopt such legislation (although the Council cannot directly

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<sup>22</sup> The Library of Congress, THOMAS Home, <http://thomas.loc.gov>.

<sup>23</sup> Statutes regulating lobbying practice, requiring certain disclosures and placing limits on the relationships between lobbyists and members, might be considered a limited form of public procedure associated with legislation.

amend a Commission proposal),<sup>24</sup> whose precise extent generally depends on the type of legislation involved and the subject matter of the legislation. But the Commission's monopoly of the right to initiate legislation gives it broad discretion regarding the form, objective, content and the timing of any proposal, and the authority to decide what kind of preparation work should be done before the actual submission of the proposal to the other institutions. The existence of this framework makes treatment of the procedures for developing legislative proposals sensible in a study of European "administrative law."

Of course the political realities<sup>25</sup> give the Council and Parliament considerable influence over what will emerge as the Commission's proposal. Nonetheless, it must be the Commission that proposes. And while the Commission has felt free to develop its own set of practices in a non-binding format that confers no judicially enforceable rights on participants, an understandable regard for its credibility as an institution has led the Commission to structure the path to legislative proposals in ways that offer considerable transparency and opportunity for public contribution to the process.

#### *A. Notice of Development*

Proposals emerge only because at some point it has been decided to develop them. Useful generalizations about this initial stage are limited. Promptings from Member States, the Council or the Parliament, lobbyists' suggestions, and consideration internal to the Commission and/or its DGs are all possible choices. Although the EC Treaty is silent as to internal processes the Commission must follow before sending legislative proposals to the Council and the European Parliament, the 1999 Amsterdam Treaty Amendments, without explicitly creating private rights of enforcement, added a certain legal effect to the Commission's political incentives. The Amendments required that:

4. For any proposed Community legislation, the reasons on which it is based shall be stated with a view to justifying its compliance with the principles of subsidiarity and proportionality;<sup>26</sup> the reasons for concluding that a Community objective can be better achieved by the Community must be substantiated by qualitative

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<sup>24</sup> EC Treaty art. 250.

<sup>25</sup> Thus, what appears to be a fairly limited and general right of input under the present Treaties has in fact been used "to frame very specific proposals which it [the Council] wishes the Commission to shape into concrete legislation." CRAIG & DE BURCA, *supra* note 16, at 69. The draft Constitution would have made clear an expectation that legislative initiatives would in fact arise outside the Commission. *See e.g.*, Treaty Establishing a Constitution for Europe, Dec. 16, 2004, 2004 O.J. (C 310) 1, arts. III-332 (majority Parliamentary request for proposal, requires reasons for declination), III-345 (majority Council request for proposal, requires reasons for declination), & I-47(4) (a million citizens from a significant number of states may frame a request) [hereinafter Draft Constitution]. For a thoughtful analysis, see Paul Craig, *European Governance: Executive and Administrative Powers Under the New Constitutional Settlement*, 3(2-3) INT'L J. CONST. L. 407 (June 2005).

<sup>26</sup> The principles allocating responsibility as between the EU and its Member States—roughly, that the EU may act only to the degree reasonable to secure its limited purposes and even then only in circumstances, and to the extent, that its Member States are incapable by their own actions of achieving them.

or, wherever possible, quantitative indicators. . . .

9. Without prejudice to its right of initiative, the Commission should:

—except in cases of particular urgency or confidentiality, consult widely before proposing legislation and, wherever appropriate, publish consultation documents;

—justify the relevance of its proposals with regard to the principle of subsidiarity; whenever necessary, the explanatory memorandum accompanying a proposal will give details in this respect. The financing of Community action in whole or in part from the Community budget shall require an explanation;

—take duly into account the need for any burden, whether financial or administrative, falling upon the Community, national governments, local authorities, economic operators and citizens, to be minimized and proportionate to the objective to be achieved;

...

The consequence is to create pre-proposal obligations of consultation and analysis in conjunction with legislative proposals that might seem quite familiar to persons acquainted with American agency rulemaking. The manner in which these obligations are carried out is the business of the immediately following pages.

Preliminary stages may involve the preparation of Commission white papers or green papers exploring policy alternatives—a stage that frequently involves its own consultative processes, as discussed below both in general,<sup>27</sup> and in connection with the proposed regulation of the chemical industry.<sup>28</sup> The development of legislative proposals are generally assigned to the Directorate General responsible for the subject matter, which will begin informal consultations with Member State experts and others as drafts are prepared. As with rulemakings in the United States, full public engagement begins no later than the appearance of the project on the Commission's work plan and—certainly relative to the time it usually takes to bring a proposal to finality—this brings the project into early public view.<sup>29</sup>

The Commission's work plan is published in numerous formats at its worksite,

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<sup>27</sup> See *infra* p. 664 ff.

<sup>28</sup> See *infra*, notes 54–60 and 78–88 and accompanying text.

<sup>29</sup> Nonetheless, one encounters suggestions that pre-proposal consultation occur at an earlier stage, and some provision for that by individual DGs. A study by the U.K.'s Better Regulation Task Force included the following case study:

On 1 July 2005, DG SANCO introduced new guidelines on developing policy proposals ... requir[ing] desk officers to produce a Scoping Paper - a single document that sets out all the information necessary to discuss, launch and develop an initiative from its inception to the time it is submitted to the Commissioner for a decision. With certain exceptions, a Scoping Paper is required for all new legislative proposals and non-legislative proposals leading to a Commission decision.... Under this new system, by integrating stakeholder engagement into the policy process from the very beginning, DG SANCO estimates that the first informal consultations could take place *as much as two and a half years before an approved proposal is published in the Commission's Work Programme*. (emphasis added).

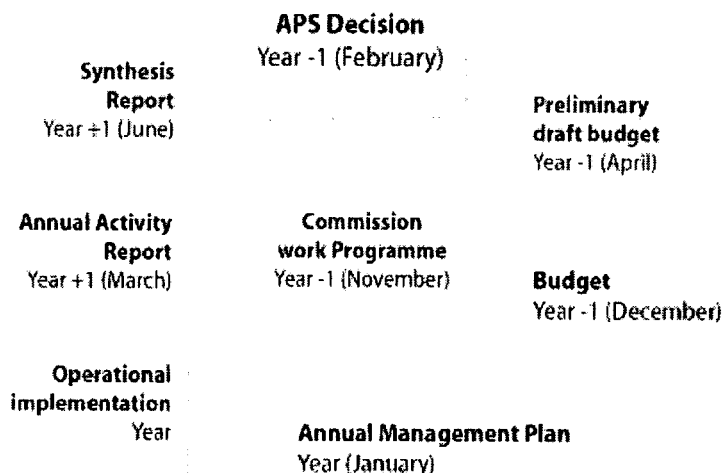
Better Regulation Task Force, *Get Connected: Effective Engagement in the EU* 29–30 (Sept. 2005), available at <http://www.brc.gov.uk/downloads/pdf/getconnected.pdf> [hereinafter *Get Connected*].

from a five-year strategic plan to a three month rolling programme.<sup>30</sup> Perhaps the most useful of these, because they contain contact information within the responsible DG, are the “roadmaps”<sup>31</sup> Commission guidance requires its directorates to develop and publish concerning the proposals adopted as elements of the APS and WP.<sup>32</sup> Like entries in the American regulatory agenda, these give a brief account of the matters under development, following a uniform framework for preliminary impact

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<sup>30</sup> See The Commission’s Work Programme, [http://europa.eu.int/comm/off/work\\_programme/index\\_en.htm](http://europa.eu.int/comm/off/work_programme/index_en.htm). In the following diagram, the APS is the Annual Policy Strategy, a general policy document that sets out the priorities of the Commission for the following year. See *Communication from the Commission to the European Parliament and the Council: Annual Policy Strategy*, COM (2005) 73 final (March 2, 2005). It is generally adopted in February of the preceding year and takes the form of a non-binding communication from the Commission to the European Parliament and the Council. Although a Commission document, it takes account of feedback received from the Parliament and the Council, and can therefore be considered to be the result of an inter-institutional dialogue. The annual Commission Work Programme, adopted in November of the year preceding the year during which it should be carried out and then published, lays out how and where the Commission will act in order to pursue the priorities and the key initiatives that were announced in the APS. Then each DG establishes an Annual Management Plan (AMP) in order to translate the priority initiatives and the strategic objectives of the Commission into concrete operations, and to provide an instrument enabling the management to plan, follow up and report on all the activities and resources of each DG.

### Strategic Planning and Programming Cycle



<sup>31</sup> See *Programming circular—Commission Legislative and Work Programme 2005*, SEC (2004) 1175.

<sup>32</sup> See *Progress report on implementing better regulation for growth and jobs and up-date of the Commission’s Guidelines for Impact Assessment*, SEC (2005) 790 (June 10, 2005) (putting the guidance document before the Commission as an instrument intended to “clarify” and “reinforce” staff obligations to provide roadmaps, consult widely, analyze impacts and alternatives, etc.); *Impact Assessment Guidelines*, SEC (2005) 791 (June 15, 2005), available at [http://europa.eu.int/comm/secretariat\\_general/impact/docs\\_en.htm](http://europa.eu.int/comm/secretariat_general/impact/docs_en.htm).

analysis.<sup>33</sup> They must provide, among other things, an estimate of the time required

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<sup>33</sup> See, e.g., Roadmaps: Commission Work Programme 2005, Roadmap 2005/ENTR/019, *A Proposal for a Regulation on the authorisation, supervision and vigilance of human tissue engineered products*, at 10, available at [http://europa.eu.int/comm/off/work\\_programme/20050128\\_clwp\\_roadmaps.pdf](http://europa.eu.int/comm/off/work_programme/20050128_clwp_roadmaps.pdf). The roadmap states in its entirety:

Lead DG and contact person: DG ENTR, F/3 - Christian Siebert, Deputy HoU

Expected date of adoption: June-July 2005

A. Initial impact assessment screening

1. What are the main problems identified?

"Human tissue engineered products" are engineered human cells and tissues developed according to specific processes in order to maintain, restore or improve diseased/injured tissues in the human body. Existing EC legislation does not address these products in a specific and comprehensive manner. Although Directive 2004/23/EC has recently introduced minimal rules on the quality and safety of human tissues and cells, it leaves room for more detailed requirements on manufactured products derived from tissues and cells. In the absence of a fully harmonised regulatory framework, Member States apply different requirements for the manufacture and authorisation of human tissue engineered products. This results in obstacles to intra-community trade. Regulatory discrepancies restrict patients' access to innovative tissue engineering therapies and may act as barriers to guaranteeing a high level of public health protection in the European Union.

2. What are the main policy objectives?

The main objective of the proposal is to improve the free movement of human tissue engineered products in the European Union, while guaranteeing a high level of safety for European patients.

3. What are the policy options? What regulatory or non-regulatory instruments could be considered?

Given the potential health risks associated with human tissue engineered products, the only policy instrument to be envisaged is a binding legal act. Different options are currently under consideration with a view to establishing an authorisation procedure which guarantees the quality, safety and efficacy of human tissue engineered products. It is essential to provide a coherent and stable regulatory framework, which is strictly enforced in all Member States where human tissue engineered products are manufactured or imported. A regulation is therefore envisaged. It will facilitate the application of common rules in the absence of specific national legislation on human tissue engineered products in some Member States.

4. What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the enclosed guide)?

The proposal will be based on the results of studies carried out by the Joint Research Centre's Institute for Prospective Technological Studies (JRC-IPTS) of the European Commission. These studies will analyse the economic, social and environmental impacts of the proposal. Ethical aspects will also be considered in collaboration with the European Group on Ethics in Science and New Technologies (EGE).

The main parties that will be affected by the proposal are tissue engineering companies and, possibly, some hospitals and tissue banks.

B. Planning of further impact assessment work

5. What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when?

The JRC-IPTS has already completed a study on the current European market in human tissue engineered products and its future developments (<http://www.jrc.es>). The assessment of economic, social and environmental impacts of the proposal is currently under way. Ethical impacts are also being considered. The impact assessment is expected to be completed during the first quarter of 2005 at the latest.

6. Which stakeholders & experts will be consulted, how and at what stage?

Extensive consultations have already taken place with Member States and interested parties (consultation on the need for legislation in 2002; public consultation document and stakeholders' conference in April 2004; several consultation meetings with Member States and industry representatives). Discussions have highlighted a fairly broad consensus, in particular amongst industry and governments, in favour of a specific EU regulatory framework for human tissue engineered products. The proposal also responds to requests for harmonisation by leading Members of the European Parliament. The results of public consultations are available at <http://pharmacos.eudra.org/F3/human-tissue/index.htm>. Dialogue with the main stakeholders will be maintained during the preparation of the draft proposal.

7. Will an inter-service steering group be set up for the IA?



for completing the IA, as well as a brief statement on (1) the likely impacts of each policy option, (2) which impacts warrant further analysis, (3) who is likely to be affected, and (4) an outline of the consultation plan.<sup>34</sup> Of particular importance for interested persons outside the Commission and any groups it may itself invite to participate in consultations, the roadmaps identify contact persons, sometimes including their telephone extensions; this easily permits an outsider early self-identification to responsible bureaucrats as a stakeholder or other interested party. The roadmap identifying numbers, unsurprisingly, correspond to those identified in the work programme. While it is hard to assess whether the obligation to produce roadmaps is universally complied with (as one might also say about the Federal Regulatory Agenda that is the American equivalent), the Commission "Guidelines stress the importance of *comprehensive and high-quality Roadmaps* to allow interested parties to see what the Commission has done and still plans to do, thereby facilitating the preparation of their input as part of the *mandatory consultation* process."<sup>35</sup>

### *B. Impact Assessment*<sup>36</sup>

Impact assessment, proportionate to the significance of the action being undertaken, is a required element of the Commission's development of legislative proposals. For the Commission, but not for the American Congress, this is a seriously considered obligation, albeit one that like the American counterpart for regulations, E.O. 12,866, is enforced solely by internal means.<sup>37</sup> The Commission maintains a dedicated impact assessment website with links to all documents,<sup>38</sup> including most impact assessments that have been completed.<sup>39</sup> Effective as of

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No. However, DG Enterprise is working in close cooperation with other Commission services (DG Sanco, DG Research and other interested services).

<sup>34</sup> The Roadmap must also indicate whether an Inter-Service Steering Group will be established. See the discussion of such a group *infra* Part IV. When a DG does not plan to convene such a group, it must provide reasons.

<sup>35</sup> *Progress report on implementing better regulation for growth and jobs and up-date of the Commission's Guidelines for Impact Assessment*, SEC (2005) 790, *supra* note 32, at 3 (emphasis in original).

<sup>36</sup> In considering the Union's impact assessment procedures, this report does not concern itself with disputes regarding their possible political tendencies to permit or promote excessive regulation, as some assert. See Lawrence Kogan, *Exporting Precaution: How Europe's Risk-free Regulatory Agenda Threatens American Free Enterprise* (Washington Legal Foundation 2005), available at <http://www.wlf.org/upload/110405MONOKogan.pdf>. The new guidance document, it may be observed, seems intended to promote greater use of quantification and monetization of anticipated impacts for major proposals. *Progress report on implementing better regulation for growth and jobs and up-date of the Commission's Guidelines for Impact Assessment*, SEC (2005) 790, *supra* note 32, at 3.

