Chapter 2

RULEMAKING

Creating Regulations, Directives and Soft Law in the European Union

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Norm Creation in the European Union

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I. Executive Summary

This report summarizes the administrative law involved in making generally applicable laws and rules at the European Community (the "EC") in the European Union (the "EU"). It is based on specific sector reports in the areas of competition, the environment, financial services, food safety, telecommunications, and the workplace.[1] It deals with the participation of the European Commission in lawmaking, both in proposing legislation to the Council and Parliament and in exercising delegated implementing powers under legislation through various committees ("comitology") and through interaction with national and EU-level standards organizations (the "new approach" process for setting "technical" standards). It also addresses the evolving role of EC agencies. It does not deal with the legislative processes of the Council or Parliament.

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

It seems useful to warn the reader at the outset that the comparison part of the project is imperfect in a variety of respects. First, to be wholly successful, any project in comparative law had better aspire to understand the whole of the societies and institutions being compared, not just pieces of them. The very complexity of the European Union political and legal framework works to defeat that hope. Second, the study draws on studies that experienced Brussels practitioners have made of six particular sectors of the EU, as noted above, with the helpful advice of high-level Commission staff. These six sectors are varied, but far from the universe of the Union's concerns; even among them, these reports reveal significant variation in practice from sector to sector – and this despite the Commission's objective of moving towards a degree of uniformity. Third, the study addresses *only* activities taking place at the European level – in general, although not exclusively, within the EU itself. Yet

[1] The term "workplace sector" is not commonly used in the EU. The main Commission Directorate-General involved with this sector, for instance is known as "DG Employment, Social Affairs, and Equal Opportunities."

lawmaking in Europe is an intermixture of EU and Member State activity, particularly when it comes to the adoption of measures to implement EU legislation – the activity American lawyers would most readily identify as rulemaking. While American analogies are available – for example, the EPA oversees State Implementation Plans in the area of environmental law (that may involve *state* legislative or rulemaking activities) as well as engaging in its own rulemaking – these analogies are not so well developed in the American literature of administrative law, and the extent of interpenetration in Europe is considerably greater.[2] Finally, any study is complicated, as well, by the variety of languages and political systems among the Member States.

The report looks at European-level procedures for generating abstract norms. It does so at three or perhaps four levels of decreasing formality, proceeding from the more to the less formal. In American terms, one might describe these as the constitutional level, the statutory level, the regulatory level, and the level of non-binding administrative guidance. In Europe one moves from treaty, to measures requiring affirmative adoption by the Council of the European Union and the Parliament, to implementing measures, to "soft law." Unsurprisingly, diversity increases as one descends.

It may seem strange to the American reader that this study treats the development of proposals for legislation as a matter of administrative rulemaking, but there are reasons specific to the rather different European context for doing so. Specifically, the European Commission, the European Community institution most closely resembling the US Executive Branch, has as a general matter a monopoly on the initiation of legislation. Thus, it has an important part to play in the initiation and proposal of legislation. It plays this part as an administrative body, in ways that in important respects mirror the administrative rulemaking process in the US. Further, at this stage in its evolution, the EU has developed its processes for administrative rulemaking pursuant to legislative delegations much less fully than has the US. In many ways, the European Commission's role in proposing legislation has been more important, transparent, and open to structured public participation to date than its role in delegated rulemaking – just the opposite from the situation prevailing in the US.

Although there is an increasing volume of delegated rulemaking by the Commission (and much debate over the propriety of this process), this activity is much less structured and is much more likely to be obscured from public view than would be true in the United States. There is no EU equivalent of the American Administrative Procedure Act, imposing relatively uniform and legally binding procedures across all of administrative practice that provide broadly for public participation and are judicially enforceable at the behest of citizens, NGO's and the regulated community.

