

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

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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, world-wide. 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 the day I landed in Italy preparing to write this essay, the International Herald Tribune carried two stories that in their way framed the project. The front page story was headlined "On the EU Battlefield: Armies of lobbyists assail Brussels,"¹ and opened with an account of lobbyists' reaction to a European Commission decision that a vegetable sauce with more than 20 percent lumps was itself a vegetable and so subject to tariffs as much as twenty times higher than sauce as a 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 Trib 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 like Friends of the Earth as well as Unilever is there and fighting.

The second story was an op-ed piece, "EU's growth triggers identity crisis,"² 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. Just what is Europe, and why should anyone want it?

* Betts Professor of Law, Columbia Law School. This essay would not have been possible without the generous support of the Rockefeller Foundation at its Study and Conference Center in Bellagio, Italy. It has benefitted greatly from conversations there, at the European University Institute, and at the Law Faculty of the University of Bologna, as well as with American colleagues such as George Bermann, Francesca Bignami, Joanne Scott, and the American lawyers assisting the American Bar Association's study of European Union administrative procedures that provided its initial push. Its mistakes and misconceptions are, of course, my own.

¹ Graham Bowley, April 5 2005, p. 1, 4.

² William Pfaff, p. 7.

The questions are 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 Aconstitution, which few have read. By now,@ the Trib wrote, Aapproval 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.@ In France shortly, it appears, the ratification will be voted upon as if it were a referendum on the popularity of the government of Jacques Chirac B not a happy prospect on several counts.

The draft EU constitution would rationalize and have considerable implications for the manner in which issues that attract lobbyists to Brussels might be resolved. It embodies commitments on access, transparency, influence and accountability likely to be influential even if the draft is not approved. And if it is not ratified, so that the EU continues to function under its present treaty regimes, the fact of the EU still has remarkable implications for Europe=s national governments. As one author recently wrote, Aup 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.@³ 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 paper is associated with a larger project intended to help Americans understand how the European Commission (the EU executive) works, in comparison to what they themselves are accustomed to, and in a context in which access, transparency, influence and accountability are increasingly important. It is the product of an effort to understand the manner in which the Commission shapes legal texts B statutes, regulations, even influential advice B in comparison to American approaches.

European Union law can be framed within a nesting hierarchy that would be familiar to Americans B or, for that matter, to the citizens of any modern, developed legal order. At the highest levels of the legal order, one finds a single constitutional document that is the product of extraordinary procedures rarely invoked (or, as in the EU at present, a few treaties each adopted after extraordinary international negotiation; if the current draft Constitution is ratified, it will replace them all). At the next level, one finds laws, statutes, enacted by a Congress or parliament, no more than a few hundred yearly. Beneath that, subsidiary legislation or regulations adopted by executive authority B departments, agencies, ministries B under legislative authorization; typically, at this level of detail, thousands annually. Then one may find documents offering guidance or other forms of Asoft law,@ not in itself binding on citizens although still influential, in still greater profusion. And this distribution of normative instruments holds true for Europe. In 1996, for example, the European Parliament and Council adopted 484 Alegislative@ acts; in the same year,

³ Christoph Demmke, Comitology in the Environmental Sector, in Mads Andenas and Alexander Turk, eds., *Delegated Legislation and the Role of Committees in the EC* 279 (Kluwer Law 2000). A footnote adds details: 35% in Denmark, 50% in Netherlands and Germany, 80% in the UK and up to 95% in Portugal, Greece, Italy and Spain.

following very different processes and under rather light supervision, the European Commission adopted 5147 Aregulations,@ with a great deal of uncounted Asoft law@ below that.⁴

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 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.⁵

§ 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 it does is framed or credible as the exercise of expert judgment; we commonly think of Alegislative 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 (Athe 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 B 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 B although politics may still have a role to play. 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

⁴ Georg Haibach, ASeparation and Delegation of Legislative Powers: A Comparative Analysis,@ in Andenas and Turk, n. 3 above, 53. To similar effect, for different years and making comparisons to similar European national experience, see Gunther Schafer, Linking Member State and European Administrations B the Role of Committees and Comitology, id. at 3, 6, 9; Josef Falke, Comitology, From Small Councils to Complex Networks, id. at 331, 336.

⁵ For example, that African-American school children are psychologically, developmentally disadvantaged by segregated education. *Brown*

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, Ahard looks,@ that place a high value on factual accuracy and afford much less room for politics than legislators enjoy.⁶

§ And at the fourth level, Asoft law,@ we really 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 that 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 theses differing normative texts B constitutions, statutes, regulations, guidance documents B with a set of institutional expectations that shape his understandings.

§ Each of these levels B constitution, statute, regulation, soft law B 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) make rules; the staff of a subordinate bureau create guidance documents. Different individuals and different procedures are responsible for the wording of statutes, of regulations, and of advice.

§ ASeparation 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 cannot force consideration of any measure and scarcely participates in the work of its drafting and detailed consideration. Regulations and soft law are the product of the executive, in which neither the Congress as a whole nor any of its individual members can participate (save for the possibility of enacting statutes in disapproval).

§ There is the expectation, too, that the 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.

⁶ Sierra Club v. Costle; Baltimore Gas & Electric.

§ Within the executive itself, the exact nature of presidential authority over agency choices is unsettled. Do the agencies possess their own authority, whose exercise he 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 B the only such figure in the executive. 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 B ministers 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, as it is today and as it is imagined by its draft constitution, 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.⁷ Its institutional arrangements, and its civil servants, are acutely sensitive to the proposition that its member states are nations, and it 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

⁷ The Draft European Constitution, if ratified, will replace the prior treaties, but it is not a Aconstitution@ in the usual national sense. Although titled a constitution, its text consistently presents itself as a treaty B as, for example, throughout the AGeneral and Final Provisions@ of Part IV. Both the provisions for Aratification,@ Art. IV-447, and the provision for ordinary amendment or revision, Art. IV-443 require the unanimity one would expect in the treaty context, and describe ratification as occurring in each Member State Ain accordance with their respective constitutional requirements,@ Arts. IV-443.3, 447.1. These local requirements doubtless refer to treaty ratification not constitutional approval. Save that each of the signatories is a parliamentary democracy, they need signify no referendum or other procedure for popular involvement. This is a AWe the States,@ not a AWe the People@ document.

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 supra-national and national effort Americans would find difficult to appreciate.

§ One can construct its other normative documents in a hierarchy outwardly similar to American expectations: A legislative acts@ that are the product of what might seem a bicameral legislature acting in coordination with an executive authority; Arules@ 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 Arules@ or implementing measures having the force of law; and soft-law guidance, as well, generally requires its approval.