<sup>37</sup> *Communication from the Commission on Impact Assessment*, COM (2002) 276 final (June 5, 2002). Precursor regimes required analysis of budgetary impacts, and impacts on small and medium sized enterprises. Guidance issued during the summer of 2005 considerably strengthened the analytic requirements involved. *Impact Assessment Guidelines*, SEC (2005) 791, *supra* note 32.

<sup>38</sup> Impact assessment in the Commission: Introduction, [http://europa.eu.int/comm/secretariat\\_general/impact/index\\_en.htm](http://europa.eu.int/comm/secretariat_general/impact/index_en.htm).

<sup>39</sup> Impact assessment in the Commission: Impact Assessment in Practice, [http://europa.eu.int/comm/secretariat\\_general/impact/practice\\_en.htm](http://europa.eu.int/comm/secretariat_general/impact/practice_en.htm). A small number of the statements here are restricted from public access.

2005, all items on the Commission's legislative and work programme require impact assessment. A preliminary assessment appears in the roadmap document; an extended impact assessment accompanies the proposal to Commission for approval and then to the Council and Parliament, at which time it is made available on the web. That it is developed in two stages, with the first appearing in the published "road maps" and including contact information, effectively assures interested parties an opportunity to make their views heard.

The mechanics of and general adherence to this guidance are, necessarily, works in progress. Prior to the communications of 2002, practice was highly variable from directorate general to directorate general. The new guidelines of June 2005—issued in the shadow of the rejection of the draft Constitution in France and the Netherlands and so perhaps signaling renewed Commission awareness of its need to build credibility—promise yet more disciplined attention to the process. Under the 2005 Impact Assessment Guidelines, the impact assessment process has six basic steps:

- What is the problem?
- What are the objectives?
- What are the policy options?
- What are the likely economic, social and environmental impacts?
- How do the options compare?
- How could future monitoring and evaluation be organized?<sup>40</sup>

What the Commission *means* by "impact assessment" differs somewhat from how Americans would understand the process. The Commission published an initial guidance document, "Impact Assessment in the Commission," in the fall of 2002,<sup>41</sup> elaborating the expected processes for developing both preliminary and extended Impact assessments, with models for each. This document made clear that these analyses were seen as aids to a political process, and thus might often be appropriately qualitative in character. It strongly emphasized the obligation of consultation with interested parties and relevant experts. "Consultation with interested parties is an important part of the impact assessment process, and is carried out according to a set of minimum standards."<sup>42</sup> These minimum standards were themselves specified in Commission communications<sup>43</sup> and the consultations are conducted through the Commission's "your voice" website. "In order to be credible, impact assessment cannot be carried out behind 'closed doors.'"<sup>44</sup>

The 2002 Communication described the desired analysis in terms much broader than might be familiar to American audiences. Impact analysis was presented as a technique for identifying policy options and alternatives by considering the likely forward consequences of a proposed action, as it would also be seen in the United states. Yet for the Commission, these impacts were to be "expressed in economic,

<sup>40</sup> *Impact Assessment Guidelines*, SEC (2005) 791, *supra* note 32, at 2–3 (Table of Contents).

<sup>41</sup> *Impact Assessment in the Commission: Guidelines* (2002), [http://europa.eu.int/comm/secretariat\\_general/impact/docs/ia\\_technical\\_guidelines\\_en.doc](http://europa.eu.int/comm/secretariat_general/impact/docs/ia_technical_guidelines_en.doc) [hereinafter Initial Guidance Document].

<sup>42</sup> See The impact assessment process: Consultation and use of expertise, [http://europa.eu.int/comm/secretariat\\_general/impact/expert\\_en.htm](http://europa.eu.int/comm/secretariat_general/impact/expert_en.htm).

<sup>43</sup> *Communication on General principles and minimum standards for consultation of interested parties by the Commission*, COM (2002) 704 final (Dec. 11, 2002); *Communication on Principles and Guidelines—“Improving the knowledge base for better policies,”* COM (2002) 713 final (Dec. 11, 2002).

<sup>44</sup> Initial Guidance Document, *supra* note 41, at 9.

social and environmental terms,” (emphasis added) with no particular emphasis on quantification or cost-benefit balancing.<sup>45</sup> “[S]trict cost-benefit analysis may not always supply the most relevant information; for example, the degree of irreversibility . . . [t]he precautionary principle . . . [and the] impact on established policy objectives . . . should be assessed.”<sup>46</sup> American authors have criticized this aspect sharply, urging the EU to “specify[] that the primary objective of regulation is to maximize net benefits.”<sup>47</sup> Yet these authors do not appear to recognize the rather different institutional function that impact assessment serves in the European context; they rely on data much of which is national in character and largely predates the recent Commission measures.

One hundred pages of supplementary guidelines and illustrative annexes published in the summer of 2005<sup>48</sup> offered a basis for “*rigorous and comprehensive analysis . . . easily accessible to the non-specialist*.”<sup>49</sup> Yet, like its predecessor, the new guidance does not supply any single, or binding, decision criteria. It notes that Impact Assessment is a decision *tool*, but that it will not govern the “political” decision of the Commission, much less that of the Parliament or the Council. The new Guidance does, however, go much further than prior guidance both in “screening” to arrive at a shortlist of options (using the criteria of “effectiveness, efficiency, and consistency”) and in structuring the consideration and ranking of options. It requires that for all options considered, which must include the “no action” option, the Impact Assessment Report must “consider all the relevant *positive* and *negative* impacts alongside each other, regardless of whether they are expressed in qualitative, quantitative or monetary terms.”<sup>50</sup> While the Commission presents this approach as a “simple multi-criteria analysis,” and carefully distinguishes it from the alternative approaches of “cost-benefit analysis, which compares positive and negative impacts expressed in the same units, normally in monetary terms, and cost-effectiveness analysis, which compares the costs of achieving a given objective,” in fact the approach suggested by the Commission is compatible with what is commonly considered cost-benefit analysis in the United States, where the term “formal” or “quantified” cost-benefit analysis is normally properly reserved for the fully quantified type of assessment.<sup>51</sup>

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<sup>45</sup> For an examination of the EU directives specifically concerning environmental assessments, see Joanne Scott & Jane Holder, *Law and “New” Environmental Governance in the European Union*, in *NEW GOVERNANCE AND CONSTITUTIONALISM IN EUROPE AND THE US* (G. de Búrca & J. Scott eds., 2005). Addressing its procedures requiring provision for public participation at the local level, they find democratizing tendencies supportive of new governance ideas—“a more inclusive, less technicist environmental assessment procedure, with public involvement in decision making expressed in the manner of an entitlement to participate and to access to the courts to enforce its provisions.” *Id.* at 6.

<sup>46</sup> *Communication from the Commission on Impact Assessment*, at 15-16, COM (2002) 276 final.

<sup>47</sup> Robert Hahn & Robert Litan, *Counting Regulatory Benefits and Costs: Lessons for the US and Europe*, 8(2) J. INT’L ECON. L. 473, 473 (2005); see also Kogan, *supra* note 36.

<sup>48</sup> *Impact Assessment Guidelines*, SEC (2005) 791, *supra* note 32.

<sup>49</sup> *Progress report on implementing better regulation for growth and jobs and up-date of the Commission’s Guidelines for Impact Assessment*, SEC (2005) 790, *supra* note 32, at 2-3 (emphases in original).

<sup>50</sup> *Impact Assessment Guidelines*, SEC (2005) 791, *supra* note 32, at 39 (emphasis in original).

<sup>51</sup> On the other hand, when the Commission defines “multi-criteria analysis” in its Annex to the Impact Assessment Guidelines. *Impact Assessment Guidelines*, SEC (2005) 791, Annex 13.3, available at [http://europa.eu.int/comm/secretariat\\_general/impact/docs/SEC2005\\_791\\_1A\\_guidelines\\_anx.pdf](http://europa.eu.int/comm/secretariat_general/impact/docs/SEC2005_791_1A_guidelines_anx.pdf). It does

Bear in mind that we are here discussing the development of *legislative* proposals, matters to be submitted to Parliament and the Council. Impact assessment is *not* required for executive implementing measures, what Americans would call rulemaking. This choice is perhaps a reflection of where the most important measures will be undertaken, but it is also one of several elements of EU arrangements tending to separate the technical from the political in the development of legislation. Impact analyses, then, operate more for the control/edification of the external institutions to whom legislative proposals are eventually sent, the Council and the Parliament, than for the Commission itself. Decisions subject to comitology do not appear in the Work Programme, and are normally exempt from the procedure.

The contrast with American practice could hardly be more striking. In the United States, impact analysis is principally understood as a technique by which the President may discipline and influence executive action; although impact analysis is also promised in connection with legislative measures, it has yet to be seriously undertaken in that context. For the EU, impact assessment is much more a device for informing legislators than for controlling a dispersed bureaucracy.

In the United States, impact analysis is less consistently a public process. Regulations of the Council on Environmental Quality require agencies to use notice-and-comment procedures when making environmental impact analyses, thus involving the public;<sup>52</sup> and Regulatory Flexibility Act analyses for impact on small business may also involve public consultations. Yet open consultations generally are *not* conducted for today's most important form of impact analysis, economic impact analysis made under EO 12866. To be sure, one may be able to learn when an EIS has been submitted for review by careful observation of the website maintained by OMB's Office of Information and Regulatory Analysis. This posting occurs, however, only after the agency hopes to have completed its analysis; OIRA does not make the documents public or directly invite public participation, and the eventual inclusion of the documents in the agency's rulemaking docket may come too late for effective commentary on it.

The EU's initial guidance documents require those responsible for impact assessment consultations not only to summarize their results, but also to "indicate how the consultation influenced the development of the proposal, and any remaining critical or dissenting opinions."<sup>53</sup> The character of an extended impact assessment document completed under the initial guidelines can perhaps be appreciated by looking at the report developed for the Commission initiative known as REACH (Registration, Evaluation, Authorisation and Restrictions of CHemicals),<sup>54</sup> one of the more controversial legislative actions proposed in recent years, that in April 2005 had not yet reached its conclusion. The proposal, captured in six enormous files on the Commission's website,<sup>55</sup> runs about 1200 pages (mostly technical annexes the

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not require that a "net benefits" hurdle or a "maximizing net benefits" test be used for multi-criteria analysis.

<sup>52</sup> See Scoping, 40 C.F.R. § 1501.7 (requirement) and Notice of Intent, 40 C.F.R. § 1508.22 (substance to be included).

<sup>53</sup> Initial Guidance Document, *supra* note 41, at 27.

<sup>54</sup> *Extended Impact Assessment*, SEC (2003) 1171/3 (Oct. 29, 2003), concerning *Proposal for a New EU Regulatory Framework for Chemicals—REACH*, COM (2003) 644 final (Oct. 29, 2003).

<sup>55</sup> Proposal for a Regulation of the European Parliament and of the Council concerning the

Commission, characterized as not new<sup>56</sup>); the extended impact assessment, quite general (albeit well-informed about the character of the European chemical industry, its environmental impacts, and the cost-effectiveness and benefits in general of the measures proposed), comprises thirty-three pages.<sup>57</sup> One could compare the recently adopted American regulation on tire pressure monitoring (a simpler subject) for which the rule itself comprised seven pages in the Federal Register,<sup>58</sup> and the Final Regulatory Impact Analysis published on the agency website ran 249 pages.<sup>59</sup> Under the Commission's 2005 guidance, still, an Impact Assessment Report should be no longer than thirty pages (excluding annexes), following a set format.<sup>60</sup>

### C. Stakeholder Consultation (and Report)

The Commission is committed to extensive consultations with all concerned elements of society as part of its process for developing legislative proposals. It has carried this commitment through in a series of Communications<sup>61</sup> and websites committed in various ways to the process.<sup>62</sup> Although it is grounded in the

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Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and [...] Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals, COM (2003) 644 final (Oct. 29, 2003), available at [http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003\\_0644en.html](http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en.html).

<sup>56</sup> Press Release, European Commission, Commission publishes draft new Chemicals Legislation for consultation (May 7, 2003), <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/646&format=HTML&aged=1&language=EN&guiLanguage=en>.

<sup>57</sup> For an account of initial experience with Impact assessments, see *Report on European Governance (2003-2004)*, SEC (2004) 1153 (Sept. 22, 2004) and *Report from the Commission: "Better Lawmaking 2003,"* at Annex 3, COM (2003) 770 final (Dec. 12, 2003). At least initial experiences with Impact assessments suggested that they could be highly politicized. Bignami recalls that when she was reviewing the bargaining history of the Data Protection Directive, there was a tiff about the regulatory impact statement: the Commission produced one; the United Kingdom, antagonistic to the entire Directive, said it wasn't good enough and produced its own showing how burdensome the Directive would be; and the Commission produced another, more favorable one. Thus, a possible question for sectoral reporters: how extensive are the Commission's regulatory Impact assessment statements in your field? Have you noticed any recent changes in practice?

<sup>58</sup> Federal Motor Vehicle Safety Standards, 70 Fed. Reg. 18,184 (Apr. 8, 2005). The statement of basis and purpose accompanying the rule ran 49 pages. *Id.* at 18, 136.

<sup>59</sup> See National Highway Traffic Safety Administration, Final Regulatory Impact Analysis, Tire Pressure Monitoring System, FMVSS No. 138 (Mar. 2005), at [http://dmses.dot.gov/docimages/pdf91/325337\\_web.pdf](http://dmses.dot.gov/docimages/pdf91/325337_web.pdf).

<sup>60</sup> *Impact Assessment Guidelines*, SEC (2005) 791, *supra* note 32, at 14.

<sup>61</sup> See *Commission Proposal for General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM (2002) 277 final (June 5, 2002). Comments on this Commission Proposal, collected at the Commission's website, see *Consultation Standards*, [http://europa.eu.int/comm/secretariat\\_general/sgc/consultation/histo\\_en.htm](http://europa.eu.int/comm/secretariat_general/sgc/consultation/histo_en.htm), led to two final documents: *Commission Communication Towards a Reinforced Culture of Consultation and Dialogue—General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM (2002) 704 final (Dec. 11, 2002) and *Commission Communication on the Collection of Expertise by the Commission: Principles and Guidelines*, COM (2002) 713 final, (Dec. 11, 2002).

<sup>62</sup> See, e.g., Your Voice in Europe (where consultations are conducted and reported upon), [http://europa.eu.int/yourvoice/consultations/index\\_en.htm](http://europa.eu.int/yourvoice/consultations/index_en.htm); CONECCS Home, Consultation, the European Commission and Civil Society (providing a database of consultative bodies and civil society organizations), [http://europa.eu.int/comm/civil\\_society/coneccs/index\\_en.htm](http://europa.eu.int/comm/civil_society/coneccs/index_en.htm).

Amsterdam Treaty Amendments of 1999, the Commission has expressed its commitment in soft law terms that do not create enforceable rights in private parties.<sup>63</sup> Its explanation of this choice both illustrates the importance of soft law in its practice and the Commission's determination to avoid precise imitation of American institutions as it understands them:

Some of those consulted questioned the Commission's decision to set consultation standards in the form of a Commission communication (i.e., in the form of a policy document) instead of adopting a legally-binding instrument. They argued that this would make the standards toothless and the Commission would be unable to ensure the consistency and coherence of its consultation processes.