[2] Indeed, it might be thought that the US models for cooperative federalism are themselves based on European law practices involving the use of the directive in existence when, for example, the early US environmental legislation of the 1970's was originally drafted. [**Check with Leon Billings**]

Understanding the European Union, and the role of rulemaking in it, requires paying close attention to the nature, incentives, and agendas of the specific political institutions making it up, with a special focus on the role of the Member States. Many of those institutions bear a surface resemblance to their analogues in the US, but the European Union is a fundamentally different governance system. First, it is a government not of the peoples or citizens of Europe, but of the nation states of Europe, the Member States. The legal situation is much more that of the initial American confederacy than its subsequent constitutional form as a federal republic. The EU is not a representative democracy in the same sense that its Member States are. Its Member States, which created it and have controlled it from the outset, have both a need and a strong incentive to retain that control. As a result, the underlying reality behind most EU events reflects the agendas of the various Member States, acting as such. Second, it is a governance system in rapid and continuing evolution, and has been so for the 50 or more years since its founding. That evolution is from a loose confederation of nation states towards a more integrated federation of such states, and from an entity wholly controlled and run by the executive branches of those nation states towards an entity with a greater and greater role for directly elected representatives of the citizens of Europe through the European Parliament. This trend collides, of course, with the need and desire of the Member States to retain control over EU governance. But at this point, it is only a trend – and the recent rejection of the draft "constitutional" treaty by important states only underscores the contingency of that trend.

The result is that most of the European Union institutions and practices in the rulemaking area cannot be well understood without fully appreciating the struggles over time of the Member States, acting through the Council and through comitology committees, to retain control over the results of EU legislation and legislative processes, and to avoid judicial accountability (or, more recently, accountability to the Parliament) for that exercise of power. Member States bring their national institutional agendas with them when they act through their Executive Branch representatives in those two fora.

Two other differences may be useful for the American reader to bear in mind. First, most of the EU Member States are parliamentary democracies, without the separation of powers represented by the separate roles of the Executive and Legislative Branches in the US. Second, most of those Member States also have civil, not common law legal systems. Both differences have profound if sometimes indirect impact on lawmaking and rulemaking processes and the expectations and incentives of the institutional actors.

The EU Commission, the EU's executive branch, has its own institutional interests, incentives, and agenda. The Commission is an appointed bureaucracy; it has no base of democratic legitimacy and accountability tied to any European public. Yet it is intended to be, and sees itself as, the defender of the European idea; it is frequently in opposition to the parochial interests of the Member States as expressed through their participation in the Council and the comitology process committees. To help it keep its political footing with its various publics and to legitimize what it does, the Commission has worked hard to develop more transparent "administrative" processes. Likewise, it

has had no hesitancy to force such processes on Member States when it could, and has urged them on the Council, Parliament and European agencies. It has, however, been both slow and careful about enacting legally binding requirements applicable to itself, under which it might actually be held accountable in court by Member States. (Current EU law does not afford citizens, NGO's or the members of the regulated community standing to challenge generally applicable EU governmental actions.)

As will be apparent from much of the discussion below, the political interplay among various of the Member States, and between Member States and the EU-level institutions such as the Commission and the Parliament, has largely determined the shape of the norm-generating process and dominated its operation to date. Yet the Commission has made great strides in developing administrative governance tools, and in persuading other European institutions to use them. This report details the generic reforms the Commission has sponsored. Individual sector reports detail the incubation of those reforms in specific areas, or the successful application in specific substantive areas of the legislative reforms the Commission has laid down.

What the Commission has not yet done, however, is to commit itself broadly to legally binding requirements applicable to its own administrative process. This is perhaps a natural outcome during the initial period of laying down a regulatory foundation for the new Europe, And what the Council and Parliament have not yet done is to provide judicial accountability for Commission and European agency actions through a right of judicial review of generally applicable rules accorded to anyone other than themselves (*i.e.*, to citizens, NGO's and the regulated community). In these respects, one might think that the EU is where the US was before it enacted the APA.