§ 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. If anything, the President=s position is weak even in parliamentary terms; the post rotates on a fixed schedule, thanks to the Union=s structure.

§ The practice of comitology makes the Commission=s ostensibly independent rulemaking contingent on national as well as international bureaucratic consensus.

§ 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 them to be expert as well as consensual B their authority grounded in technocratic rather than political judgment. Popular will is in some sense feared, and judicial checking of sums is thought unnecessary, an invitation to unwonted legalism.

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

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, with particular attention to the use and impact of internet resources. 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, 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.

I. Framing legislation

We start, then, with the framing of legislation B Astatutes,@ in the American context; Aregulations@ and Adirectives@ under the current EU treaties; AEuropean laws@ and AEuropean framework laws@ should the draft EU constitution be ratified. Like statutes, Aregulations@ and directives have the force of law; but in a treaty-grounded institution, they speak primarily to the membership of nation-states. ARegulations,@ a form less interesting to our study, may have direct legal effect permitting enforcement by individuals.⁸ Directives, by contrast, are legislative acts that Ashall 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.@⁹ This formulation self-evidently creates opportunities for delegation to member states; 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;¹⁰ 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 Aleave 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

⁸ A Regulation@ is a Community legislative act described in the EC Treaty as being Abinding in its entirety and directly applicable in all Member States.@ Art. 249 (ex 189). A[I]f they are immediately part of the domestic law of Member States [without requiring implementing legislation] there is no reason why B so long as their provisions are sufficiently clear, precise and relevant to the situation of an individual litigant B they should not be capable of being relied upon and enforced by individuals before their national courts.@ Paul Craig & Grainne De Burca, *EU Law B Text, Cases and Materials* 190 (3d ed. 2003).

⁹ Art. 249 (ex 189).

¹⁰ MARPOL 73/78.

directly enforce.¹¹ 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.¹²

The discussion here will be limited to the framing of proposals for legislation, treating debate and enactment as matters outside the purview of this essay. This 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 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,¹³ 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.¹⁴

The 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 such as 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 rulemaking, now fully engageable on the internet, or for the public analytic regimes agencies are required to follow in developing their rulemaking proposals. Congress has, indeed, instructed itself to engage in environmental, economic, and other forms of analysis in connection with legislative

¹¹ Arts. 226, 228.

¹² Craig & De Burca, *op cit* n. 8 above, at 227; see generally *id.*, *The Legal Effects of Directives*, at p. 202 ff. 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.

¹³ <http://thomas.loc.gov>.

¹⁴ 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.

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.

Matters in the European Union are quite different, and it is the existence of a regularized procedural framework for the development of legislative proposals that makes treatment of the matter sensible in a study such as this one. Under both the treaties and the draft European Constitution, essentially all legislative business B 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 B must originate with the Commission. Of course the political realities,¹⁵ reflected in some provisions in the draft constitution,¹⁶ give the Council and Parliament considerable influence over what will emerge as the Commission=s proposal.¹⁷ Nonetheless, it must be the Commission that proposes. And the path to a proposal is structured 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. Preliminary stages may involve the preparation of Commission white papers or green papers exploring policy alternatives B a stage that frequently involves its own consultative processes, as discussed below both in general,¹⁸ and in connection with the proposed regulation of the chemical industry.¹⁹ 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 B certainly relative to the time it usually takes to bring a proposal to finality B this assures an early appearance of the project in public view.

¹⁵ Thus, what appears to be a fairly limited and general right of input under the present Treaties has in fact been used Ato frame very specific proposals which it [the Council] wishes the Commission to shape into concrete legislation.@ Craig and de Burca, n. 8 above, at 69.

¹⁶ The draft Constitution makes clear the expectation that legislative initiatives will in fact arise outside the Commission. See e.g., Arts III-332 (majority Parliamentary request for proposal, requires reasons for declination), III-345 (majority Council request for proposal, requires reasons for declination), and I-47.4 (a million citizens from a significant number of states may frame a request). Once the Commission has proposed a legislative action, the Council (but not the Parliament) will be constrained in the action it can take; save for budgetary matters and the conciliation procedure that is invoked when it and Parliament cannot agree, Art. III-396, the Council may amend a Commission proposal Aonly by acting unanimously.@ Art. III-395.1.

¹⁷ Respecting the draft Constitution, see the thoughtful analysis of the possible frameworks in Paul Craig, *European Governance: Executive and Administrative Powers Under the New Constitutional Settlement* (2005).

¹⁸ See p. 36 ff. below.

¹⁹ See text at n. 34 below.

The Commission's work plan is published in numerous formats at its worksite, from a five-year strategic plan to a three month rolling programme.²⁰ Perhaps the most useful of these, because it contains contact information within the responsible DG, are the Roadmaps.²¹ Like entries in the American regulatory agenda, these give a brief account of the matters under development following a uniform framework for preliminary impact analysis.²² They identify contact persons, sometimes

²⁰ http://europa.eu.int/comm/off/work_programme/index_en.htm,

²¹ Apparently detailed in SEC(2004)1175, that I've not been able successfully to ask for here.

²² E.g., the roadmap for 2005/ENTR/019, a Proposal for a Regulation on the authorisation, supervision and vigilance of human tissue engineered products, http://europa.eu.int/comm/off/work_programme/20050128_clwp_roadmaps.pdf p. 10:

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

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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.

including their telephone extensions, thus permitting 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.

b) Impact assessment

Impact assessment is a required element of the Commission's development of legislative proposals. For the Commission, as not for the American Congress, this is a seriously considered obligation, albeit one created by Commission Communication²³ (that is, as soft law, internal to the Commission) and not legislation.²⁴ The Commission maintains a dedicated Impact assessment website with links to all documents,²⁵ including most impact assessments that have been completed.²⁶ Effective as of 2005, all items on the Commission's legislative and work program

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?

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

²³ COM(2002) 276 final, A Communication from the Commission on Impact Assessment. Precursor regimes required analysis of budgetary impacts, and impacts on small and medium sized enterprises.

²⁴ American practice in this regard varies. Executive Order EO 12866, for example, is explicit that it creates no judicially enforceable obligation, although bureaucratic enforcement is stringent; but the obligation to perform environmental impact analyses, the prototype American impact analysis regime, is judicially enforceable under the National Environmental Policy Act. NEPA obligations were widely and some thought disruptively enforced by persons seeking to prevent undesired projects (rather than secure useful analysis); this experience informed the Executive Order's insistence, and subsequent congressional provision in acts like the Unfunded Mandate Reform Act, that judicial review would be unavailable.