However, the Commission remains convinced that a legally-binding approach to consultation is to be avoided, for two reasons: First, a clear dividing line must be drawn between consultations launched on the Commission's own initiative prior to the adoption of a proposal, and the subsequent formalised and compulsory decision-making process according to the Treaties. Second, a situation must be avoided in which a Commission proposal could be challenged in the Court on the grounds of alleged lack of consultation of interested parties. Such an over-legalistic approach would be incompatible with the need for timely delivery of policy, and with the expectations of the citizens that the European Institutions should deliver on substance rather than concentrating on procedures.

Moreover, the fear expressed by some participants in the consultation process that the principles and guidelines could remain a dead letter because of their non-legally binding nature is due to a misunderstanding. *It goes without saying that, when the Commission decides to apply the principles and guidelines, its departments have to act accordingly.*<sup>64</sup>

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<sup>63</sup> As reflected in the Environmental Sector Report for this study, available at <http://www.abanet.org/adminlaw/eu/SectRptRule-environmental.pdf> at 60, stronger commitments have been undertaken, in the environmental context only, pursuant to Articles 6 and 7 of the Aarhus Convention. See, e.g., U.N. Economic Commission for Europe Committee on Environmental Policy, Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Aarhus, Denmark, arts. 6 & 7 (June 23–25, 1998), available at <http://www.mem.dk/aarhus-conference/issues/public-participation/ppartikler.htm>.

<sup>64</sup> *Communication on General principles and minimum standards for consultation of interested parties by the Commission*, COM (2002) 704 final (Dec. 11, 2002) (emphasis added). The guidance documents of June 2005 equally forbore about staff obligation; while the increasing stringency of the commitments is clear, empirical data on the extent of compliance with them are hard to obtain. See *Impact Assessment Guidelines*, SEC (2005) 791, *supra* note 32.

The U.K.'s Better Regulation Task Force, in its *Get Connected: Effective Engagement in the EU* report, both expressed "surprise[]" that the Commission does not publish information about how well individual Directorates General comply with the agreed standards for consultation," thinking that information a part of the citizen's "right to know," and indicated agreement with the soft law approach. "The problem with a legally binding requirement to consult is that it creates an opportunity and perhaps even an incentive for those dissatisfied with a particular policy outcome to challenge proposals in court on

Recall that these are principles developed and, as the contents of the Your Voice site<sup>65</sup> suggest, most often honored in connection with the development of legislative drafts, not rulemaking.

A recent assessment of the Commission's consultation practice welcomed its implementation but questioned whether—particularly in light of the June 2005 impact assessment guidelines<sup>66</sup>—the “principles and standards for consultation should only apply to major policy initiatives.”<sup>67</sup> “Even where the general principles and minimum standards are applicable,” the report continued:

[T]hey are not binding on the Commission services. While we have found good examples of thorough and extensive consultation, we have also found that many consultation exercises fail to meet the Commission's minimum standards and that compliance is patchy both between and within Directorates General.

We have found it difficult to make a reliable assessment of compliance with the minimum standards as information is not easily available and some of them are anyway qualitative. Nevertheless, in June 2005 we reviewed all the open and closed consultations on the Commission website and found that nine out of 40 consultations (or 23%) allowed less than eight weeks to respond. Two consultations were barely eight weeks long and took place over the Christmas period. Of the other standards, the Commission itself acknowledges that it needs to do better in providing reasoned feedback to respondents and in demonstrating how it has taken account of their views.<sup>68</sup>

It is perhaps remarkable to American readers, but entirely consistent with EU expectations, that this somewhat critical, external report rejected any suggestion that the consultation mechanism be made legally binding.

The problem with a legally binding requirement to consult is that it creates an opportunity and perhaps even an incentive for those dissatisfied with a particular policy outcome to challenge proposals in court on the grounds of inadequate consultation. This would prolong the legislative process and introduce considerable uncertainty over when and how any legislation enters into force . . . . The United States puts a legal duty on government agencies to consult to a minimum standard on significant proposals. There is no equivalent legal duty anywhere in the EU and we do not think it proportionate to introduce one.<sup>69</sup>

Given the EU's dependence on continued acceptance of its initiatives by its Member States, one easily understands that the public processes of stakeholder

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the grounds of inadequate consultation . . . . We want to find ways to help the Commission's consultation process become more effective and efficient, not to slow down the delivery of policy or to enrich the legal profession.” *Get Connected*, *supra* note 29, at 3, 25.

<sup>65</sup> Your Voice in Europe, *supra* note 62.

<sup>66</sup> *Impact Assessment Guidelines*, SEC (2005) 791, *supra* note 32.

<sup>67</sup> *Get Connected*, *supra* note 29, at 22.

<sup>68</sup> *Id.* at 24.

<sup>69</sup> *Id.* at 25.

consultation are hardly the only means by which the Commission's bureaucrats inform themselves about pending issues.<sup>70</sup> Nor would one wish to suggest that members of Parliament or the Council, who will eventually have to act on Commission proposals (and so wish to maneuver to shape their development), learn their constituencies' views only in this way. Political pressures and lobbying in all its forms are only to be expected.<sup>71</sup> Yet the use of stakeholder consultations as a routine means of exploring public views across the whole of the European spectrum, and the manner in which they are treated both by respondents and by the Commission itself, offer a striking contrast to the American framework for legislative development.

Perhaps because these consultations are undertaken at an early stage in the development of proposals for legislation, before a proposal has assumed concrete form, they have a different character than what might be thought the American analog, the "notice" American agencies publish in connection with notice and comment rulemaking. In usual American practice, the draft is created first and the public consulted afterwards, and this has a number of consequences. First, it contributes to a certain rigidity and defensiveness on the agency side; the process of creating the draft is itself political—compromises need to be made within the drafting body and stances taken, that may then be difficult to depart from whatever input is received. Second, it can emphasize the political character of the response to the proposal from the public side. While some commentators may respond to

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<sup>70</sup> Two specific advisory bodies—the European Economic and Social Committee (representing various socio-economic organizations in Member States) and the Committee of the Regions (made up of representatives of local and regional authorities)—as well as Member States are regularly consulted.

Special committees may also be used for this purpose, of course. See, e.g., Commission Decision concerning the creation of an advisory group on the food chain and animal and plant health 2004/613/EC, 2004 O.J. (L 275) 17. See Food Safety—Committees—Advisory Group, [http://europa.eu.int/comm/food/committees/advisory/index\\_en.htm](http://europa.eu.int/comm/food/committees/advisory/index_en.htm). One might analogize a committee with this function to the groups formed under the American Negotiated Rulemaking Act, 5 U.S.C. §§ 561-570a. The formation process in the EU, if the documents at this site are typical, invite general applications, and the Commission then selects committee members on such bases as their pan-European character and potential contribution to the group as a whole. The 36 organizations selected for this committee appear to have these characteristics, including NGOs as well as industrial representatives, and unions, federations, organizations, etc. See List of members of the advisory group on the food chain and animal and plant health, 2005 O.J. (C 97) 2 (three seats allocated to the European Consumers Organization "in order to facilitate the representation of European consumer."). Unlike the NRA, no process external to Commission politics is provided for testing the Commission's success in achieving a representative body. This is no different from many other respects in which EU law eschews formal legalisms; while the Commission's incentives suggest that they might rarely if ever be necessary, one arguable result is to keep advice within an "establishment" community, even if a broadly representative one.

One public indicator of the establishment characteristic of this consultative activity is the Commission's CONECCS site, which lists both the Commission's formal or structured consultative bodies, in which civil society organizations participate, and the non-profit making civil society organizations, organized at European level, from which those consultative bodies tend to be drawn. CONECCS Home, Consultation, the European Commissions and Society (CONECCS), [http://europa.eu.int/comm/civil\\_society/coneccs/index\\_en.htm](http://europa.eu.int/comm/civil_society/coneccs/index_en.htm). Looking the other way is the Commission's assertion on its general "civil society" site that "there is no general registration or accreditation system for interest groups. The Commission does not want to limit its consultations to a certain number of pre-screened or accredited organisations." Civil Society, General Overview, [http://europa.eu.int/comm/civil\\_society/apgen\\_en.htm](http://europa.eu.int/comm/civil_society/apgen_en.htm).

<sup>71</sup> See *infra* notes 88 and 93 and accompanying text.



particular details of a concrete proposal, the process is entirely open-ended, and this invites broadside responses and political campaigns. With the internet and the development of tools for waging political campaigns there,<sup>72</sup> one can find rulemakings with hundreds of thousands of participants, many of whom submit electronic forms with unverifiable identities.<sup>73</sup> As thus structured, participation is essentially costless and easily faceless.

In contrast, Commission consultations tend to be quite structured in character, requiring responses to a series of questions about identity and interest and then asking particular questions about the matter under study.<sup>74</sup> The result is to require a not insubstantial investment of time in participation and, one imagines, to retard, if not entirely defeat, computerized response campaigns. This in and of itself may significantly improve the contributions the process makes. One recent study of American rulemaking reached the conclusion, surprising to its authors, that “the vast majority of significant differences in [the] study turned out to be not between electronic and paper submitters as we had originally proposed, but between those who submit original comments and those who submit form-based comments.”<sup>75</sup> If the tendency of the Commission’s approach is to suppress form-based comments, these results suggest, the result will be a more credible and rationalized process. The Commission’s policies, set out in its consultation documents,<sup>76</sup> require reporting of results and feedback; reports of closed consultations are made in a statistical way on the Yourvoice site.<sup>77</sup>

The ongoing REACH process, already encountered,<sup>78</sup> can perhaps stand as an example of the practice and possible extent of consultation undertaken by the Commission in the course of preparing legislative proposals—although its contentiousness, evident in the dimensions about to be recounted, counsels some caution. A Commission white paper—that is, a preliminary policy analysis—was published in February of 2001, itself the product (in part) of a meeting “with more

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<sup>72</sup> See *supra* pp. 652–53.

<sup>73</sup> For an analysis of the difficulties as well as a resourceful empirical study, see David Schlosberg, Stephen Zavestoski & Stuart Shulman, “To Submit a Form or Not to Submit a Form, That is the (Real) Question”: *Deliberation and Mass Participation in U.S. Regulatory Rulemaking*, [http://erulemaking.ucsur.pitt.edu/doc/papers/SDEST\\_Western\\_05.pdf](http://erulemaking.ucsur.pitt.edu/doc/papers/SDEST_Western_05.pdf) (2005); see also eRulemaking Research Group at the University of Pittsburgh, <http://erulemaking.ucsur.pitt.edu> (last modified Mar. 20, 2006).

<sup>74</sup> This is particularly the case for consultations undertaken through its approach to “interactive policy making.” See Interactive Policy Making, [http://europa.eu.int/yourvoice/ipm/index\\_en.htm](http://europa.eu.int/yourvoice/ipm/index_en.htm). For an example of a consultation that closed in May 2005 on the sustainable use of pesticides in Europe, see Sustainable Use of Pesticides, <http://europa.eu.int/comm/environment/ppps/home.htm>. On the relevant site one finds not only the questionnaire, but links to various documents concerned with it that may assist in understanding or responding to it.

<sup>75</sup> Schlosberg et al., *supra* note 73, at 22–23. Differences, all favorable to the engagement of those submitting original rather than form comments, concerned how much information the commenter received, whether others’ inputs were considered, whether other comments were reviewed, whether a greater understanding of other positions emerged, and whether the commenter’s own position had at all changed.

<sup>76</sup> See *supra* note 64.

<sup>77</sup> See, e.g., Response Statistics for “The Transparency of Regulations and Standards in the Area of Services,” [http://europa.eu.int/yourvoice/results/services/index\\_en.htm](http://europa.eu.int/yourvoice/results/services/index_en.htm) (July 19, 2004); Review of the New Approach, [http://europa.eu.int/yourvoice/results/4/index\\_en.htm](http://europa.eu.int/yourvoice/results/4/index_en.htm) (Mar. 31, 2002).

<sup>78</sup> See *supra*, notes 54–60 and accompanying text.

than 150 stakeholders in February 1999—regulators, scientists, industry, environmental, and consumer NGOs as well as representatives from applicant countries.<sup>79</sup> There followed stakeholder conferences on the white paper in April 2001<sup>80</sup> and May 2002<sup>81</sup>, and a November 2003 workshop<sup>82</sup> on the extended impact assessment, all thoroughly documented on the REACH website. From May to July 2003, the Commission conducted a consultation on its draft,<sup>83</sup> it attracted an unusual level of response—again, one thoroughly documented on its website: 968 participants in an Interactive Policymaking tool that was, in part, a structured questionnaire,<sup>84</sup> and a total of 6400 comments of varying length and detail.<sup>85</sup> It seems useful to reiterate here that, in contradistinction to American rulemaking processes of equivalent controversiality, virtually all these comments appear to have spoken to the proposals in knowledgeable detail; even in those relatively rare instances in which a number of people (say, workers at a given chemical plant<sup>86</sup>) are identified as having submitted identical comments, the comments (doubtless supplied by their employer and/or union) are detailed.<sup>87</sup>

In this particular proceeding, there is one artifact more reminiscent of the American scene, a declaration signed by 429 organizations and 22,464 citizens, submitted as part of the internet consultation, and so accessible from the REACH site.<sup>88</sup> Here, very clearly, is an effort at political, not intellectual or technical, influence. Yet the very structure of the declaration's site,<sup>89</sup> linked to the REACH

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<sup>79</sup> *Commission White Paper on Strategy for a Future Chemicals Policy*, at 6, COM (2001) 88 final (Feb. 27, 2001).

<sup>80</sup> Stakeholders' Conference on the Commission's White Paper on the Strategy for a Future Chemicals Policy, [http://europa.eu.int/comm/enterprise/reach/whitepaper/conferences/conf-2001\\_04\\_02.htm](http://europa.eu.int/comm/enterprise/reach/whitepaper/conferences/conf-2001_04_02.htm) (Apr. 2, 2001).

<sup>81</sup> Stakeholders' Conference on the Business Impact of the New Chemicals Policy, [http://europa.eu.int/comm/enterprise/reach/whitepaper/conferences/conf-2002\\_05\\_21.htm](http://europa.eu.int/comm/enterprise/reach/whitepaper/conferences/conf-2002_05_21.htm) (May 21, 2002).

<sup>82</sup> Schedule for Stakeholder Workshop on Extended Impact assessment of REACH, [http://europa.eu.int/comm/enterprise/reach/docs/conferences/eia\\_workshop-2003\\_11\\_21.pdf](http://europa.eu.int/comm/enterprise/reach/docs/conferences/eia_workshop-2003_11_21.pdf) (Nov. 21, 2003); Extended Impact Assessment of the New Chemicals Policy, <http://europa.eu.int/comm/enterprise/reach/eia.htm> (last modified Feb. 16, 2006).

<sup>83</sup> Commission Publishes Draft New Chemicals Legislation for Consultation, <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/646&format=HTML&aged=1&language=EN&guiLanguage=en> (May 7, 2003).