The EU is now developing a mass of experience with reform of administrative processes and governance at the EU level. It knows what it likes and does not like about the years of US experience under the APA. And it may be adapting its public participation processes to the new web-based world of technology better than are US administrative agencies. Consequently, should it conclude that the needs for legitimacy and accountability in administrative action at the EU level demand more than "soft law," it will be well positioned to develop its own form of uniform, legally binding administrative governance requirements. It will be a separate question, and likely a contentious one, whether these requirements should be judicially enforceable by more than just other EU institutions and Member States. The complexities and accountability created for American rulemaking by free and intensive judicial review are well known in Europe. The complexities are often mentioned as an evil to be avoided. The judicial accountability result is less often mentioned. Control of generally applicable executive action by the courts or by the public, rather than by other EU institutions, is frequently deplored. Given the political control of the EU by Member States, it is also not often emphasized.

In the meantime, American lawyers in many disciplines must now deal with EU administrative law on a day-to-day basis. This report is designed to help them understand the EU context, and the administrative processes now in use there.

II. Norm Creation In The EC And Its Sectors – Context And Overview

A. Introductory Note

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, some of 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 polities and elude the frustrating grip of those whose activities require public controls. They must also remain representative and accountable directly or indirectly to the underlying civilian populations whose activities they increasingly control. A study of the European Union's procedures for generating regulatory norms suggests possible lessons for America, for the Union, and quite possibly for other evolving forms of transnational governance.

On a spring day in April 2005, the International Herald Tribune carried two stories that in their way framed this project. The front page story was headlined "On the EU Battlefield: Armies of lobbyists assail Brussels,"[3] 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"; that characterization subjected it to tariffs as much as twenty times higher than sauce as "sauce" would encounter. The American public encountered comparable silliness when President Ronald Reagan's administration wanted to treat tomato ketchup as a vegetable, to get credit for supplying healthy foods in school lunch programs. "As the EU's powers have extended even deeper into companies' lives," the 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 – Friends of the Earth as well as Unilever is there and fighting.[4]

The second story was an op-ed piece, "EU's growth triggers identity crisis,"[5] addressing the prospect that the stress of European enlargement would imperil the European project at the very moment of an effort to adopt a European constitution, then pending ratification. Just what is Europe, and why should anyone want it? The

[3] Graham Bowley, April 5 2005, p. 1, 4.

[4] Seven months later, the Wall Street Journal would report, to similar effect, on the travails of the Kellogg Company trying to secure uniform access to EU markets for its breakfast cereals. G. Thomas Sims, "Uncommon Market; Corn Flakes Clash Shows the Glitches in European Union," Wall Street Journal (Eastern Ed.), Nov. 1, 2005, P. A1.

[5] William Pfaff, p. 7.

questions were grounded in the reality of differing national ambitions and fears – ambitions and fears having rather little to do with the technical rearrangements of the draft "constitution, which few had read. By now," the Trib wrote, "approval of the constitution has been turned into a referendum on issues that have little or nothing to do with the constitution, such as Turkish membership in the EU, the Stability Pact, the Bolkstein directive on liberalizing rules for the service industry, and local partisan rows."

Stunning defeats of the draft in referenda in France and the Netherlands shortly consigned the draft constitution to oblivion, at least temporarily.[6] As a result, the EU continues to function under its present treaty regimes. And that still has remarkable implications for Europe's national governments. As one author recently wrote, "up to 90% of all environmental legal acts within the national legal systems [of the European Union] are of EU origin and national parliaments sometimes … have nothing to do other than simply transform European directives into national legislation."[7] 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 under control by the executive bureaucracies of EU Member States with their own differing national bureaucratic agendas, to what extent corporativist, etc.?