²⁵ http://europa.eu.int/comm/secretariat_general/impact/index_en.htm.

²⁶ http://europa.eu.int/comm/secretariat_general/impact/practice.htm. A very few of the statements here are restricted from public access.

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 Aroad maps@ and including contact information, effectively assures interested parties an opportunity to make their views heard.

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. It operates more for the control/edification of the external institutions to whom the 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.

Perhaps in consequence of this different use, what the Commission *means* by Aimpact assessment@ differs somewhat from how Americans would understand the process. It is, in both contexts, a technique for identifying policy options and alternatives by considering the likely forward consequences of a proposed action, but for the Commission these impacts are to be Aexpressed in economic, social *and* environmental terms,@ (emphasis added) with no particular emphasis on quantification or cost-benefit balancing. A[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.@²⁷ American authors have criticized this aspect sharply, urging the EU to A[A] specify[] that the primary objective of regulation is to maximize net benefits.@²⁸ 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.

A guidance document, AImpact Assessment in the Commission,@ published in the fall of 2002,²⁹ elaborates the expected processes for developing both preliminary and extended Impact

²⁷ COM(2002) 276 final at 15-16.

²⁸ Robert Hahn and Robert Litan, Counting Regulatory Benefits and Costs: Lessons for the US and Europe [forthcoming, Joanne Scott].

²⁹ http://europa.eu.int/comm/secretariat_general/impact/docs/ia_technical_guidelines_en.doc.

assessments, with models for each. It makes clear that these analyses are seen as aids to a political process, and are thus often appropriately qualitative in character. It strongly emphasizes the obligation of consultation with interested parties and relevant experts. A consultation with interested parties is an important part of the impact assessment process, and is carried out according to a set of minimum standards.³⁰ These minimum standards are themselves specified in Commission communications³¹ 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.³²

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,³³ 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; neither it nor OIRA makes the documents public or directly invites public participation.

The EU's guidance document requires 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.³⁴ The character of the extended impact assessment document can perhaps be appreciated by looking at the report developed for the Commission initiative known as REACH (*Registration, Evaluation, Authorisation and Restrictions of Chemicals*),³⁵ 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,³⁶ runs about 1200 pages (mostly, to

³⁰ See http://europa.eu.int/comm/secretariat_general/impact/expert_en.htm.

³¹ COM(2002) 704 final; see also COM(2002) 713 final.

³² Guidance document at 9.

³³ See 40 CFR ' ' 1501.7 (requirement) and 1508.22 (substance to be included).

³⁴ At 26.

³⁵ SEC(2003) 1171/3, concerning COM(2003) 644 final.

³⁶ http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en.html

be sure, technical annexes the Commission characterized as not new³⁷); 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 33 pages.³⁸ 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,³⁹ and the Final Regulatory Impact Analysis published on the agency website, 249.⁴⁰

c) Stakeholder consultation (and report)

The Commission has committed itself to extensive consultations with all concerned elements of society as part of its process for developing legislative proposals. It has done so in a series of Communications⁴¹ and websites committed in various ways to the process.⁴² The commitment is one of soft law, not enforceable, and the Commission's explanation of this choice both illustrates the importance of soft law in its practice, and its 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

³⁷ <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/646&format=HTML&aged=1&language=EN&guiLanguage=en>.

³⁸ An account of initial experience with Impact assessments appears in SEC(2004) 1153, Report on European Governance (2003-2004), and in COM(2003) 770 final, Report from the Commission on Better Lawmaking, Annex 3. 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 UK, 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?

³⁹ 70 Fed.Reg. 18184-91 (April 8, 2005); the statement of basis and purpose accompanying the rule ran 49 pages, id. at 18136-84.

⁴⁰ See http://dmses.dot.gov/docimages/pdf91/325337_web.pdf.

⁴¹ A consultation document, AToward a reinforced culture of consultation and dialogue ...,@ COM(2002) 277 final, led after inputs collected at http://europa.eu.int/comm/secretariat_general/sgc/consultation/histo_en.htm to two final documents, AToward a reinforced culture of consultation and dialogue ...,@ COM(2002) 704 final and AOn the collection and use of expertise by the Commission: Principles and Guidelines,@ COM(2002) 713 final, both published Nov. 12, 2002.

⁴² E.g., http://europa.eu.int/yourvoice/consultations/index_en.htm, the Yourvoice website where consultations are conducted and reported upon; http://europa.eu.int/comm/civil_society/coneccs/index_en.htm, providing a database of consultative bodies and civil society organizations

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.*⁴³

Recall that these are principles developed and, as the Yourvoice site⁴⁴ suggests, consistently honored in connection with the development of legislative drafts, not rulemaking.

Given the EU's dependence on continued acceptance of its initiatives by its Member States, one easily understands that the public processes of stakeholder consultation are hardly the only means by which the Commission's bureaucrats inform themselves about pending issues.⁴⁵ Nor

⁴³ COM(2002) 704 final, p. 10 (emphasis added).

⁴⁴ N. 42 above.

⁴⁵ Two specific advisory bodies B 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) B as well as Member States are regularly consulted.

Special committees may also be used for this purpose, of course. See, e.g., COM (2004) 613 (O.J. 28.8.2004, L 275/17, establishing an advisory group on the food chain and animal and plant health, particularly for these (among other) purposes. 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. 550 ff. 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 the Official journal for April 21, 2005, C 97/02, http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_097/c_09720050421en00020002.pdf, with three seats allocated to the European Consumers Organization in order to facilitate the representation of European consumers. 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

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.⁴⁶ 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 B 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 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,⁴⁷ one can find rulemakings with hundreds of thousands of participants, many of whom submit electronic forms with unverifiable identities.⁴⁸ 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.⁴⁹ The

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. http://europa.eu.int/comm/civil_society/coneccs/index_en.htm. Looking the other way is the Commission=s assertion on its general Acivil society@ site, http://europa.eu.int/comm/civil_society/apgen_en.htm that Athere 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.@

⁴⁶ See text at nn. 64 and 75 below.

⁴⁷ See text at p. 6 above.

⁴⁸ The difficulties, and a resourceful empirical study, are thoughtfully developed in David Schlosberg, Stephen Zavetoski, and 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, available for downloading at http://erulemaking.ucsur.pitt.edu/doc/papers/SDEST_Western_05.pdf. And see the website of the erulemaking research group at the University of Pittsburgh, <http://erulemaking.ucsur.pitt.edu/>.