<sup>84</sup> For an analysis, see Internet Consultation on Draft Chemicals Legislation (the REACH System), [http://europa.eu.int/yourvoice/results/253/index\\_en.htm](http://europa.eu.int/yourvoice/results/253/index_en.htm). Of the 968, only 80 indicated that they had sent comments additional to those presented through the interactive tool; about 60% of the filings were made on behalf of individuals. 587 filings came from Germany; no other country contributed more than 81 (U.K.). For the comments attached to these filings, see Stakeholder Reactions, [http://europa.eu.int/comm/environment/chemicals/pdf/ipm\\_stakeholder\\_reactions.pdf](http://europa.eu.int/comm/environment/chemicals/pdf/ipm_stakeholder_reactions.pdf).

<sup>85</sup> Internet Consultation on Draft Chemicals Legislation (the REACH System), <http://europa.eu.int/comm/environment/chemicals/consultation.htm> (last modified July 15, 2005); Contributions to the Public Consultation on REACH, <http://europa.eu.int/comm/enterprise/reach/consultation/contributions.htm>.

<sup>86</sup> See, e.g., European Commission, REACH Regulation Public Internet Consultation, [http://europa.eu.int/comm/enterprise/reach/docs/consultation/others/886\\_other.doc](http://europa.eu.int/comm/enterprise/reach/docs/consultation/others/886_other.doc) (where 156 identical comments from the workers of Clariant, France).

<sup>87</sup> Each such comment fills sixty-five computer screens in this case.

<sup>88</sup> Internet Consultation on Draft Chemicals Legislation (the REACH System), <http://europa.eu.int/comm/environment/chemicals/consultation.htm> (last modified July 15, 2005).

<sup>89</sup> Chemical Reaction, <http://www.chemicalreaction.org>.

site, helps one to understand the unusual character of the Commission's role. Supporting the proposal, and stating a fear that chemical manufacturers will be working to weaken it, the declaration site features an interactive map with country-by-country links to lists of members of the European Parliament, organized by district and indicating which members have already pledged to support the proposal and which have not. Clicking on a supporter's name activates a short congratulatory email to which the sender may add additional thoughts and must add identifying information; clicking on a member who has not yet pledged support activates a four-paragraph e-mail calling for support—again, a communication offering little more than the feelings of a constituent, and to which, again, the sender may add additional thoughts and must add identifying information. The point is that these e-mails will be going to members of Parliament, not the Commission—people with constituencies and votes, not those responsible for technical analysis and drafting. The European process appears to have succeeded to a significant degree in severing politics from policy analysis at the legislative level, and making of the latter an unusually interactive and transparent process.

Nothing of the kind exists at the legislative level in American politics. All, in effect, is politics. Similar mechanisms exist for conveying a point of view to one's legislators, as anyone who has come within range of the mailing list for moveon.org or its competitors well knows. But a centrally managed, multi-year process of consultation during the drafting process, organized by those responsible for drafting and not by those who hope to influence them politically, is simply unknown.

Stakeholder consultation is not necessarily broad-gauge. The consultations page for DG Employment and Social Affairs remarks that, "[c]onsultations on Employment and Social Affairs issues are as a rule with Social Partners (employers' organisations and trade unions). A full list can be found on the European social dialogue - Main joint texts page."<sup>90</sup>

A recent Commission Secretariat document, briefly discussing experience with public consultation and reporting "a growing public consultation culture," seems to suggest more generally that consultations with established partners are preferred.<sup>91</sup> Yet in its inception, as Francesca Bignami has pointed out, the move to "civil society participation," a striking departure from national expectations about lawmaking in Europe, was intended to secure a broad political base, not to reflect established corporatist practices.

What then . . . was the Commission doing by saying it would consult "civil society?" No less than that it should continue to rule because it was closer to the good government ideal of today. The overtly political nature of the White Paper makes interpretation unnecessary. The Commission was explicit:

Better consultation and involvement, a more open use of expert advice and a fresh approach to medium-term planning will allow it to consider much more critically the demands from the Institutions

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<sup>90</sup> Employment and Social Affairs—Consultations, [http://europa.eu.int/comm/employment\\_social/consultation\\_en.html](http://europa.eu.int/comm/employment_social/consultation_en.html); see also Key Documents, [http://europa.eu.int/comm/employment\\_social/social\\_dialogue/docs\\_en.htm](http://europa.eu.int/comm/employment_social/social_dialogue/docs_en.htm).

<sup>91</sup> *Report on European Governance (2003-2004)*, SEC(2004) 1153, § 2.2 (Sept. 22, 2004); see also *Report from the Commission: "Better Lawmaking 2003,"* at Annex 2, COM (2003) 770 final (Dec. 12, 2003).

and from interest groups for new political initiatives. It [the Commission] will be better placed to act in the general European interest.

And hence, to finish the thought, the Commission should retain its position at the epicenter of European integration:

Both the proposals in the White Paper and the prospect of further enlargement lead in one direction: a reinvigoration of the Community method. This means ensuring that the Commission proposes and executes policy; the Council and the European Parliament takes decisions; and national and regional actors are involved in the EU policy process.<sup>92</sup>

#### *D. Lobbying and Its Regulation*

The Commission has adopted a relatively detailed code of conduct for itself<sup>93</sup>—albeit one that has not prevented the whiff of public scandal<sup>94</sup>—but in other respects the European Union thus far seems to have found it unnecessary to adopt more than hortatory measures to deal with lobbying activities. The Commission's Code of Good Administrative Behavior,<sup>95</sup> directed to its staff, lacks any detailed provisions on conflict of interest; staff regulations on conflicts of interest and external activities are brief and concerned principally with employment during or after service with the Commission that might be inconsistent with Commission responsibilities.<sup>96</sup> Its various communications on consultation and dialogue, similarly contain no provisions corresponding to American lobbying legislation. A 1999 communication to the Commission asking about lobbying regulation produced this response from Mr. Santer:

The obligation for American companies to declare their lobbying activities, including the amount they spend on such activities, derives from the registration system which applies to all organisations lobbying U.S. federal bodies.

This registration system is not compatible with the Commission's approach, which is based on openness to all interest groups and guarantees them equal treatment while recommending that they

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<sup>92</sup> Francesca Bignami, *Creating European Rights: National Values and Supranational Interests*, 11(2) COLUM. J. EUR. L. 241, 323 n.356 (2005) (citing *White Paper on European Governance*, at 33–34, COM (2001) 428 final (July 25, 2001)).

<sup>93</sup> Code of Conduct for Commissioners, [http://europa.eu.int/comm/reform/2002/code\\_conduct\\_en.htm](http://europa.eu.int/comm/reform/2002/code_conduct_en.htm).

<sup>94</sup> The code provides, *inter alia*, that a Commissioner should not accept a gift valued at more than EUR 150. *Id.* In April 2005, Katrin Bennhold was among those reporting that Commission President Jose Barroso, had spent an undisclosed week aboard a Greek billionaire's yacht, valued by one newspaper reporting the scandal at \$26,000. Because this was "a holiday with friends" the Commission's position was that there was no "lack of respect of the code of conduct." Katrin Bennhold, *Commission chief's trip raises EU ethics questions*, INT'L HERALD TRIBUNE, April 19, 2005, at 1.

<sup>95</sup> Code of Good Administrative Behavior, [http://europa.eu.int/comm/secretariat\\_general/code/index\\_en.htm](http://europa.eu.int/comm/secretariat_general/code/index_en.htm).

<sup>96</sup> Reforming the Commission, Simplification of the Staff Regulations, [http://europa.eu.int/comm/reform/2002/chapter06\\_en.htm#1](http://europa.eu.int/comm/reform/2002/chapter06_en.htm#1).

apply a system of self-regulation.

This being so, the Commission has no plans to adopt measures which would require a radical change of policy.<sup>97</sup>

No such measures appear to have been adopted. The encouragement to self-regulation Commissioner Santer mentions appears in a Commission communication of 1992 explaining that

special interest groups are best placed to establish and enforce codes of conduct. The Commission therefore invites the sectors concerned to draw up such codes, which should include the following minimum requirements.<sup>98</sup>

Those requirements are stated in quite general terms—advising, for example, that a group should not “offer any form of inducement to Commission officials in order to obtain information or to receive privileged treatment,” but giving no concrete detail about the propriety of hosting luncheons, sending holiday gifts, or providing golfing trips to Scotland for dear friends.<sup>99</sup>

The European Parliament, too, has what may be described as minimal rules on the subject, requiring accreditation of lobbyists and quite general standards of proper behavior.<sup>100</sup> Its website carries an extensive list of accredited lobbyists resulting,<sup>101</sup> making evident that lobbying the Parliament is a major activity.<sup>102</sup> In late April,

<sup>97</sup> Answer given by Mr. Santer on behalf of the Commission, 1999 O.J. (C 348) 70.

<sup>98</sup> Minimum requirements for a code of conduct between the commission and special interest groups, [http://europa.eu.int/comm/secretariat\\_general/sgc/lobbies/communication/annexe2\\_en.htm](http://europa.eu.int/comm/secretariat_general/sgc/lobbies/communication/annexe2_en.htm).

<sup>99</sup> The reference is to a distinctly American scandal. See Philip Shenon, *Inquiry on Lobbyist Casts a Shadow in Congress*, N.Y. TIMES, April 11, 2005 at A1. Rules of the American Congress regulate with elusive precision the meals and other benefactions members are permitted to receive.

<sup>100</sup> Rules of Procedure of the European Parliament (16th ed. July 2004), Rule 9(2) and Annex IX, available at <http://www.europarl.eu.int/omk/sipade3?PUBREF=-//EP//TEXT+RULES-EP+20040720+TOC+DOC+XML+V0//EN>.

<sup>101</sup> European Parliament, Accredited Lobbyists, <http://www.europarl.eu.int/parliament/expert/staticDisplay.do?id=65&language=en&redirection>.

<sup>102</sup> Jerome Glass, *Why throw a spammer in the lobbying machine*, 11(15) EUROPEAN VOICE, Apr. 21, 2005, available at <http://www.corporateeurope.org/europeanvoice210405.html>. Glass reports “estimations of the number of lobbyists working around the EU institutions ranging from 15,000 to more than 20,000” and that:

The European Commission is to discuss at the end of the month a communication on lobbying from Siim Kallas, the vice-president in charge of administration and the fight against fraud. Following this, a Green Paper on the sector will be launched, Kallas hopes before the end of the year. As part of the debate opened by the Green Paper, the Commission will organise a roundtable with stakeholders, to exchange views on the right approach to take. Kallas’s stated aim is to regulate lobbying without increasing red tape. The commissioner expects that a proposal on a set of rules or a “voluntary code of conduct” will emerge sometime next year. He says a voluntary code of conduct is preferable to laws, for the time being. But if voluntary rules did not work, the Commission might consider binding measures at a later stage.

On April 22, 2005, the author could find no trace of these matters on Commissioner Kallas’s website, Siim Kallas-Vice President, [http://europa.eu.int/comm/commission\\_barroso/kallas/index.htm](http://europa.eu.int/comm/commission_barroso/kallas/index.htm).

Glass further reports that the EU’s approach to the risk of imbalanced lobbying, rather than curtailing communications that “help to inform lawmakers” has been to fund Non-Governmental Organisations (NGOs) in order to balance out lobbyists from industry, which still account for around 70% of the total. In addition, many lobbying companies in Brussels have signed up to a voluntary code of conduct which contains guidelines on good practice and professional behaviour.

2005, it appeared that political pressures were growing to create more formal structures, including an independent watchdog organization, in the wake of embarrassing disclosures of vacations taken with friends who were also persons highly interested in the EU's affairs.<sup>103</sup> That appearances of conflict of interest might arise from genuine friendships in political circles is hardly unknown.<sup>104</sup>

#### *E. The Commission's Internal Processes*

This does not seem an appropriate place to explore in detail the Commission's internal processes, which in any event are (appropriately, to the extent they are truly internal<sup>105</sup>) not open to public view. One characteristic, however, seems appropriate to underscore for persons seeking comparisons, however implicit, with American institutions—that the Commission is fundamentally a collective, its President (as a prime minister) *primus inter pares* but the group taking action collectively. When one considers as well the President's election by the European Parliament, the required distribution of Commissionerships and responsibilities for the Commission's various directorates among citizens of the several nations of Europe, Parliament's own need for confidence in the several Commissioners, and the Commission's character as the exclusive drafting agent for proposed European legislation, it becomes apparent that American concerns with a unitary President, and debates over the strength or weakness of his command over the rest of executive government, would be misplaced. Consensus is, of necessity, the road to decision. And this very reality contributes immeasurably to the Commission's commitments to transparency, consultation, and the effort at objectivity in its dealings with the outer world.

As Francesca Bignami so persuasively argues in the context of the Union's procedural development generally, the structure of the EU may be such as to make its actors—and perhaps especially the Commission—sensitive to the expectations of its more demanding members. The incentives for Europe's bureaucrats are quite different to those American agency staffs might experience—not only that consensus should be achieved on the particular matter they are proposing, but also that Member States and their populations on an ongoing basis perceive EU processes as attentive to their concerns:

Notwithstanding that procedural rights emerged in different historical periods and that they were informed by different cultural traditions and supranational interests, they display one striking common characteristic: they afford citizens a greater set of entitlements against European government than in their place of origin. What accounts for this surprising outcome? One contributing factor is the weak nature of the Commission as a

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<sup>103</sup> Bennhold, *supra* note 94.

<sup>104</sup> For example, Justice Scalia's refusal to recuse himself in a case involving Vice President Cheney. See *Cheney v. U.S. Dist. Ct. for the District of Columbia*, 541 U.S. 913 (2004). For a similar, if understated, view, see *Get Connected*, *supra* note 29, at 43.

<sup>105</sup> Transparency legislation in the EU as in the United States exempts from public disclosure pre-decisional internal discussions, as conducive to candor and efficiency in bureaucratic practice. See 5 U.S.C. § 552(b)(5).

government organization. The Commission relies on cooperation from national administrations and national courts in enforcing European law. It does not have a police force that it can call into action, European courts in which it can directly appear to seek the execution of orders, or jails into which it can put recalcitrant citizens. . . . It is not led by a popularly elected official, as are executive branches at the national level— . . . [but] by a College of Commissioners, headed by a President, that is appointed by common consensus among the Member States, with some input from the European Parliament. In no way can the Commission be said to enjoy an electoral mandate when it undertakes its mission

. . . .<sup>106</sup>

Thus, one could believe, to earn credibility the Commission's impulse must be to a highest rather than the lowest common denominator.<sup>107</sup>

Further reflection of these realities is perhaps to be found in the measures the Commission has adopted for transparency in its dealings with experts, and for explaining the proposals it ultimately makes for Council and Parliamentary action.

In 2002, the Commission issued guidelines defining core principles and guidelines for collecting and using the advice of experts outside the responsible Commission DG.<sup>108</sup> These require it, in the first instance, to maintain a level of in-house expertise enabling it to act as an "intelligent customer" when organizing and acting on external expertise. The use of internal resources is preferred. If outside help is to be sought, the scope and objective of the experts' involvement, and the questions they will address, are to be set out clearly. Both mainstream and divergent views are to be considered, and departments are to maintain a record of the process including the terms of reference and the main contributions of different experts or groups of experts. The experts themselves, and also the Commission, are made responsible for monitoring any possible conflict of interest issues that could jeopardize the quality of the advice. And transparency is also a central consideration: experts must highlight the evidence (e.g., sources, references) upon which they base their advice, as well as any persisting uncertainty and divergent views; within the framework of freedom of information legislation, the principal documents associated with the use of expertise—in particular the advice itself—are to be made available to the public as quickly as possible;<sup>109</sup> and departments are encouraged to permit public attendance at expert meetings, particularly on sensitive policy issues. Finally, departmental proposals for Commission decision are to be accompanied by discussion of the expert advice (whether or not it has been followed) and this information is generally to be made public when the Commission's proposal is formally adopted.