European Union law can be framed within a nesting hierarchy that would be familiar to Americans – or, for that matter, to the citizens of any modern, developed legal order. At the highest levels of the legal order, one finds limited foundational documents – a constitution, or treaties – that are the product of extraordinary procedures rarely invoked and requiring demanding procedures for ratification as well as adoption. At the next level, one finds laws, statutes, directly enacted generally by a representative legislative body like Congress or a parliament, no more than a few hundred yearly. Beneath that, subsidiary legislation or regulations adopted by executive authority – departments, agencies, ministries – under legislative authorization; typically, at this level of detail, thousands annually. Enabling legislation may authorize others than the executive – subordinate political units (states in the US, Member States in the EU), even private organizations – to adopt norms under conditions of supervision and, perhaps, required procedure. These norms interact. Then one may find in still greater profusion documents offering guidance or other forms of "soft law," not in itself binding on citizens although still influential and frequently binding on its governmental drafters until changed by them. And this distribution of normative instruments holds true for Europe. In 1996, for example, the European Parliament and Council adopted 484 "legislative" acts; in the same year, following very different processes and under rather light supervision, the European Commission adopted 5147 "regulations," with a great

[6] We note below that some aspects of the reforms attempted in the draft (for example as to EU lawmaking instruments and forms of delegation) may resurface in other contexts as the EU institutions and lawmaking processes continue to evolve.

[7] 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.

deal of Member State implementing measures, standards organization measures, and uncounted "soft law" below that.[8]

The level of this hierarchy at which a norm is developed can profoundly influence our ideas about appropriate procedures. Any normative text embodies both a view of the realities with which it deals – technical or factual propositions about the real world – and a set of political or social propositions about desired, hopefully just, outcomes. The tension between considering norms as the expression of political judgment, and considering them the product of expert technical judgment is felt differently at each level. 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 contribute 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.[9]

- 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 "legislative facts" as facts that are acceptable to be determined by a vote. Any judicial check on such legislative judgments rests either on sheer, demonstrable irrationality ("the world is flat") or on inconsistency with the higher norms of the Constitution. The Constitution might not permit legislative judgments based on propositions about racial difference, for example, even if in some technical sense the propositions were true. Ordinarily, however, we accept that legislation is proper if a majority in the legislature supports it – that is, what the majority believes the facts to be suffices.

[8] Georg Haibach, "Separation and Delegation of Legislative Powers: A Comparative Analysis," in Andenas and Turk, n. 6 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 – the Role of Committees and Comitology, *id*. at 3, 6, 9; Josef Falke, Comitology, From Small Councils to Complex Networks, *id*. at 331, 336.

[9] For example, that African-American school children are psychologically, developmentally disadvantaged by segregated education. *Brown v. Board of Education*, 347 U.S. 483 (1954).

- Once we get to the level of regulations, expert judgment about the facts begins to count for a lot – although politics may still have a role to play.[10] Congress has established a Nuclear Regulatory Commission to oversee nuclear power generation. When its commissioners adopt a regulation about necessary levels of radiation protection, their political authority as immediate delegates of Congress and appointees of the American President may carry some weight for Americans aware of the inevitable imprecision of human factual judgment about such matters.[11] Still, at this level, accuracy in assessing reality becomes much more important as a test of legitimacy. We teeter between regarding regulators as persons whose authority and actions are warranted by their apolitical expertise, and taking them as political agents (in this case, of the chief executive) whose authority and actions are to be derived not from facts they are uniquely positioned to assess, but from their relationship to that principal. We are uncertain whether the process for creating regulations is one designed for gathering and assessing facts, or one in which it is important that all points of view can be expressed. American judges have created regimes of review, "hard looks," that place a high value on factual accuracy and afford much less room for politics than legislators enjoy.[12]

- "Soft law" emerging from the Commission – say, advice that responsible staff elements have developed to define acceptable means of complying with Commission regulations – may be just as political as regulations; but in technical agencies, at least, "soft law" is primarily the product of subordinate bureaus, not the political leadership of the agency. And when it is, with policy thus made at the greatest remove from political controls, expert judgment must prevail. When responsible NRC staff have issued a guidance document stating that a containment four feet thick, built of concrete in a specified way, will successfully provide the level of radiation protection Commission regulations require for a nuclear power plant of a certain design, that document stands or falls entirely on the basis of expert judgment. The deeper one moves into the bureaucracy of administrative government, then, the more important is the model of fact-finding expertise.