⁴⁹ This is particularly the case for consultations undertaken through its approach to Ainteractive policymaking,@ http://europa.eu.int/yourvoice/ipm/index_en.htm, as for example a consultation closing in May 2005 on the sustainable use of pesticides in Europe, <http://europa.eu.int/yourvoice/forms/dispatch?form=399>. 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.

result is to require a not insubstantial investment of time in participation and, one imagines, to retard if not entirely defeat computerized response campaigns. 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.⁵⁰ The Commission's policies, set out in its consultation documents,⁵¹ require reporting of results and feedback; reports of closed consultations are made in a statistical way on the Yourvoice site.⁵²

The ongoing REACH process, already encountered,⁵³ 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 than 150 stakeholders in February 1999 - regulators, scientists, industry, environmental and consumer NGOs as well as representatives from applicant countries.⁵⁴ There followed stakeholder conferences on the white paper in April 2001⁵⁵ and May 2002⁵⁶, and a November 2003 workshop⁵⁷ 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;⁵⁸ it attracted an unusual level of response again, one thoroughly documented on its website: 968 participants in

⁵⁰ Schlosberg et al, n. 45 above, 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.

⁵¹ See n. 41 above.

⁵² See, e.g., http://europa.eu.int/yourvoice/results/services/index_en.htm, AResponse statistics for 'The transparency of regulations and standards in the area of services', 19 July 2004; http://europa.eu.int/yourvoice/results/4/index_en.htm, AResponse statistics for review of the New Approach, 31 March 2002.

⁵³ See text at p. 13 above.

⁵⁴ COM(2001) 88 final.

⁵⁵ http://europa.eu.int/comm/enterprise/reach/whitepaper/conferences/conf-2001_04_02.htm

⁵⁶ http://europa.eu.int/comm/enterprise/reach/whitepaper/conferences/conf-2002_05_21.htm

⁵⁷ http://europa.eu.int/comm/enterprise/reach/docs/conferences/eia_workshop-2003_11_21.pdf and <http://europa.eu.int/comm/enterprise/reach/eia.htm>.

⁵⁸ <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/646&format=HTML&aged=1&language=EN&guiLanguage=en>.

an Interactive Policymaking tool that was, in part, a structured questionnaire,⁵⁹ and a total of 6400 comments of varying length and detail.⁶⁰ 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 plant⁶¹) are identified as having submitted identical comments, the comments (doubtless supplied by their employer and/or union) are detailed.⁶²

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.⁶³ Here, very clearly, is an effort at political, not intellectual or technical, influence. Yet the very structure of the declaration=s site,⁶⁴ linked to the REACH 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 email calling for support B 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 emails will be going to members of Parliament, not the Commission B 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.

⁵⁹ See the analysis at 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 (UK). The comments attached to these filings are organized at http://europa.eu.int/comm/environment/chemicals/pdf/ipm_stakeholder_reactions.pdf

⁶⁰ <http://europa.eu.int/comm/environment/chemicals/consultation.htm>; <http://europa.eu.int/comm/enterprise/reach/consultation/contributions.htm>

⁶¹ E.g., 156 identical comments from the workers of Clariant, France, http://europa.eu.int/comm/enterprise/reach/docs/consultation/others/886_other.doc.

⁶² Filling 65 computer screens in this case.

⁶³ <http://europa.eu.int/comm/environment/chemicals/consultation.htm>

⁶⁴ <http://www.chemicalreaction.org/>

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

Consultations 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.⁶⁵

A recent Commission Secretariat document, briefly discussing experience with public consultation and reporting Aa growing public consultation culture,@ seems to suggest more generally that consultations with established partners are preferred.⁶⁶ Yet in its inception, as Francesca Bignami has pointed out, the move to Acivil society participation,@ a striking departure from national expectations about lawmaking in Europe, was intended to secure a broad political base, not to reflect established corporativist 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 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

⁶⁵ http://europa.eu.int/comm/employment_social/consultation_en.html, linking to http://europa.eu.int/comm/employment_social/social_dialogue/index_en.htm.

⁶⁶ SEC(2004) 1153, Report on European Governance (2003-2004), Sec. 2.2, see also Annex 2 to the Better Lawmaking Report, COM 2003 770 final.

decisions; and national and regional actors are involved in the EU policy process.⁶⁷

d) Lobbying and its regulation

The Commission has adopted a relatively detailed code of conduct for itself⁶⁸ B albeit one that has not prevented the whiff of public scandal⁶⁹ B 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,⁷⁰ 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.⁷¹ 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 US 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 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.⁷²

No such measures appear to have been adopted. The encouragement to self-regulation

⁶⁷ Bignami, n. 81 below, at 77.

⁶⁸ See http://europa.eu.int/comm/reform/2002/code_conduct_en.htm.

⁶⁹ The code provides, inter alia, that a Commissioner should not accept a gift valued at more than i 150. 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 Aa holiday with friends@ the Commission=s position was that there was no Alack of respect of the code of conduct.@ ACommission chief=s trip raises EU ethics questions,@ International Herald Tribune, Tues. Apr. 19, 2005, p. 1 and 3.

⁷⁰ http://europa.eu.int/comm/secretariat_general/code/index_en.htm

⁷¹ http://europa.eu.int/comm/reform/2002/chapter06_en.htm#1

⁷² Journal C 348/70 (1999).

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.⁷³

Those requirements are stated in quite general terms B 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,⁷⁴ but giving no concrete detail about the propriety of hosting luncheons, sending holiday gifts, or providing golfing trips to Scotland for dear friends.⁷⁴

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.⁷⁵ Its website carries an extensive list of accredited lobbyists resulting,⁷⁶ making evident that lobbying the Parliament is a major activity.⁷⁷ In late April, 2005, it appeared that political pressures were growing to create more formal structures, including an independent watchdog organization, in the

⁷³ http://europa.eu.int/comm/secretariat_general/sgc/lobbies/communication/annexe2_en.htm#public

⁷⁴ The reference is to a distinctly American scandal; see Philip Shenon, *An Inquiry on Lobbyist Casts a Shadow in Congress*, *The New York Times*, April 11, 2005. Rules of the American Congress regulate with elusive precision the meals and other benefactions members are permitted to receive. *But see* n. 69 above.

⁷⁵ Rules of Procedure of the European Parliament 9(2) and Annex IX.

⁷⁶ <http://www2.europarl.eu.int/lobby/lobby.jsp?lng=en>.