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<sup>106</sup> Bignami, *supra* note 92, at 352.

<sup>107</sup> See Francesca Bignami, *The Challenge of Cooperative Regulatory Relations After Enlargement*, in *LAW AND GOVERNANCE IN AN ENLARGED EUROPEAN UNION* 97 (George A. Bermann & Katharina Pistor eds., 2004).

<sup>108</sup> *Communication on Principles and Guidelines—"Improving the knowledge base for better policies,"* COM (2002) 713 final (Dec. 11, 2002).

<sup>109</sup> See European Parliament and Council Regulation (EC) No 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, 2001 O.J. (L 145) 43.

### *F. Explanation*

The obligation to explain proposals is treaty-based. Intended to inform the subsequent political processes (and thus generally met by preambular material in legislative proposals rather than separate explanations of “basis and purpose”), it is subject principally to political enforcement—by the Council or Parliament rather than the courts. EC Treaty Article 253 requires that all *regulations, directives, and decisions* adopted by the Parliament and Council jointly, by the Council alone, or by the Commission, “shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained by this Treaty.” This treaty requirement is normally thought to be satisfied by the recitation of “whereas” clauses at the beginning of EC legislation. Such recitals, however, only set out seriatim a set of relevant facts or factors, and do not explore trade-offs or the real reasoning of the decision.

In addition, the Commission accompanies its legislative proposals with explanatory memoranda setting out the results of consultations, and available in all languages. As characterized in the recent U.K. Better Regulation Task Force report,<sup>110</sup> these memoranda typically run to about eight pages and, by the Commission’s own account, often do little to reveal how responses to public consultations were taken into account. They are not the kind of explanation American courts would seek as an adequate reasoned explanation of a rulemaking decision.

## III. CREATING IMPLEMENTING MEASURES

One question that might be raised about European legislative acts generally is whether they are prone to leave unsettled questions requiring further lawmaking by inferior authorities. This is, of course, the dominant experience in American administrative law, and the engine of the contemporary interest in and importance of rulemaking procedures. Two decades ago, Ed Rubin underscored the increasing difficulty of the “delegation” problem in American perspective with his observation that Congress had virtually ceased solving problems legislatively—that it had moved, rather, to the habitual creation of regulators through what he styled “intransitive” legislation. As public choice analyses of congressional action are also prone to point out,<sup>111</sup> this is not simply the product of legislative incapacity to resolve all details, so that the creation of subsidiary standard-setters is a practical necessity; it also reflects the discovery of a technique for having seemed to act, without ever having to do so in a manner that entails political responsibility for the consequences. The agency, executive or independent, will actually set the standards; and consequently the agency’s leadership (or the President), not the Congress, will have to pay any political price.

By contrast, EU legislative acts are often prolix, confronting in detail issues of

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<sup>110</sup> *Get Connected*, *supra* note 29, at 39.

<sup>111</sup> See, e.g., DAVID SCHOENBROD, *POWER WITHOUT RESPONSIBILITY: HOW CONGRESS ABUSES THE PEOPLE THROUGH DELEGATION* (1993).



the kind the American Congress most often leaves to regulators. EU legislative acts address a particular, relatively detailed subject—the constraints on genetically modified organisms (GMOs) in European agricultural markets—and identify with some precision the “essential requirements” of that subject that others are required to honor in implementing legislation or regulations. In these characteristics, they much more closely resemble EPA regulations bearing on state implementation plans than they do congressional statutes intransitively creating problem-solvers who are to act on the basis of multiple, essentially political factors. Might that not suggest that EU legislation leaves little to do, few details to be filled out by subordinate legislative acts? Yet, EU legislation has other characteristics as well. It is shaped by the constraints of subsidiarity and proportionality, the frequent enough need to find diplomatic formulations capable of accommodating national differences, and the contemporary preference for flexible new governance approaches embodying repeated benchmarking and mutual learning. All these influences suggest that, for all their seeming detail, EU legislative acts will often leave considerable leeway and discretion.<sup>112</sup> Indeed, on a numerical basis EU implementing measures dominate EU legislative acts, just as in the United States regulations dominate statutes. In 1996, for example, the European Parliament and Council adopted 484 “legislative” acts; in the same year, following very different processes and under rather light supervision, the European Commission adopted 5147 “regulations,” with a great deal of uncounted “soft law” below that.<sup>113</sup>

Actions corresponding to American agency rulemaking take a variety of forms. When the EU has issued a “directive,” setting framework standards that require implementing measures, these measures are commonly—but not invariably—taken by Member States subject to EU controls for their adequacy. Because the procedures for creating these implementing measures are set by national law, they will not be addressed here; nonetheless one considering the means by which law is shaped in Europe must always consider that national implementation is a major element, and the procedures and expectations operating at that level inevitably shape the European experience. Even if in the first instance it is for member states to exercise the freedom of approach that “directives” intentionally leave, however, it may be necessary to adjust the dimensions of that freedom from time to time, as experience develops; and it will be necessary to reach judgments over time what

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<sup>112</sup> In correspondence, Bignami writes:

[T]he Data Protection Directive (adopted in 1995, in force since 1998), which I’m doing a case study on, is an example of a lot of leeway and discretion being vested in the member states. Essentially, once the text of the proposed Directive made it to the Council, the MS couldn’t agree on anything, so they agreed to disagree or make the terms so vague that most existing systems would be accommodated. And I’m becoming a bit concerned by the bias being generated by this aspect of information privacy which I didn’t anticipate.

E-mail from Francesca Bignami, Professor of Law, Duke Law School to Peter Strauss, Betts Professor of Law, Columbia Law School (Dec. 21, 2004) (on file with the author).

<sup>113</sup> The draft constitution would have identified these subsidiary norms, now described generally as implementing measures, as “European regulations”—“non-legislative act[s] of general application for the implementation of legislative acts and of certain provisions of the Constitution,” whether they applied directly to individuals, as the legislative acts now denominated “regulations” do, or they applied to Member States made responsible for their implementation, as do the legislative acts now denominated “directives.” Draft Constitution art. I-33. See *supra* note 5.

approaches do and what do not honor the directives' essential requirements. And EU "regulations" creating law directly applicable to private individuals may also require or at least permit subordinate forms of lawmaking. At least three contexts for implementing measures directly involve procedures at the EU level, predominantly in the Commission but to some degree in coordination with external international or pan-European bodies—comitology, "new approach" standards, and other forms of reference to external international or pan-European bodies.

Little of this subordinate lawmaking is developed with the detail of American rulemaking—or, for that matter, the preparation of legislative proposals by the Commission. Although examples of a process similar to that used for legislative measures can be found within the EU DGs themselves,<sup>114</sup> on the whole implementation measures are much less in public view or committed to public participation than legislative acts. The U.K. Task Force for Better Regulation characterizes comitology, the first and perhaps most prominent of these practices, in a way that echoes through the whole of the literature:

The main concern we have about the comitology procedure is one of transparency. The comitology database that lists the committees and their agendas is welcome, but information is often posted too late for stakeholders to influence the discussion. With participation in the committees restricted to Member State representatives and institutional actors, together with little public information, the process can seem a complete mystery to many people.<sup>115</sup>

Thus, as Bignami also reports,<sup>116</sup> the pattern of consultation in the EU is quite the reverse of that in the United States. The following pages discuss in turn

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<sup>114</sup> For example, the Commission has created, in association with DG Internal Market's Financial Services bureau, two committees, the European Securities Committee[ESC] and the Committee of European Securities Regulators[CESR], and it sometimes issues mandates to them in connection with the implementation of its work. See, e.g., Securities and Investments Funds—Prospectus Directive, [http://europa.eu.int/comm/internal\\_market/securities/prospectus/index\\_en.htm](http://europa.eu.int/comm/internal_market/securities/prospectus/index_en.htm). The CESR maintains a web-site, <http://www.cesr-eu.org>, that like the European Aviation Safety Agency lists ongoing and closed consultations, with relevant links for submitting comments or viewing those that have been made once the consultation is closed; and these include consultations seeking advice on possible "implementing measures" for EU directives in the securities field. But these consultations are not to be found on the DG's own web-site for "your voice" consulting. [http://europa.eu.int/comm/internal\\_market/consultations/index\\_en.htm](http://europa.eu.int/comm/internal_market/consultations/index_en.htm). And for the former committee, the ESC, all one can find, through the DG site, is a rather unrevealing collection of meeting minutes. See Securities and Investments Funds—ESC, [http://europa.eu.int/comm/internal\\_market/securities/esc/index\\_en.htm](http://europa.eu.int/comm/internal_market/securities/esc/index_en.htm); see also Yannis V. Avgerinos, *Essential and Non-essential Measures: Delegation of Powers in EU Securities Regulation*, 8 EUR. L.J. 269, 270 (2002). And see the discussion of the European Air Safety Agency, *infra* note 162 and accompanying text.

<sup>115</sup> *Get Connected*, *supra* note 29, at 19.

<sup>116</sup> Bignami, *supra* note 92, at 345 ("With the right to civil society participation, the proceduralized sequence of public notice, opportunity to comment, and government response has been introduced for acts of a general nature but, for the time-being, only for European laws, not implementing regulations. The Commission, in reasserting authority after the resignation of the Santer Commission, needed civil society to justify its role in making the fundamental, political choices contained in European legislation. It had no strategic interest in involving civil society in what was perceived as the technical domain of rulemaking. This is precisely the opposite from the American experience. In the United States, regulations must adhere to notice and comment procedures but congressional statutes, as a matter of constitutional and statutory law, are free from requirements of public debate before they are passed.").

comitology, “new approach” standards, and other forms of reference to external international or pan-European bodies.

### A. Comitology

For the Commission itself, implementing measures are most frequently the product of a process known as “comitology,” a process characterized as a means for consulting Member States.<sup>117</sup> This process is given some structure by the so-called comitology decisions,<sup>118</sup> whose outlines do not significantly involve public notice or participation. Most closely supervised by individual DGs, comitology practices vary considerably from place to place within the Commission; some Directorates (for example, Employment) employ it hardly at all where others (Agriculture, Enterprise, Sanco) report hundreds, even thousands, of annual events. The Commission Secretariat maintains a Register of Comitology covering comitology documents from January 1, 2003.<sup>119</sup> Here one can occasionally find notice of agendas in advance of meeting,<sup>120</sup> together with an indication who is invited (member-state representatives and, if useful, member-state designated experts, but not the public); drafts may be available *if* Members of Parliament will enjoy a right of scrutiny, but not otherwise.<sup>121</sup> Given the variation and this general lack of transparency, a report like this one can do little better than scratch the surface; while the attached sectoral reports attempt specific examples in their contexts, one is well advised to consult the particular practice of particular DGs in the current moment.<sup>122</sup>

Comitology procedures have changed considerably over the years, particularly as Parliament’s place has strengthened, and for this reason early studies<sup>123</sup> are of

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<sup>117</sup> See The European Commission and Civil Society—General Overview, [http://europe.eu.int/comm/civil\\_society/apgen\\_en.htm](http://europe.eu.int/comm/civil_society/apgen_en.htm).

<sup>118</sup> See Council Decisions 87/373/EEC, O.J. (L 197) 33, 35 and 1999/468/EC, O.J. (L 184) 23, 26 (Laying down the Procedures for the Exercise of Implementing Powers Conferred on the Commission). The Council Decisions were further modified by Council Regulation (EC) No. 806/2003, 2003 O.J. (L 122) 1 (qualified majority) and Council Regulation (EC) No. 807/2003, 2003 O.J. (L 122) 36 (unanimity). The text seeks only to describe the current state of practice, to the extent that can be known. For an historical account of its development; see Georg Haibach, *The History of Comitology*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC, *supra* note 4, at 185–215.

<sup>119</sup> Register of Comitology, [http://europa.eu.int/comm/secretariat\\_general/regcomito/registre.cfm?CL=en](http://europa.eu.int/comm/secretariat_general/regcomito/registre.cfm?CL=en).

<sup>120</sup> A site search for all documents bearing a December 2005 date conducted December 19, 2005 produced 235 documents, the great bulk of which related to past meetings; a search for documents bearing a January 2006 date on the same day returned six agendas of future committee meetings, only one of which (a meeting of the standing committee on medicinal products for human use) concerned a draft measure subject to a right of scrutiny; the agenda was available on the site, but the draft measure would have to be requested.

<sup>121</sup> It may be possible to request them, see the report on transparency, but notice does not often appear in advance of meeting, and in any event such requests often will not be fulfilled in a time consonant with the committees’ actions.

<sup>122</sup> Many committees used by DGs for advice or similar functions are not Comitology Committees exercising the powers or subject to the procedures established by the Comitology Decisions. These non-Comitology groups may or may be not set up by official Commission decisions; some further development about them may appear in the sectoral reports. See, e.g., Commission setting up a consultative group, to be known as the “Experts Group on Trafficking in Human Beings,” 2003/209/EC, O.J. (L 079) 25.

<sup>123</sup> See, e.g., EU COMMITTEES: SOCIAL REGULATION, LAW AND POLITICS (Christian Joerges & Ellen

uncertain continued relevance. Because Parliament, as well as the general public, is somewhat disadvantaged by comitology practice, the draft European Constitution, if ratified, would have replaced it with a lying-before practice in which Parliament would have enjoyed an opportunity of disapproval equal with the Council.<sup>124</sup> But even the draft Constitution specified no greater degree of public participation in the adopting of implementing measures than currently exists.

Comitology committees consist of Member State representatives qualified in the particular field, chaired by a non-voting representative of the Commission.<sup>125</sup> Their meetings may or may not be preceded by public notice, but in any event they will be held in small venues, to which only the members and a limited number of “experts” seconded by members will be invited. The Commission presents a proposed draft of its intended action—for our purposes, an implementing measure—to the committee which, after deliberation, delivers an opinion on the proposal. The committee then acts on the draft by qualified majority under one of four regimes, specified in the governing documents:

- If a committee is denominated “advisory,” its actions are simply advisory in character; the Commission should respond to negative advice in a final instrument taking action, but its resolution of the matter takes effect without further formalities.
- If a committee is denominated “management,” the style most likely in agricultural matters or matters with large budgetary implications, failure of the committee to approve the Commission’s draft (or a revised draft) by a qualified majority must be communicated to the Council, which has three months in which to take a different position by qualified majority. Unless it does so, the Commission draft enters into force.
- If a committee is denominated “regulatory,” the Commission’s proposal will come into force routinely if it secures qualified majority support from the committee *or*, failing that, if it secures support from the Council within three months—again, by qualified majority. The Council can amend the Commission’s proposal only by unanimous vote. Should a qualified majority of the Council *oppose* the Commission’s draft, the Commission must submit a revised proposal (or seek legislative action) to effect an implementing measure. However, the Commission proposal will take effect, even if not approved in committee, if three months expire without either qualified majority support or qualified majority disapproval being expressed in Council. As the most demanding of the ordinary forms of comitology,

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Vos eds., 1999) (collection of essays).

<sup>124</sup> Paul Craig questions the sufficiency of this after-the-fact review to control the Commission’s “significant power over complex regulatory choices.” Paul Craig, *European Governance: Executive and Administrative Powers Under the New Constitutional Settlement*, 3 INT. J. CONST. L. 407, 430 (2005); see also Paul Craig, *The Hierarchy of Norms*, in 1 EUROPEAN UNION LAW FOR THE TWENTY-FIRST CENTURY 75–94 (Takis Tridimas & Paolisa Nebbia eds., 2004). It may be noted that a Commission proposal it characterizes as anticipating “within the framework of the current Treaty, the spirit of the innovations in the draft Constitution” by placing Parliament and the Council “on a strictly equal footing for controlling the exercise by the Commission of implementing powers for matters subject to co-decision.” *Report on European Governance (2003-2004)*, SEC (2004) 1153, 14. This proposal has been pending a Council opinion since April 2004. See European Parliament—Procedure File, <http://www2.europarl.eu.int/oeil/FindByProcnum.do?lang=2&procnum=CNS/2002/0298>.

<sup>125</sup> KOEN LENAERTS & PIET VAN NUFFEL, CONSTITUTIONAL LAW OF THE EUROPEAN UNION 614–19 (2005) (this description draws on paras. 16-009-014).

“regulatory” comitology is the principal concern of the following discussion.

- The fourth style, “safeguard,” is a rarely invoked amalgam.

To this conventional description one should add an appreciation for the increasingly important role of the European Parliament. If, as is now usual, the underlying legislative act was adopted by co-decision, drafts are also transmitted to Parliament; Parliament then has a month in which it may adopt a resolution indicating its view that the draft exceeds the Commission’s delegated powers. Should this happen, the Commission is obliged to reexamine its draft and to report, with reasons, the action it intends to take. Resubmission to such parliamentary review is provided whenever the Commission substantially modifies its action from an earlier draft, if the underlying legislative act was adopted by co-decision.

As appears from the Commission’s most recent reports on the working of committees,<sup>126</sup> these elaborate provisions are rarely invoked, and committee contributions are, at least on the surface, minor. Parliament has yet to enact a resolution characterizing a draft as beyond Commission authority. The very great bulk of Commission DG proposals are ratified without significant change or opposition by the committees—and as a result, the Council is rarely consulted, at least formally. There were *no* referrals to the Council in 2003; seven, in 2002. Of course one may say, as the Commission does,<sup>127</sup> that the relative imbalance of DG and committee or Council work reflects the sensitivity of DG staff to committee and Council preferences. The claim is very hard to evaluate in the absence of transparency in the comitology process, however. The drafts the Commission submits to comitology committees are not published outside the committees; committee agendas are usually reported (if at all) after the fact of meeting; and minutes of committee meetings are quite summary.<sup>128</sup>

Consider, moreover, the implications of the following table, constructed from data about regulatory comitology in these two recent reports<sup>129</sup>:

DG	2001–03 committees <sup>130</sup>	2001–03 regulatory procedures <sup>131</sup>	2001–03 meetings <sup>132</sup>	2002–03 opinions <sup>133</sup>	2002–03 instruments <sup>134</sup>

<sup>126</sup> *Report from the Commission on the working of committees during 2003*, COM (2004) 860 final (Jan. 7, 2005); *Report from the Commission on the working of committees during 2002*, COM (2003) 530 final (Sept. 8, 2003).

<sup>127</sup> *Id.* § 1.4 (for both sources).

<sup>128</sup> See, e.g., Regulatory Committees, [http://europa.eu.int/comm/food/committees/regulatory/index\\_en.htm](http://europa.eu.int/comm/food/committees/regulatory/index_en.htm) (the comitology page of SANCO, the DG concerned with health and food safety issues).

<sup>129</sup> For a similar analysis of earlier experience appears, see Falke, *supra* note 5, at 331, 343.

<sup>130</sup> Where the number varied, the highest number is given. Variance was minor.

<sup>131</sup> Where the number varied, the highest number is given. Variance was minor. Number of regulatory committees does not include number reported as operating under more than one procedure, and so is low.

<sup>132</sup> All purposes; statistics broken out by type not available.

<sup>133</sup> All types of opinions, whether favorable or not, in all types of procedures

<sup>134</sup> This is the measure of implementing measures adopted by the Commission.

ENTR	33	18	146	1037	953
EMPL	8	3	42	26	5
AGRI	30	4	1039 <sup>135</sup>	2868	2868
TREN	45	21	108	70	43
ENV	35	26	155	137	79
INFSO	13	4	97	90	71
MARKT	12	6	80	14	11
TAXUD	9	4	335	93	88
SANCO	22	9	332	858	636
JAI	7	1	57	33	17
TRADE	13	2	98	123	106
AIDCO	8	2	120	344	320
OLAF	1	1	4	0	0
TOTAL <sup>136</sup>	256	100			5197 <sup>137</sup>

The volume of work, together with the Commission's status as the unique source of implementing measures, strongly suggest that the DGs are, effectively, in charge. That more than 5200 comitology acts would fail to attract Parliamentary correction even once, and involve the Council only seven times, may reflect Commission caution; but it certainly also suggests Commission initiative and success. In the more active DGs, the number of instruments significantly outnumber the number of (generally half-day) meetings; the length of SANCO agendas suggests that discussion of any given item is most often perfunctory.

For EMPL, TREN, ENV, MARKT, TAXUD, and JAI, on the other hand, one can observe a ratio of two or more meetings per instrument, suggesting that, at least in these contexts, the committees can be rather deeply engaged with Commission proposals. Again, direct opportunities for external knowledge and participation are limited. Occasional accounts one can find in the literature—for example, of the

<sup>135</sup> Predominantly management meetings

<sup>136</sup> May include DGs without *any* regulatory procedures

<sup>137</sup> These DGs only; other DGs not using regulatory procedure contributed a not insignificant additional number of instruments.

handling of the BSE crisis<sup>138</sup>—are certainly consistent with the Commission's claims. But the process is not one currently open to contemporary observation or general public participation or influence.<sup>139</sup> And one general account of comitology practice in ENV, under prior regimes and thus now perhaps outdated, suggests not only the problems with its "secret life," but quite specifically that, relative to its committees, and as a matter of practical politics, the Commission is in "quite a strong position."<sup>140</sup>

In the circumstances, the consistent observation that transparency and citizen involvement are missing at the level of comitology suggests at least the possibility that engaged oversight is absent because it is ill-informed. The observation is supported by a search of the Commission's web sites. The Commission's general overview of civil society and its consultation standards explains, "the consultation standards do not apply to comitology consultation."<sup>141</sup> The Yourvoice site, again, references few if any consultations about implementing measures. Individual DG websites seem little better. And the Secretariat-General's Register of Comitology, as earlier noted,<sup>142</sup> is also quite limited in the access it provides.

The pharmaceuticals unit of DG Enterprise (ENTR)—one of the more active DGs insofar as implementing measures are concerned—publishes a not inconsiderable list of implementing measures for Directive 2001/20/EC (pharmaceuticals).<sup>143</sup> No link for consultations appears on its website. By consulting the "news" link that is there,<sup>144</sup> one can find invitations to comment on draft guidance documents, coordinated with the European Medicines Agency site,<sup>145</sup> but no information about comitology activities. The ENTR consultations link<sup>146</sup> is no more informative. The comitology process, mild as it may be, is hidden from view.

As with legislation, then, it may be that the most interesting aspect in the development of implementing measures, as with legislative acts, lies in the Commission's internal processes for developing the proposals on which comitology acts. Unlike the legislative process, however, it is unclear that these processes, either, result in exposure to or engagement of the public. It may be that such invitations are given, without identifying the consultations as ones eventually destined for comitology. The multiple signals of forthcoming endeavor, and invitations to engagement, characteristic of the build-up to legislative acts are

<sup>138</sup> Schafer, *supra* note 5, at 20. For the case study on comitology in connection with GMOs, see Annette Toeller & Herwig Hoffman, *Democracy and the Reform of Comitology*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC, *supra* note 4, at 25, 37. These were, of course, both highly controversial matters and so unlikely to be representative of general practice.

<sup>139</sup> Toeller & Hoffman, *supra* note 138, at 22.

<sup>140</sup> Demmke, *supra* note 4, at 279, 285, 287.

<sup>141</sup> The European Commission and Civil Society, [http://europe.eu.int/comm/civil\\_society/apgen\\_en.htm](http://europe.eu.int/comm/civil_society/apgen_en.htm).

<sup>142</sup> See *supra* note 119.

<sup>143</sup> European Commission, Enterprise and Industry DG, Pharmaceuticals, <http://pharmacos.eudra.org/F2/pharmacos/dir200120ec.htm>.

<sup>144</sup> European Commission, Enterprise and Industry DG, Pharmaceuticals, <http://pharmacos.eudra.org/F2/pharmacos/new.htm>.

<sup>145</sup> European Medicines Agency, <http://www.emea.eu.int>.

<sup>146</sup> The European Commission, Enterprise and Industry, Consultations, <http://europa.eu.int/comm/enterprise/consultations/list.htm>.

missing here.

One way of thinking about the comitology process, strongly suggested by general concerns about the European “democracy deficit” and in particular by recent work of Martin Shapiro, is as an element of the “natural tendency for technocracy to displace democracy” in matters with high science or technological content.<sup>147</sup> For Europe, in particular, “the great enemy of successful . . . transnational regulation . . . appears to be the selfish pursuit of particular national interests by the member states or rather by their democratically elected, political leaders responding to their particular domestic constituencies with electoral clout. Transnational regulatory technocrats become the transnational regulatory heroes in pursuit of the transnational general interest. . . . The nationality requirement [of comitology committee membership] is . . . a bow to member state political control . . . [but] in most instances, the shared professional or expert standards, practices, values, assumptions and agreed truths of the particular specialized expertise shared by committee members is likely to overwhelm national differences or indeed any political considerations.”<sup>148</sup> Shapiro, one might add, is a person not impressed with the virtues of technocracy, of “government regulation of what we eat by the deliberation of nutritionists.”<sup>149</sup>

### *B. European Agencies as Actors*

Comitology is a process that develops implementing measures through the Commission itself. One might also imagine—and to a limited extent find—European legislation creating agencies that, like American independent regulatory commissions, would be empowered to enact implementing measures in a delimited field of action.

One reason for the relative unimportance of the “independent agency” as a source of what Americans would call regulations lies in the Commission’s vigorous defense of what it considers its role as Europe’s “unitary executive.”<sup>150</sup> (While the words are the same as Americans would use, the situation of the EU executive is necessarily quite different from that of the American President.) Accepting that regulatory agencies may be created at the EU level, the Commission has asserted that “[t]he main advantage of using [them] is that their decisions are based on purely technical evaluations of very high quality and are not influenced by political or contingent considerations”; while they “can be granted the power to take individual decisions in specific areas, [such agencies] cannot adopt general regulatory measures” and “cannot be granted decision-making powers in areas in which they would have to arbitrate between conflicting public interests, exercise political discretion, or carry out complex economic assessments.”<sup>151</sup> This makes it sound like

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<sup>147</sup> Martin Shapiro, *Some Free Associations on Administrative Judicial Review* 3 (Draft Paper presented at the University of San Diego, Jan. 20, 2005) (on file with author).

<sup>148</sup> *Id.* at 3-4.

<sup>149</sup> *Id.* at 5.

<sup>150</sup> *Communication from the Commission of the European Communities on the Operating Framework for the European Regulatory Agencies*, at 2, COM (2002) 718 final (Dec. 11, 2002).

<sup>151</sup> *Communication from the Commission of the European Communities on the Operating Framework for the European Regulatory Agencies*, at 5, 8, COM (2002) 718 final (Dec. 11, 2002); see



agency adoption of implementing measures is excluded. Yet commentators have found this a “startling statement,” one that “flies in the face of fifty years of experience with independent regulatory bodies in the United States and Europe, which has shown that it is simply impossible to structure agencies in this way.”<sup>152</sup>

The EU’s central website for European agencies<sup>153</sup> identifies eight as having regulatory functions, the Office for Harmonisation in the Internal Market,<sup>154</sup> the Community Plant Variety Office,<sup>155</sup> the European Medicines Agency,<sup>156</sup> the European Food Safety Authority,<sup>157</sup> the European Maritime Safety Agency,<sup>158</sup> the

also Governance in the European Union—Better Lawmaking: Decentralisation Through Agencies, [http://europa.eu.int/comm/governance/governance\\_eu/decentral\\_en.htm](http://europa.eu.int/comm/governance/governance_eu/decentral_en.htm).

<sup>152</sup> Joanne Scott & David M. Trubek, *Mind the Gap: Law and New Approaches to Governance in the European Union*, 8 EUR. L.J. 1, 16 (2002). “Agencies” and their powers appear to be at the center of lively controversy in the secondary literature about even the possibility of separating technocratic expertise from normative/political/democratic responsibility. See also Christian Joerges, “*Deliberative Supranationalism*”: Two Defences, 8 EUR. L.J. 133, 145 (2002) (arguing that the virtue of committees, as opposed to agencies, is that they offer superior hope (if sufficiently transparent) of mediating between expertise and democracy in a knowledge society); Giandomenico Majone, *Delegation of Regulatory Powers in a Mixed Polity*, 8 EUR. L.J. 319 (2002) (Majone is one of the stronger proponents of the agency model); Xénophon A. Yataganas, *Delegation of Regulatory Authority in the European Union: The Relevance of the American Model of Independent Agencies* (Jean Monnet Working Paper 3/01, 2001) (arguing the political necessity of some delegations to independent agencies).

<sup>153</sup> The Agencies of the European Union, [http://europa.eu.int/agencies/index\\_en.htm](http://europa.eu.int/agencies/index_en.htm). Each assesses fees for its services, and thus is essentially self-supporting.

<sup>154</sup> Office of the European Union, Trade Marks and Designs, <http://oami.eu.int>. Concerned with Community trademarks and design registration; its 2004 annual report is devoid of mention of “rulemaking” or “implementing measure,” and one finds no evident links from its website to such matters.

<sup>155</sup> Community Plant Variety Office, <http://www.cpvo.eu.int/index800.php>. This office is essentially a Community patent office for plant varieties. In 2004, the CPVO adopted administrative guidelines for determining plant varieties, pursuant to authority granted in Commission Regulation (EC) 1239/95, art. 30, 1995 O.J. (L 121) 37. See European Union Plant Variety Office Guidelines, available at <http://www.cpvo.eu.int/documents/lex/guidelines/VDguidelinesEN.pdf>. The site gives no indication of the procedures followed, nor evident links to similar matters currently under consideration. The “administrative council” responsible for these decisions does not appear in the organization chart on the agency’s website.