⁷⁷ Jerome Glass, *Why throw a spammer in the lobbying machine* *EuropeanVoice.com* Vol. 11, No. 15 (21 April 2005), <http://www.europeanvoice.com/current/article.asp?id=22716>, 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, 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.

wake of embarrassing disclosures of vacations taken with friends who were also persons highly interested in the EU=s affairs.⁷⁸ That appearances of conflict of interest might arise from genuine friendships in political circles is hardly unknown.⁷⁹

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 internal⁸⁰) not open to public view. One characteristic, however, seems appropriate to underscore for persons seeking comparisons, however implicit, with American institutions B 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,⁸¹ the structure of the EU is such as to make its actors B and perhaps especially the Commission B sensitive to the expectations of its most demanding members. The impulse, that is, may be to a highest rather than the lowest common denominator. The incentives for Europe=s bureaucrats are quite different to those American agency staffs might experience B not only that consensus should be achieved on the particular matter they are proposing, but also that Member States and their populations must 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

⁷⁸ Id.; Bennhold, n. 69 above.

⁷⁹ Scalia=s opinion refusing to recuse himself in re VP Cheney.

⁸⁰ Transparency legislation in the EU as in the United States, 5 U.S.C. 552(b)(5), exempts from public disclosure pre-decisional internal discussions, as conducive to candor and efficiency in bureaucratic practice.

⁸¹ Francesca Bignami, ACreating Rights in the Age of Global Governance: Mental Maps and Strategic Interests in Europe, Duke Law School Research Paper No. 63, October 2004, available for download at http://e-prints.law.duke.edu/archive/00000705/01/bignami_Creating_rights_10.04.pdf

striking common characteristic: they afford citizens a greater set of entitlements against European government than in their place of origin. What is the common thread that explains this surprising outcome? It is the weak nature of the Commission as a 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 does not have independent enforcement powers. Politically too the Commission is weak. It is not led by a popularly elected official, as are executive branches at the national level--a directly elected president in presidential systems of government, or a prime minister and cabinet appointed after parliamentary elections in parliamentary systems of government. It is led 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. In responding to challenges from national judges, lawyers, and statesmen, as in the case of a right to a hearing, the Commission cannot use legal enforcement powers. In responding to challenges from national voters and elected officials, as in the case of the right to transparency and civil society participation, the Commission cannot use the political mandate of a popular vote. The Commission cannot say, as generally national executive authorities do when faced with demands for rights, that it governs in the name of the people and therefore, the will of the majority and the greater good must, under the circumstances, prevail over the rights of the individual.⁸²

⁸² And in a further essay, Francesca Bignami, *The Challenge of Cooperative Regulatory Relations After Enlargement*, Duke Law School Research Paper Series No. 55, September 2004, available for download at <http://ssrn.com/abstract=527552>, at 33-34, she writes

... I conceive of integration as an incremental process in which previous successes can generate momentum for more collective European governance, albeit among national regulators rather than supranational officials and interest groups. ... I find that common European interests and values are generated through the daily operation of national and supranational public bodies, and not only through treaty making and direct bargaining among government ministers and heads of state. ... I conceive of integration as proceeding through coordination and cooperation among 15 different administrative and political systems rather than the construction of a single, federalist system. In my view, anarchy rather than hierarchy is the better metaphor. The continuing importance of national politics cannot be underestimated. ... [B]y national politics I do not mean prime minister and government cabinet. Rather, I mean civil servants facing pressure from their governments, electorates, elites, and courts, civil servants who negotiate with other civil servants under similar pressures. In this view of integration, there are certainly interest groups and citizens who benefit from the collective European policies and vindicate such policies through politicians, administrators, and courts. But those European claims are still made primarily through national institutions. The national political process, not the Brussels complex, is therefore able to exert considerable control over the success or failure of such claims.

The corollary of the continuing importance of national politics in my understanding of European governance is the more limited organizational capacity of the two principal supranational institutions, the Commission and the European Court of Justice. To put it bluntly, the Commission, the European Court of Justice, and national courts are not as powerful as some of the literature would have it. ... [T]he member states have yet to give the Commission the resources or the authority of a federal administration, complete with full time policy making experts, rule making powers, local branches, enforcement officers, and the power to impose administrative and/or criminal sanctions. With very few exceptions, national regulators sitting and voting on committees, not the Commission acting independently, are responsible for administrative rule making and interpreting primary legislation. And national regulators, acting in

II. 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 Adelegation@ problem in American perspective with his observation that Congress had virtually ceased solving problems legislatively B that it had moved, rather, to the habitual creation of regulators through what he styled Aintransitive@ legislation. As public choice analyses of congressional action are also prone to point out,⁸³ 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 the kind the American Congress most often leaves to regulators. EU legislative acts address a particular, relatively detailed subject B the constraints on genetically modified organisms (GMOs) in European agricultural markets B and identify with some precision the Aessential 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, 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.⁸⁴ Even if

consultation with other national regulators and the Commission, are responsible for day-to-day enforcement.

⁸³ See, e.g., David Schoenbrod, *Power Without Responsibility* (1993).

⁸⁴ 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.

in the first instance it is for member states to exercise the freedom of approach that Adirectives@ intentionally leave, 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 approaches do and what do not honor the directives= essential requirements.

Implementing measures@⁸⁵ B the exercise of a subordinate, delegated authority by Union elements B are obvious means for answering those questions in a general and principled way. 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 Alegislative@ acts; in the same year, following very different processes and under rather light supervision, the European Commission adopted 5147 Aregulations,@ with a great deal of uncounted Asoft law@ below that.⁸⁶ Although the Union=s legislative acts frequently leave implementation to member states, in at least two respects they may delegate some authority for the development of subsidiary norms having the force of law to EU actors.⁸⁷ The first of these possibilities arises in delegations to the Commission, acting through a responsible Directorate under the procedures of Acomitology@; the second, in delegations to independent European agencies acting under the Commission=s more general supervision. The first is the more common, and will get the bulk of attention here.

One reason for the relative unimportance of the A-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 Aunitary executive.@⁸⁸ (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.⁸⁹) Accepting that regulatory agencies may be created at the EU level, the Commission has asserted that A[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 Acan be granted the power to take individual decisions in specific areas, [such agencies] cannot adopt general regulatory measures@ and Acannot be granted decision-making powers in areas in which they would have to arbitrate between conflicting public

⁸⁵ *Commission Regulations and Commission Directives*, for example.

⁸⁶ See n. 4 above.

⁸⁷ The draft Constitution would identify these subsidiary norms, now described generally as implementing measures, as AEuropean regulations@ B Anon-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 Aregulations@ do, or they applied to member states made responsible for their implementation, as do the legislative acts now denominated Adirectives.@ Draft Constitution Art. I-33 cl. 4.

⁸⁸ COM(2002) 718 final, at 2.