<sup>156</sup> European Medicines Agency, <http://www.emea.eu.int>. Formerly the European Agency for the Evaluation of Medicinal Products, this agency (connected with the pharmaceuticals unit of DG Enterprise and Industry) is the European equivalent of the American FDA. It appears to engage in active generation of guidance documents and standards for both human and veterinary medicine following consultations that are not obvious from the front page of its site, but presumably are well known to stakeholders. See EMEA Implementation of the New EU Pharmaceutical Legislation, <http://www.emea.eu.int/htmls/general/direct/legislation/legislationhuman.htm> (human medicines) and <http://www.emea.eu.int/htmls/general/direct/legislation/legislationvet.htm> (veterinary medicines). It appears that this information is often also published on the DG ENTR Pharmaceuticals Unit website, <http://pharmacos.eudra.org/F2/pharmacos/new.htm>. The rules of its committees explicitly undertake public consultation on “concept papers, draft guidelines and general regulatory developments . . . with all interested parties (industry, health care professionals, patients/consumers or other).” Rules of Procedure of the Committee on Medicinal Products for Human Use, art. 23, EMEA/CHMP/111481/2004, available at <http://www.emea.eu.int/pdfs/human/regaffair/11148104en.pdf>.

<sup>157</sup> European Food Safety Authority, <http://www.efsa.eu.int>. Given particular impetus by “mad cow disease,” this agency offers subscriptions for news highlights and notices of consultations on its front page. Its principal responsibilities concern risk assessment, and it is not clear that any of its products have the force even of soft law.

<sup>158</sup> European Maritime Safety Agency, <http://www.emsa.eu.int>. EMSA, like EASA, is an adjunct to DG Energy and Transport, but unlike that agency, discussed in the text following, no “rulemaking” unit or activity is readily discernable on its website.

European Aviation Safety Agency,<sup>159</sup> the European Network and Information Security Agency,<sup>160</sup> and the European Railway Agency.<sup>161</sup> These generally are constituted in a broadly representative way, with managing committees comprised of one representative from each member nation; the agencies may often be given similarly representative “committees” with which to consult. None is openly linked with the EU’s consultative legislative practice; neither the “your voice” consultation site (in its listing of open and closed consultations) nor the links it provides to consultations on DG sites directly refer to any of these agencies. Yet, as indicated in the immediately preceding series of footnotes, and the text next following this sentence, a quick survey of agency sites for public consultations and the formulation of implementing measures reveals a considerable variety of activity.

The EASA, in particular, has a directorate denominated “rulemaking,”<sup>162</sup> that engages in a process strongly resembling American notice and comment rulemaking<sup>163</sup> (including, in contradistinction to Commission practice, an apparent disposition to draft its proposals *prior* to initial public consultation) to generate standards on a variety of subjects.<sup>164</sup> Like the Commission, it maintains a published rulemaking programme<sup>165</sup> and undertakes to engage in risk and regulatory impact assessment in connection with its activities; all submissions are published, and it has established advisory groups of experts and national authorities with which it undertakes to consult before acting. The rules it adopts constitute “soft law” in the European understanding; either they are proposals for Commission action (with or without Council or Parliament participation) that if taken will render them binding on others or, in and of themselves, they merely indicate a basis on which regulatory requirements can be honored. That is, where the Commission has not itself been called upon to act, regulated persons are not *obliged* to comply with the EASA standards; but they are assured that they will be found in compliance with regulatory obligations (created by EU directives, etc.) if they do comply with the EASA standards.

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<sup>159</sup> European Aviation Safety Agency, <http://www.easa.eu.int/home>.

<sup>160</sup> European Network and Information Security Agency, <http://www.enisa.eu.int> (established in March 2004).

<sup>161</sup> European Railway Agency, <http://www.era.eu.int/>. The Railway Agency is the EU’s newest agency, under formation as an adjunct to DG Energy and Transport, there to join the Maritime Safety and Aviation Safety agencies. See European Commission—Rail Transport and Interoperability, [http://europa.eu.int/comm/transport/rail/era/index\\_en.htm](http://europa.eu.int/comm/transport/rail/era/index_en.htm); Organisation Chart of DG “Energy and Transport,” [http://europa.eu.int/comm/dgs/energy\\_transport/matthias\\_ructe/organigram\\_en.html](http://europa.eu.int/comm/dgs/energy_transport/matthias_ructe/organigram_en.html).

<sup>162</sup> European Aviation Safety Agency, [http://www.easa.eu.int/home/rulemaking\\_en.html](http://www.easa.eu.int/home/rulemaking_en.html).

<sup>163</sup> The Agency’s website carries direct links both to notices of proposed amendments (corresponding to notices of proposed rulemaking in American practice and offering links to electronic comment forms) and to “comment response documents” where agency staff indicate their proposed responses to comments that have been filed, in advance of final agency adoption of a rule.

<sup>164</sup> See European Parliament and Council Regulation (EC) No. 1592/2002, art. 13(b), 2002 O.J. (L 240) 1, 8 (authorizing the EASA to “issue certification specifications, including airworthiness codes and acceptable means of compliance, as well as any guidance material for the application of this Regulation and its implementing rules”); see also European Aviation Safety Agency, *Decision of the Management Board concerning the procedure to be applied by the Agency of the issuing of opinions, certification specifications and guidance material (“Rulemaking Procedure”)*, EASA MB/7/03 final (June 27, 2003), available at [http://www.easa.eu.int/doc/About\\_EASA/Manag\\_Board/2003/2003\\_06\\_17\\_mb\\_decision\\_en.pdf](http://www.easa.eu.int/doc/About_EASA/Manag_Board/2003/2003_06_17_mb_decision_en.pdf).

<sup>165</sup> European Aviation Safety Agency, *2005 Rulemaking Programme*, available at [http://www.easa.eu.int/doc/Regulation/Docs/decision\\_ED\\_2004\\_09\\_RM\\_annex.pdf](http://www.easa.eu.int/doc/Regulation/Docs/decision_ED_2004_09_RM_annex.pdf).

*C. Delegation Out: Reliance on International Bodies and European Standards Organizations*

The Commission and expert bodies act together in the formulation of norms in at least two other contexts worthy of mention, but not elaborate discussion.<sup>166</sup> In both of these settings, in contrast to comitology, it appears that one can secure advance notice of the matters to be discussed, and perhaps seek to influence the discussion.

The first arises where other international bodies are ultimately responsible for the generation of standards (as for example the Codex Alimentarius Commission that the FAO and WHO have jointly created to develop standards, guidelines and related texts concerning food purity).<sup>167</sup> Here, the Commission may use a committee format to develop joint positions with Member States on matters to be considered on forthcoming agendas. And for these committees (not comitology committees), agendas and discussion papers may be noticed and made available in advance of meetings.<sup>168</sup>

Second, some Commission directives employ what it has denominated the “new approach” in matters affecting the single market—that is, in American terms, where one might fear safety or similar concerns are being used by states to mask favoritism to local industry.<sup>169</sup> New approach directives, in themselves, define only the “essential requirements” of regulatory controls in technical fields—say, safety standards for pressurized containers—and not particular means of achieving compliance with these requirements. They also create Commission mandates to European standards organizations (rather than “comitology” committees) to identify,

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<sup>166</sup> See *supra* note 61, concerning the use of advisory committees early in the legislative drafting process.

<sup>167</sup> See FAO/WHO Food Standards CODEX Alimentarius Home, [www.codexalimentarius.net](http://www.codexalimentarius.net).

<sup>168</sup> Thus, on April 20, 2005, one could find the List of Specialised Committees and Task Forces—Codex Committee on Food Additives and Contaminants (CCFAC), available at [http://europa.eu.int/comm/food/fs/ifsi/eupositions/ccfac/ccfac\\_index\\_en.html](http://europa.eu.int/comm/food/fs/ifsi/eupositions/ccfac/ccfac_index_en.html), where the webpage listed a series of position papers and analyses prepared for the forthcoming meeting of EU Commission and Member State officials in the Hague, April 25–29, as the Codex Committee on Food Additives and Contaminants, in preparation for the Codex Alimentarius Commission meeting in Rome July 4–9. The DG Health and Consumer news bulletin for the day, Sanco-news, carried a link to an item freshly added to the Committee’s agenda that day. Subsequent issues carried similar information about forthcoming agenda items. No issue of Sanco-news received during the period April 18, 2005—carried any advance notice of comitology meetings, or links to documents to be discussed at them.

<sup>169</sup> See, e.g., European Parliament and Council Directive 98/34/EC, 1998 O.J. (L 204) 37. Experience under this Directive is extensively reported in a *Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee—The operation of Directive 98/34/EC from 1999 to 2001*, COM (2003) 200 final (May 23, 2003). A Commission Communication and an accompanying Commission staff working document, “The Challenges for European Standardisation,” available at [http://europa.eu.int/comm/enterprise/standards\\_policy/role\\_of\\_standardisation/index.htm](http://europa.eu.int/comm/enterprise/standards_policy/role_of_standardisation/index.htm), express considerable enthusiasm for experience to date, the hope both for exploitation of “room for improvement” and the high desirability of “making use of standards in areas of Community legislation beyond the Single Market.” *Communication from the Commission to the European Parliament and the Council on the Role of European Standardisation in the Framework of European Policies and Legislation*, at 1, 3, COM (2004) 674 final (Oct. 18, 2004). The general question of private standards development, and its relation to governance issues in the EU (and the United States, and international markets generally) is fully explored in HARM SCHEPEL, *THE CONSTITUTION OF PRIVATE GOVERNANCE* (2005). See especially *id.* at 50-67, 101-44.

in technical standards, particular means of complying with these essential requirements. Commission guidance directs the organizations to adopt these technical standards only after providing the Commission, Member States and others notice of their proposals and an opportunity to comment on them during a fixed (and extendable) stand-still period.<sup>170</sup> It is by this means that, it is hoped, the wheat of genuine protection can be winnowed from the chaff of favoritism to local industry. DG Enterprise has established a Technical Regulation Information System (TRIS) website,<sup>171</sup> permitting anyone to enroll for e-mail notification of drafts published in areas of interest, thus assuring broad public opportunity to comment on proposed technical standards during the "stand-still" period.<sup>172</sup> If they are accepted by the Commission and officially published, the standards establish presumptively valid means of satisfying the essential requirements the directives define.

The adoption of technical standards has the effect of soft, not hard law<sup>173</sup>—essentially the same as an American business would experience if it followed "guidance" an agency had issued describing in detail particular actions it would accept as complying with its regulations. Such assurance is particularly important where, honoring contemporary preferences for maximizing the initiative left to regulated industries, hard law instruments have set standards to be met ("essential requirements," what qualities a safe ladder should have) rather than specified exact behaviors that are required (exactly how a ladder must be built). Thus, for example, manufacturers whose products meet the standards have effective protection against product liability actions.<sup>174</sup> National implementation of the same directives is to honor these standards once created.

One can get the impression that this work is uniquely done by *national* standard-setting organizations acting in coordination with *national* authorities. The Commission's published guide to the New Approach largely speaks in these terms,

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<sup>170</sup> See Guide to the Implementation of Directives based on the New Approach and the Global Approach (2000), ch. 4, "Compliance with directives," available at <http://europa.eu.int/comm/enterprise/newapproach/legislation/guide> [hereinafter *Guide*].

<sup>171</sup> DG Enterprise—TRIS, <http://europa.eu.int/comm/enterprise/tris>. The Commission's 2003 report discussing this website remarks that "it is essential for businesses to know about [notified drafts], on the one hand in order to adapt their products in advance . . . and on the other so that they can alert their governments and the Commission to any unjustified barriers." *Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee—The operation of Directive 98/34/EC from 1999 to 2001*, at 31, COM (2003) 200 final (May 23, 2003); see also *id.* at 36 (attributing "the reactions of the Commission and the Member States [as in] a large part due to the intervention of businesses"). No reference is made to the value to notice to others.

<sup>172</sup> The notices I have thus far received in several months' enrollment have all concerned national standards, with full text available only in the language of origin. Brief English summaries are provided, along with the promise of translations in a few weeks time; but no notice of an available translation has yet arrived.

<sup>173</sup> Technical standards "cannot replace a legal text or change what the legislator has provided." *Guide, supra* note 170, at 3. "Only the text of the directive is authentic in law." *Id.* at 4. Note that the standards, once produced, are not public documents as such; it appears people must purchase them as transposed by national authorities. The directives themselves are collected at New Approach Standardisation in the Internal Market, <http://www.newapproach.org/Directives/DirectiveList.asp>.

<sup>174</sup> Conformity with a harmonized standard produces a "presumption of conformity with the essential requirements of the applicable New Approach directive." *Guide, supra* note 170, at 28. A manufacturer may choose a different path, but then will have the burden of establishing that its products conform to the essential requirements.

and one finds a similar orientation to national standards on the TRIS website. But the Commission's Report on Experience under the New Approach contains a four-page list of mandates given to pan-European organizations such as the European Committee for Standardization (CEN)<sup>175</sup> "following consultation with the Member States,"<sup>176</sup> to develop Union-wide harmonized standards;<sup>177</sup> elsewhere, it lists twenty-seven mandates issued 1999-2001.<sup>178</sup> The CEN website gives, sector by sector, elaborate reports on the progress of mandated standards through its processes.<sup>179</sup> In doing so, it makes evident that it, too, proceeds very largely by committee action.<sup>180</sup> And a very recent "Communication from the Commission to the Council and the European Parliament" on "Better Regulation for Growth and Jobs in the European Union" strongly suggests that the future lies with increasing reliance on this private/public mechanism for law-generation.<sup>181</sup>

#### IV. GIVING RELIABLE ADVICE

It remains to address the realm of "soft law," settings in which the Commission or its delegates seek to develop what, in the American context, would fall within the realm of general statements of policy, interpretive rules, or staff manuals intended to structure staff behaviors. In American practice these matters, that might be lumped together under the rubric "guidance documents" or "publication rules," are generally free of procedural requirements; the one clear procedural constraint respecting them is that an agency is permitted to rely upon them to the detriment of a member of the public only if they have previously been published and indexed, or specifically brought to the member's attention. Generally, such publications are adopted with the purpose of governing an agency's subordinate staff, by committing it to act in the predicted manner when identified facts are presented or found; but while they doubtless influence public behaviors through awareness of this intent and their consequent predictive value, they do not, in themselves, create any obligation on members of the public. Hence, "soft law."

Enough has already been said to indicate that the Commission is often itself a source of soft law documents,<sup>182</sup> and that—as in the "New Approach" directives<sup>183</sup>—it may delegate to others, even outside the EU itself, the authority to create them.

<sup>175</sup> European Committee for Standardization, <http://www.cenorm.be/cenorm/index.htm>.

<sup>176</sup> *Guide*, *supra* note 170, at 28.

<sup>177</sup> *Id.* at 40–43.

<sup>178</sup> *Id.* at 12; see also SCHEPEL, *supra* note 169, at 108–09 (The tables make clear that even for the most important European standard-setters (Germany, France, and the United Kingdom) by 1997, the proportion of purely national standards adopted had dropped below 10%, European standards exceeded 70%, and the remainder were international).

<sup>179</sup> See CEN—All Domains by Subject, <http://www.cenorm.be/cenorm/businessdomains/businessdomains/domains.asp>. It appears that drafts as well as final standards must be purchased from national standards organizations.

<sup>180</sup> See SCHEPEL, *supra* note 169, at 101–44 (describing CEN and its processes).

<sup>181</sup> *Communication on Better Regulation for Growth and Jobs in the European Union*, COM (2005) 97 final (Mar. 16, 2005); see also SCHEPEL, *supra* note 169.