⁸⁹ Cf. p. 22 above.

interests, exercise political discretion, or carry out complex economic assessments.⁹⁰ This makes it sound like 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.⁹¹

The EU's central website for European agencies⁹² identifies seven as having regulatory functions, the [Office for Harmonisation in the Internal Market](#),⁹³ the [Community Plant Variety Office](#),⁹⁴ the [European Medicines Agency](#),⁹⁵ the [European Food Safety Authority](#),⁹⁶ the [European](#)

⁹⁰ COM(2002) 718 final at 5, 8; see also http://europa.eu.int/comm/governance/governance_eu/central_en.htm.

⁹¹ Joanne Scott and David Trubek, *Mind the Gap: Law and New Approaches to Governance in the European Union* 8 *European 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 Defenses*, id. 133, 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, at 145; Giandomenico Majone, *Delegation of Regulatory Powers in a Mixed Polity*, 319, one of the stronger proponents of the agency model; and Xenophon A. Yataganas, *Delegation of Regulatory Authority in the European Union*, Jean Monnet Working Paper 3/01 (2001), arguing the political necessity of some delegations to independent agencies.

⁹¹ Joanne Scott and David Trubek, *Mind the Gap: Law and New Approaches to Governance in the European Union* 8 *European 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 Defenses*, id. 133, 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, at 145; Giandomenico Majone, *Delegation of Regulatory Powers in a Mixed Polity*, 319, one of the stronger proponents of the agency model; and Xenophon A. Yataganas, *Delegation of Regulatory Authority in the European Union*, Jean Monnet Working Paper 3/01 (2001), arguing the political necessity of some delegations to independent agencies.

⁹² http://europa.eu.int/agencies/index_en.htm. Each assesses fees for its services, and thus is essentially self-supporting.

⁹³ 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.

⁹⁴ 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. <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.

⁹⁵ 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

[Maritime Safety Agency](#),⁹⁷ the [European Aviation Safety Agency](#) and the [European Network and Information Security Agency](#).⁹⁸ 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' that engages in a process strongly resembling American notice and comment rulemaking¹⁰⁰ (including, in contradistinction to Commission practice, an apparent disposition to draft its proposals *prior* to initiating public consultation) to generate standards on a variety of subjects.¹⁰¹ Like the

<http://www.emea.eu.int/htms/general/direct/legislation/legislationhuman.htm> (human medicines) and <http://www.emea.eu.int/htms/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.eu-dra.org/F2/pharmacos/new.htm>; and 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)'. Art. 23, Rules of Procedure of the Committee on Medicinal Products for Human Use, EMEA/CHMP/111481/2004

⁹⁶ 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.

⁹⁷ 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.

⁹⁸ The EU's newest agency, and the nature of its work is not yet clear on the website. A European Railway Agency is under formation as an adjunct to DG Energy and Transport, there to join the Maritime Safety and Aviation Safety agencies. See http://europa.eu.int/comm/transport/rail/era/index_en.htm, http://europa.eu.int/comm/dgs/energy_transport/home/organigram/doc/organi_en.pdf (DG organization chart).

⁹⁹ http://www.easa.eu.int/home/rulemaking_en.html.

¹⁰⁰ 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.

¹⁰¹ See Art. 13 of EC Regulation 1592 (2002), OJ L 240/8 (7.9.2002), authorizing the EASA, inter alia to (b) 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;

And see http://www.easa.eu.int/doc/About_EASA/Manag_Board/2003/2003_06_17_mb_decision_en.pdf, establishing the EASA's rulemaking procedures.

Commission, it maintains a published rulemaking programme¹⁰² 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 them.

Although other examples of a similar process can be found within the EU DGs themselves,¹⁰³ on the whole implementation measures are much less in public view or committed to public participation than legislative acts. As Bignami reports,¹⁰⁴ the pattern of consultation in the EU is quite the reverse of that in the United States.

... 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 the normative support of 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 U.S., 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.

¹⁰² http://www.easa.eu.int/doc/Regulation/Docs/decision_ED_2004_09_RM_annex.pdf

¹⁰³ For example, the Commission has created, in association with DG Internal Market & 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., 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. And for the former committee, the ESC, all one can find, through the DG site, is a rather unrevealing collection of meeting minutes. 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. 268, 270 (2002).

¹⁰⁴ Francesca Bignami, The Challenge of Cooperative Regulatory Relations After Enlargement, n. 82 above, at 90-91.

For the Commission, rather, implementing measures are most frequently the product of a process known as Comitology, a process given some structure by the so-called comitology decisions,¹⁰⁵ and characterized as a means for consulting Member States,¹⁰⁶ but whose outlines do not significantly involve public notice or participation.

Comitology procedures have changed considerably over the years, particularly as Parliament's place has strengthened, and for this reason early studies¹⁰⁷ are of uncertain continued relevance. Because Parliament, as well as the general public, is somewhat disadvantaged by comitology practice, the draft European Constitution, if ratified, will replace it with a *lyng-before* practice in which Parliament will have an opportunity of disapproval equal with the Council.¹⁰⁸ But the draft Constitution does not specify any 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.¹⁰⁹ The Commission presents a proposed draft of its intended action B for our purposes, an implementing measure B to the committee which, after deliberation, delivers an opinion on the proposal. (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 to 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.) The committee then acts on the draft by qualified majority under one of four regimes, specified in the governing documents:

¹⁰⁵ Decisions 87/373/EEC and 1999/468/EC, as further modified by Council Regulations 806(2003) (qualified majority) and 807(2003) (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, e.g., Georg Haibach, *The History of Comitology*, in Andenas and Turk, n. 3 above, pp. 185-215.

¹⁰⁶ http://europe.eu.int/comm/civil_society/apgen_en.htm p. 4, visited April 12, 2005, updated as of March 15, 2005.

¹⁰⁷ E.g., the collection of essays in Christian Joerges and Ellen Vos, *EU Committees: Social Regulation, Law and Politics* (Hart Publishing 1999).

¹⁰⁸ The sufficiency of this after-the-fact review to control the Commission's significant power over what may be complex regulatory choices is questioned in Paul Craig, *European Governance: Executive and Administrative Powers Under the New Constitutional Settlement* 42 (2005) and Paul Craig, *The Hierarchy of Norms*, in

. It may be noted that a Commission proposal it characterizes as anticipating *A* 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 p. 14, has been pending a Council opinion since April, 2004. <http://www2.europarl.eu.int/oeil/FindByProcnum.do?lang=2&procnum=CNS/2002/0298>, visited April 28, 2005.

¹⁰⁹ This description draws on Paras. 14-054-061 of Koen Lenaerts and Piet Van Nuffel, *Constitutional Law of the European Union* (2005), pp. 614-19.

- § If a committee is denominated Aadvisory,@ 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. (Should it substantially modify its action from its draft, and the underlying legislative act was adopted by co-decision, Parliament must again be notified and might again adopt a disapproving resolution.)
- § If a committee is denominated Amanagement,@ 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 Aregulatory,@ the Commission=s proposal will come into force routinely if it secures qualified majority support from the committee *or*, failing that, it secures support from the Council within three months B 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.
- § The fourth style, Asafeguard,@ is a rarely invoked amalgam.

AREgulatory@ comitology, the most demanding form, is our principal concern.

As appears from the Commission=s most recent reports on the working of committees,¹¹⁰ 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 B 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,¹¹¹ 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 reported, if at all, after the fact of meeting; and minutes of committee meetings are quite summary.¹¹²

¹¹⁰ COM(2003)530 final (concerning 2002) and COM(2004)860 final (concerning 2003).

¹¹¹ *Id.* at p. 5 (both).

¹¹² See, e.g., 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, and the links there provided.

Consider, moreover, the implications of the following table, constructed from data about regulatory comitology in the two footnoted reports¹¹³:

DG	2001-03 committees ¹¹⁴	2001-03 regulatory procedures ¹¹⁵	2001-03 meetings ¹¹⁶	2002-03 opinions ¹¹⁷	2002-03 instruments ¹¹⁸
ENTR	33	18	146	1037	953
EMPL	8	3	42	26	5
AGRI	30	4	1039 ¹¹⁹	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

¹¹³ A similar analysis of earlier experience appears in Josef Falke, *Comitology: From Small Councils to Complex Networks*, Andenas and Turk, n. 3 above, at 331, 343 ff.

¹¹⁴ Where the number varied, the highest number is given. Variance was minor.

¹¹⁵ 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.

¹¹⁶ All purposes; statistics broken out by type not available.

¹¹⁷ All types of opinions, whether favorable or not, in all types of procedures

¹¹⁸ This is the measure of implementing measures adopted by the Commission.

¹¹⁹ Predominantly management meetings

OLAF	1	1	4	0	0
TOTAL ¹²⁰	256	100			5197 ¹²¹

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;¹²² 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 agendas¹²³ 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 B for example, of the handling of the BSE crisis¹²⁴ B 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.¹²⁵ And one general account of comitology practice in ENV, under prior regimes and thus now perhaps outdated, suggests not only the problems with its Asecret life,@ but quite specifically that, relative to its committees, and as a matter of practical politics, the Commission is in Aquite a strong position.@¹²⁶

In the circumstances, Bignami's observation that transparency and citizen involvement are missing at the level of comitology suggests at least the possibility that engaged oversight is absent

¹²⁰ May include DGs without *any* regulatory procedures

¹²¹ These DGs only; other DGs not using regulatory procedure contributed a not insignificant additional number of instruments.

¹²² McNollgast on police alarms/fire alarms

¹²³ N. 112 above.

¹²⁴ Gunther Shafer, Linking Member State and European Administrations B The Role of Committees and Comitology, in Andenas and Turk, n. 3 above, 3, 20 ff. See also the case study on comitology in connection with GMOs in Annette Toeller and Herwig Hoffman, Democracy and the Reform of Comitology, id. at 25, 37 ff. These were, of course, both highly controversial matters and so unlikely to be representative of general practice.

¹²⁵ Id. at 22.

¹²⁶ Christoph Demmke, Comitology in the Environmental Sector, Andenas and Turk, n. 3 above, 279, 285, 287.

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."¹²⁷ The "Your voice" site, again, references few if any consultations about implementing measures. And individual DG websites seem little better.

The pharmaceuticals unit of DG Enterprise (ENTR) is one of the more active DGs so far as implementing measures are concerned and publishes a not inconsiderable list of implementing measures for Directive 2001/20/EC (pharmaceuticals).¹²⁸ No link for consultations appears on its web site. By consulting the "News" link that is there,¹²⁹ one can find invitations to comment on draft guidance documents, coordinated with the European Medical Agency site,¹³⁰ but no information about comitology activities. ENTR consultations link¹³¹ 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 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.¹³² 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

¹²⁷ http://europe.eu.int/comm/civil_society/apgen_en.htm p. 4, visited April 12, 2005, updated as of March 15, 2005.

¹²⁸ <http://pharmacos.eudra.org/F2/pharmacos/dir200120ec.htm>

¹²⁹ <http://pharmacos.eudra.org/F2/pharmacos/new.htm>

¹³⁰ Note 95 above.

¹³¹ <http://europa.eu.int/comm/enterprise/consultations/list.htm>

¹³² "Some Free Associations on Administrative Judicial Review," draft paper presented at the University of San Diego January 20, 2005, p. 3.

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.¹³³ Shapiro, one might add, is a person not impressed with the virtues of government regulation of what we eat by the deliberation of nutritionists.¹³⁴

III. Other uses of committees or their equivalent

The Commission and expert bodies act together in the formulation of norms in at least two other contexts worthy of mention, but perhaps not elaborate discussion.¹³⁵ 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 purity¹³⁶). 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, agendas and discussion papers may be noticed and made available in advance of meetings.¹³⁷

Second, some Commission directives employ what it has denominated the New approach¹³⁸ 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.

¹³³ Id. at 3-4.

¹³⁴ Id. at 5.

¹³⁵ See also n. 45 above, concerning the use of advisory committees early in the legislative drafting process.

¹³⁶ http://www.codexalimentarius.net/web/index_en.jsp

¹³⁷ Thus, on April 20, 2005, one could find at http://europa.eu.int/comm/food/fs/ifsi/eupositions/ccfac/ccfac_index_en.html 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.

¹³⁸ Directive 98/34/EC. Experience under this Directive is extensively reported in COM(2003) 200 final, a report from the Commission on the operation of the directive from 1999 to 2001. A 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, SEC(2004) 1251 pp. 2 & 4 and an accompanying Commission staff working document, A The challenges for European standardisation, express considerable enthusiasm for experience to date,

directives, in themselves, define only the essential requirements of regulatory controls in technical fields. For example, 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 technical committees) to identify 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.¹³⁹ 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,¹⁴⁰ permitting anyone to enrol for e-mailed notification of drafts published in areas of interest, thus assuring broad public opportunity to comment on proposed technical standards during the stand-still period provided for.¹⁴¹ 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 law¹⁴² and essentially the same as an American business would experience if it followed the 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

the hope both for exploitation of a room for improvement and the high desirability of making use of standards in areas of Community legislation beyond the Single Market. 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 Harms Schepel, *The Constitution of Private Governance* (Hart Publishing 2005). See especially *id.* at 50-67 and 101 ff.