<sup>182</sup> E.g., its instructions to staff concerning consultation practice. See *supra* note 61 and accompanying text.

<sup>183</sup> See *supra* note 173 and accompanying text.

As in its generation of legislative acts (and in its requirements of others), its practice in developing general policy and instructions to staff is highly consultative, with these matters appearing in work plans, otherwise well publicized, and made the occasion for public consultations whose results are both exposed and openly discussed. Indeed, the bulk of consultations appearing on the Yourvoice website, directly or through links to DGs appear to fit this category. The practice is grounded in the EU's foundational treaties and subsequent Commission Communications,<sup>184</sup> although one confidently supposes that strong political incentives as well as these formal obligations underlie it.

Here, too, these steps are preliminary and tend to be quite structured and pointed—the Commission exposes the questions on which it wishes public commentary, and does not present its policy choices until after this consultative process has been completed. Its questionnaires tend to elicit, and its reports to highlight in their statistical character, the distributional issues (across Europe, and across stakeholder constituencies) that its formal commitments arise from. But the firm and explicit commitment to consultations like these is considerably stronger than one would find attached to most American agency processes for generating soft law.<sup>185</sup>

A frequent preoccupation of Commission approaches is with securing breadth of representativeness—for example, the practice (often mandated although increasingly difficult with the Union's growth) of including a delegate of each Member State on committees—while avoiding what is understood as private interest representation. An association of European automobile manufacturers might claim its place, alongside a broadly based union of automobile workers and a European association of automobilists; but Fiat, or the union representing the employees at VW's Wolfsburg facilities, or the Automobile Club of Stockholm usually could not expect a committee role. (Each, of course, could respond to public consultations.) The umbrella organizations are thought to have the capacity, even the responsibility, to mediate selfish member concerns with some attention to the greater European good.

A somewhat ironic illustration of this tension between assuring transparency and broad participation, on the one hand, and concern about self-interested activity, on the other, can be found in the administration of the Commission's implementation of its Water Framework Directive.<sup>186</sup> This important and highly complex measure seeks to organize river basin management across Europe (and consequently often

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<sup>184</sup> See The European Commission and Civil Society—General Overview, [http://europe.eu.int/comm/civil\\_society/apgen\\_en.htm](http://europe.eu.int/comm/civil_society/apgen_en.htm) (collecting and linking sources). As noted previously, this site is explicit that “the consultation standards do not apply to comitology consultation.” See *supra* text accompanying note 141.

<sup>185</sup> A notable exception is the FDA, which by statute and internal regulation is committed to “good guidance practices” producing similar levels of notice and engagement. See FDA Guidance Documents for Regulated Industry, <http://www.fda.gov/opacom/morechoices/industry/guidedc.htm>. As that site reflects, the FDA annually publishes a list of guidance under development in the Federal Register, with an invitation to the public to participate. It maintains an electronic docket, from which comments may be filed; it does not appear that the docket itself is populated with any comments that may have been submitted until proposed guidance has been published. See Dockets Open for Comment, <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA>.

<sup>186</sup> European Parliament and Council Directive 2000/60/EC, 2000 O.J. (L 327) 1 (establishing a framework for Community action in the field of water policy); see also The EU Water Framework Directive—Integrated River Basin Management for Europe, [http://europa.eu.int/comm/environment/water/water-framework/index\\_en.html](http://europa.eu.int/comm/environment/water/water-framework/index_en.html).

across national boundaries) by establishing a framework for member state implementation, employing all the perspectives one might expect of such a venture: water resource development and allocation, pollution control, flood and drought control, etc. First for pilot river basins, and then for all Europe's river basins generally, the Directive seeks to generate information and management plans that will achieve good water status for all European waters by 2015. It establishes a complex implementing structure of working groups and local river basin authorities acting under the supervision of a strategic coordinating group and "the European water directors," a group comprised of national ministers responsible for water issues and the water director of the EU's DG Environment. The multi-national character of this collective is the natural product of the national responsibilities entailed. The collective has undertaken to develop soft law guidance for the staged implementation of the directive under a "Common Implementing Strategy."<sup>187</sup> A separate and considerably less public comitology committee, variously called the WFD Committee and the Article 21 Committee (after the article of the Directive establishing a comitology regime), works with the Commission in developing any implementing measures.

DG Environment maintains a library resource, the Communication and Information Resource Centre Administrator (CIRCA), providing access to documents and information concerning a number of work groups responsible for implementing environmental regulations and directives.<sup>188</sup> Part of this resource is a Water Framework Directive library comprising a wide range of guidance and other documents developed for the WFD under the guidance of the Water Directors;<sup>189</sup> the library included, in particular, a several hundred page document<sup>190</sup> developed by one of its working groups and offering extensive guidance how Member States should fulfill their obligations to provide public participation under the Directive's Article 14.<sup>191</sup> As is common, however, and although both Article 14 and this guidance

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<sup>187</sup> See Implementing the EU Water Framework Directive, <http://europa.eu.int/comm/environment/water/water-framework/implementation.html>. For a discussion of the strategy, see Scott & Holder, *supra* note 45, at 12 (remarking on the flexibility and reflexivity of the results).

<sup>188</sup> Communication and Information Resource Centre Administrator (CIRCA), <http://forum.europa.eu.int/Public/irc/env/Home/main>.

<sup>189</sup> See CIRCA—ENV:WFD CIRCA: "Implementing the Water Framework Directive," [http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework\\_directive/guidance\\_documents/](http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework_directive/guidance_documents/). It may be advisable first to register as a user of CIRCA, a registration process that is not controlled.

<sup>190</sup> Visited Apr. 10, 2005, [http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework\\_directive/guidance\\_documents/participation\\_guidance&vm=detailed&sb=Title](http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework_directive/guidance_documents/participation_guidance&vm=detailed&sb=Title).

<sup>191</sup> European Parliament and Council Directive 2000/60/EC, art. 14, 2000 O.J. (L 327) 1, 16. Reflecting preambular commitments and supported by disclosure requirements, Article 14 provides:

Public information and consultation

1. Member States shall encourage the active involvement of all interested parties in the implementation of this Directive, in particular in the production, review and updating of the river basin management plans. Member States shall ensure that, for each river basin district, they publish and make available for comments to the public, including users:

(a) a timetable and work programme for the production of the plan, including a statement of the consultation measures to be taken, at least three years before the beginning of the period to which the plan refers;

(b) an interim overview of the significant water management issues identified in the river basin, at least two years before the beginning of the period to which the plan

strongly emphasize the need for consultation in advance of action, the library contains only completed documents—not opportunities for public consultations.<sup>192</sup> Portions of the WFD's CIRCA site *do* contain preparatory documents: working papers on the basis of which guidance was developed, etc. It is evidently supposed that the site will be used by the members of its working groups to coordinate with one another across the continent. To gain access to these aspects of the site, one must be admitted to membership in the WFD site in particular, either as an observer or participant. And, as is *not* true for access to the first level of the CIRCA site, this requires an application, and permission may be denied.

Interested to learn what he could about the development of the public participation guidance, the author of this study applied for observer membership in the WFD site (and also for one other, for working groups for the Noise Directive also located on the CIRCA site). He informed both groups that he was “a university professor in the United States researching issues about public participation in American and EU law, and would greatly appreciate access to the CIRCA materials on . . . .”<sup>193</sup> Although promptly admitted to the Noise Directive working group, he was rejected for the WFD group with the following explanation:

Unfortunately, we have to refuse your application to the restricted part of WFD CIRCA on the basis of the criteria agreed in the meeting of the Strategic Co-ordination Group of 27 November 2001. For your information please find below these criteria.

The restricted part of WFD CIRCA is exclusively reserved for members of our Working Groups and other experts who are indirectly involved in our extensive work programme. On the basis of the information that you provided, we were not convinced that a private or economic interest could be excluded. For your information, the following activities fall under this criterium: consultancy work for other institutions other than the Commission university studies and projects individual industry representatives.

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refers;

(c) draft copies of the river basin management plan, at least one year before the beginning of the period to which the plan refers.

On request, access shall be given to background documents and information used for the development of the draft river basin management plan.

2. Member States shall allow at least six months to comment in writing on those documents in order to allow active involvement and consultation.

3. Paragraphs 1 and 2 shall apply equally to updated river basin management plans.

*Id.*

<sup>192</sup> See European Commission, *Common Implementation Strategy for the Water Framework Directive (2000/60/EC): Public Participation in Relation to the Water Framework Directive*, Annex III (Guidance Document No. 8 2003), available at [http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework\\_directive/guidance\\_documents/](http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework_directive/guidance_documents/). Annex III reported the working process of the group responsible for developing it. It begins, “Practice what you preach, is what we believe.” *Id.* at 199. Yet the account given is entirely of self-chosen consultations with “experts and target groups”; there is no indication of *any* open public consultation in the process.

<sup>193</sup> E-mail from the author to the Communication and Information Resource Centre Administrator (Apr. 9, 2005) (on file with author).



In conclusion, we had to refuse your application for full access to the WFD CIRCA system.<sup>194</sup>

No recourse was stated or evident.

The WFD undertaking is extraordinarily complex and demanding, and both economic and national stakes are high. The wish to exclude “a private or economic interest” is not hard to appreciate, and one may believe too that within the engaged framework of NGO participants and observers there exists rich opportunity for knowledgeable critique.<sup>195</sup> As remarked at the outset of these paragraphs, there is inevitably a tension between assuring transparency and broad participation, on the one hand, and concern about self-interested activity, on the other. That the tension should be resolved against a *general* transparency and participation, even in enterprises devoted to assuring those outcomes, is nonetheless striking.

## V. CONCLUSION

The American Congress lacks the contextual incentives to treat its own work of legislative drafting with anything approaching the rigor and public exposure the Commission observes in preparing its legislative proposals. But one imagines it might find in those practices, or American administrative agencies might find for themselves, genuine opportunities for improvement of American rulemaking processes as we enter the information age. One of their striking characteristics, in comparison with our own, is what might be described as their youth—and therefore plasticity. In the United States, rulemaking procedures are an adult enterprise, and their encounters with contemporary developments, notably those of the information age, have produced change only at the margins; in Europe, where conceptions are much less concretely pre-formed, those interactions seem much more dramatically to have shaped their growth.

Particularly impressive in this regard is the manner in which the Commission structures its “stakeholder consultations.” The importance of policy is more likely to drive their use than the formal level at which the text is generated and/or its binding character; consultations are more likely to be undertaken at the earliest stages of procedure, pre-proposal, than subsequently, and so it is perhaps less likely that final policy positions have already been formed. And the structuring of the consultations—from the questionnaires used with the “interactive policymaking” tool the Commission has developed, to the links to relevant documentation these questionnaires often contain—serves a range of interests important to public dialogue. It emphasizes the seriousness of the inquiry; focuses it on the matters of particular interest to the drafter; it permits some statistical analyses of correspondences between social position and point of view; and, not irrelevantly, it

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<sup>194</sup> E-mail to the author (Apr. 11, 2005); *see also* Access to the WFD CIRCA Interest Group, <http://forum.europa.eu.int/irc/env/wfd/info/data/get%20registered%20on%20wfd%20circa.htm>.

<sup>195</sup> *See, e.g.*, World Wide Fund for Nature & European Environmental Bureau, “Tips and Tricks” for Water Framework Directive Implementation 29 (Mar. 2004), *available at* [http://www.eeb.org/activities/water/200403\\_EEB\\_WWF\\_Tips&Tricks.pdf](http://www.eeb.org/activities/water/200403_EEB_WWF_Tips&Tricks.pdf); World Wide Fund for Nature & European Environmental Bureau, EU Water Policy: Making the Water Framework Directive Work 17–23 (Feb. 2005), *available at* <http://www.eeb.org/activities/water/making-WFD-work-February05.pdf> (both much more pleased with the guidance discussed in text than with its general national implementation by Member States).

tends to suppress the merely political response by discouraging mass electronic postcard campaigns. American rulemaking tends to serve up a final and rather fully developed proposal; and the notice-and-comment process is quite unstructured. "Well, whadaya think?" invites the whirlwind, in a way the developing EU techniques of consultation may have a greater potential to avoid.

The highly interactive character of norm-generation in the EU, perhaps especially in its techniques for developing soft law, is not only an understandable reaction to the political sensitivities of its position in relation to its Member States. It may also reflect an important adaptation to the general circumstances of contemporary government, as hierarchy comes to be replaced by more fluid and interactive consultative networking. Here, one recurs to the quite fluid interactions among European institutions and the authorities of Member States; recall that this discussion has—of necessity—been restricted to what occurs at the level of Europe, but that much implementation, even of European law, is left to the institutions *and* procedures of Member States, under forms of central supervision as often persuasive as disciplinarian. One must bear in mind, as well, that in the legislative context, if not the executive, fluid interactivity may be somewhat easier for parliamentary systems than our own; the greater integration between parliament and government, the apparent unity of political responsibility for legislation *and* regulation, has tended to leave questions of control over regulatory development (like control over legislative development) to the political scientists rather than lawyers and courts. The Minister must answer, quite directly, to parliament; and parliament must answer for the Minister. "This ongoing connection," Peter Lindseth wrote, "helps to reconcile the reality of delegation (and the agency autonomy that inevitably comes with it) with the legal-cultural ideals of representative democracy grounded in the constitutional legislature that most liberal states have inherited from the eighteenth and nineteenth centuries."<sup>196</sup> Even in the national context, as Lindseth persuasively continued, "[t]he diffusion and fragmentation of normative power away from constitutional legislatures over the course of the twentieth century reached a point that, to some observers at least, it has become questionable to claim empirically (if not normatively) that the legislature serves as the constitutional principal in the modern system of regulatory norm-production."<sup>197</sup> "The complexity of modern administrative governance has overwhelmed the old notion of a hierarchically-controlled 'chancellor democracy' as established by Adenauer in the 1950s. Now commentators speak merely of a 'coordination democracy,' in which the chancellor serves only as a policy manager at the center of a highly pluralist institutional network."<sup>198</sup> In the United States too, despite presidential preferences for a tight command structure, our future may lie in this direction.

If there are American lessons for Europe, they may lie in the realm between legislative development and soft law. The political imperative for "comitology" is clear enough in the sensibilities of the EU's Member States. While the European

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<sup>196</sup> Peter Lindseth, *Agents Without Principals?: Delegation in an Age of Diffuse and Fragmented Governance* 3 (University of Connecticut School of Law Working Paper Series, Working Paper No. 18, Feb. 2004), available at <http://lsr.nellco.org/uconn/ucwps/papers/18>.

<sup>197</sup> *Id.*

<sup>198</sup> *Id.* at 12 (citing STEPHAN PADGETT, ADENAUER TO KOHL: THE DEVELOPMENT OF THE GERMAN CHANCELLORSHIP, Introduction, 18–19, n.19 (Stephan Padgett ed., 1994)).

Parliament's resistance to it is already clear, the future shape of "implementing measure" procedure is not. The Commission so consistently follows and encourages broadly consultative regimes in its other activities, and in those allied organizations that may be authorized to develop soft law guidance in its stead, that one wonders if the current obscurity and privacy of its practice in respect to implementing measures can or should long continue. Here, one might think, the notice and comment processes that the Commission in fact promotes among European agencies and standards organizations could find a proper place.