¹³⁹ See *Guide to the Implementation of Directives based on the New Approach and the Global Approach* (2000), esp. at Ch. 4 *Compliance with Directives* and p. 28.

¹⁴⁰ <http://europa.eu.int/comm/enterprise/tris/>. The Commission's 2003 report discussing this website, n. 138 above, 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 (At 31; see also 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.

¹⁴¹ The notices I have thus far received in several months of enrolment 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.

¹⁴² Technical standards cannot replace a legal text or change what the legislator has provided. *Guide*, n. 139 above, at 3. Only the text of the directive is authentic in law. 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 <http://www.newapproach.org/Directives/DirectiveList.asp>.

products meet the standards have effective protection against product liability actions.¹⁴³ 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, 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)¹⁴⁴ following consultation with the Member States,¹⁴⁵ to develop Union-wide harmonized standards;¹⁴⁶ elsewhere, it lists 27 mandates issued 1999-2001.¹⁴⁷ The CEN website gives, sector by sector, elaborate reports on the progress of mandated standards through its processes.¹⁴⁸ In doing so it makes evident that it, too, proceeds very largely by committee action.¹⁴⁹ And a very recent Communication from the Commission to the Council and the European Parliament on A 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.¹⁵⁰

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

¹⁴³ Conformity with a harmonized standard produces a presumption of conformity with the essential requirements of the applicable New Approach directive. A manufacturer may choose a different path, but then will have the burden of establishing that its products conform to the essential requirements.

¹⁴⁴ <http://www.cenorm.be/cenorm/index.htm>

¹⁴⁵ See Guide, n. 139 above, Table 4/1, p. 28.

¹⁴⁶ N. 138 above at 40-43.

¹⁴⁷ Id. at p. 12. Tables in Schepel, n. 138 above at 108-09, 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.

¹⁴⁸ The website is at <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.

¹⁴⁹ Schepel, n. 138 above, describes CEN and its processes at p. 101 ff.

¹⁵⁰ SEC(2005) xxx at 9; and see the Commission documents and Schepel, cited in n. 138 above, *passim*.

practice these matters, that might be lumped together under the rubric *Aguidance documents* or *Apublication 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, *Asoft law*.

Enough has already been said to indicate that the Commission is often itself a source of soft law documents,¹⁵¹ and that *Bas in the ANew Approach* directives¹⁵² *Bit may delegate to others, even outside the EU itself, the authority to create them. 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,¹⁵³ 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 *Bit 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.¹⁵⁴*

¹⁵¹ E.g., its instructions to staff concerning consultation practice, see text at n. 43 above.

¹⁵² See text at p. 35 above.

¹⁵³ See the *Aoverview on the Commission=s framework of consultation and dialogue with civil society and other interested parties* at http://europe.eu.int/comm/civil_society/apgen_en.htm, collecting and linking sources. As noted previously, n. 127 above, this site is explicit that *Athe consultation standards do not apply to comitology consultation*.

¹⁵⁴ A notable exception is the FDA, which by statute and internal regulation is committed to *Agood guidance practices* producing similar levels of notice and engagement. See <http://www.fda.gov/opacom/morechoices/industry/guidedc.htm>. As that site reflects, 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, <http://www.access-data.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA>, 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. <http://www.fda.gov/ohrms/dockets/default.htm>.

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.¹⁵⁵ This important and highly complex measure seeks to organize river basin management across Europe (and consequently often 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.¹⁵⁶ 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.¹⁵⁷

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;¹⁵⁸ the

¹⁵⁵ EC(2000) 60. See http://europa.eu.int/comm/environment/water/water-framework/index_en.html

¹⁵⁶ See <http://europa.eu.int/comm/environment/water/water-framework/implementation.html>

¹⁵⁷ <http://forum.europa.eu.int/Public/irc/env/Home/main>

¹⁵⁸ <http://forum.europa.eu.int/Public/irc/env/wfd/home>. It may be advisable first to register as a user of CIRCA, a registration process that is not controlled.

library includes, in particular, a several hundred page document¹⁵⁹ 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 14.¹⁶⁰ As is common, however, and although both Article 14 and this guidance strongly emphasize the need for consultation in advance of action, the library contains only completed documents & not opportunities for public consultations.¹⁶¹ Portions of the WFD's CIRCA site *do* contain preparatory documents, working papers on the basis of which guidance was developed, etc., and 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

¹⁵⁹ http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework_directive/guidance_documents/participation_guidance&vm=detailed&sb=Title

¹⁶⁰ Art. 14 of the Water Framework Directive, reflecting preambular commitments and supported by disclosure requirements, 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 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.

¹⁶¹ Annex III to the Guidance on Public Participation in the WFD, n. 159 above, reported the working process of the group responsible for developing it. A practice what you preach, is what we believe, it begins. 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.

on@¹⁶² 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.

In conclusion, we had to refuse your application for full access to the WFD CIRCA system.¹⁶³

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 Aa 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 knowledgable critique.¹⁶⁴ 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

¹⁶² Email of April 9, 2005

¹⁶³ Email of April 11, 2005 for the WFD Help Desk. See also <http://forum.europa.eu.int/irc/env/wfd/info/data/get%20registered%20on%20wfd%20circa.htm>

¹⁶⁴ See, e.g., Worldwide Fund for Nature and European Environmental Bureau, >Tips and Tricks= for Water Framework Directive Implementation (2004) and EU Water Policy: Making the Water Framework Directive Work (2005), both much more pleased with the guidance discussed in text than with its general national implementation by Member States. (2004) at 29; (2005) at 17-23. See http://www.eeb.org/activities/water/200403_EEB_WWF_Tips&Tricks.pdf and <http://www.eeb.org/activities/water/making-WFD-work-February05.pdf>.

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 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, are 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. That adaptation 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.¹⁶⁵ Even in the national context, as Lindseth persuasively continued, the diffusion and fragmentation of normative power away from constitutional legislatures over

¹⁶⁵ Peter Lindseth, "Agents Without Principals?: Delegation in an Age of Diffuse and Fragmented Governance" 3 (February 2004). University of Connecticut School of Law. University of Connecticut School of Law Working Paper Series. Working Paper 18. <http://lsr.nellco.org/uconn/ucwps/papers/18>

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.¹⁶⁶ 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.¹⁶⁷ 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 Acomitology@ is clear enough in the sensibilities of the EU=s Member States. While the European Parliament=s resistance to it is already clear, the future shape of Aimplementing 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.

¹⁶⁶ Ibid.

¹⁶⁷ Id. at 12, citing Stephan Padgett, Introduction: Chancellors and the Chancellorship, in Adenauer to Kohl: The Development of the German Chancellorship (Stephan Padgett ed. 1994).