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

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[10] On the interrelation of expert and political rationales of legitimacy, *see* Matthew Adler, "Justification, Legitimacy, and Administrative Governance," Issues in Legal Scholarship – The Reformation of Administrative Law, Art. 3 (Berkeley Electronic Press 2005).

[11] *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87 (1983).

[12] *E.g.*, *Sierra Club v. Costle*, 657 F.2d 298 (D.C. Cir. 1981); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

- Each of these levels – constitution, statute, regulation, soft law – is the product of a distinct institution. The people, acting complexly through a variety of institutions/agents, make constitutions; the legislature makes statutes; the political leadership of an executive agency (or the courts) 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.

- "Separation of powers" considerations, in the American perspective, sharply differentiate legislative from executive authority and activity. Statutes are the work of the legislature. The President can recommend legislation and can attempt to block (veto) entire enactments of which he disapproves; but he cannot force consideration of any measure and he scarcely participates in the work of its drafting and detailed consideration. Regulations and soft law are the product of processes in which neither the Congress as a whole nor any of its individual members are entitled formally to exercise decisional authority, save for the possibility of enacting statutes in disapproval.[13]

- There is the expectation, too, that the constitutionally established institutions and their authority are quite fixed, not contingent. Since the Civil War at least, there has been no sense that the authority of Congress depends from day to day on the continued acquiescence of states in a problematic union. When the President and the executive branch act, they have at best a weak obligation to engage in consensual dealings among executive authorities with equivalent responsibilities in the states.

- Within the executive itself, the exact nature of presidential authority over agency choices is unsettled. Do the agencies possess their own authority, whose exercise the President merely oversees; or is their authority necessarily derivative of his own, so that he may not only see to their faithful execution of the laws but also substitute his own judgment for theirs on disputable matters?[14] Whichever choice one makes between these contending views, to Americans it is clear that the President is a popularly elected, and thus politically accountable figure – essentially the only such figure in the executive.[15] Consequently they understand his exercise of authority to be hierarchical, not democratic; Americans do not imagine the executive as a collective.

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[13] This is hardly to deny the possibilities of informal influence, as by oversight hearings, appropriations measures, casework, and the like.

[14] Peter L. Strauss, Overseer or "the Decider"? – The President in Administrative Law, 75 The Geo. Wash. L. Rev. (forthcoming 2007).

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

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. Such a person 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, the equivalent of American cabinet Secretaries, may also sit in Parliament; and in any event they are directly answerable to it for the regulations their administrations adopt. And the parliamentary cabinet is much more a collective body; ministers often share electoral responsibility with their Prime Minister, and the duration of their government may depend both on its continuing success in parliament, and on the ministers' continuing collective willingness to constitute a government. Much less likely is any idea that the prime minister has a particular, unique, and electorally grounded authority to dictate the proper outcome of any disputed matter within the executive.

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

- Both as the child of treaties, and as a reflection of the content of those treaties, the Union and its institutions are contingent on the continued interaction of states in a way Americans may find hard to appreciate. Its primary laws are the product of international concord, not popular will.[16] Its institutional arrangements, and its civil servants, need to be sensitive to the proposition that the Member States are nations, and the EU is not. Those nations have linguistic identities (reflected in the obligation to translate governing documents into all official languages of Member States), unshared (and often long) histories and characters, and differing legal and governmental institutions and orientations. Rivalries reflected in both diplomatic and martial history stretch far into the past. Collective action at the European level is far from instinctual, and almost invariably requires a level of integration of 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: "legislative acts" that are the product of what might seem a bicameral legislature acting in coordination with an executive authority; "rules" produced by the executive authority; and guidance emerging from its bureaus. Yet strikingly, the European Commission, the Union executive, unambiguously holds important responsibilities in the creation of *all* these documents: on most matters, the EU legislature can act *only* on proposals that come from it; the

[16] The Draft European Constitution, had it been ratified, would not have been a "constitution" in the usual national sense. Although titled a constitution, its text consistently presented itself as a treaty – as a "We the States," not a "We the People" document.

Commission is the source of most pan-European "rules" or implementing measures having the force of law; and soft-law guidance, as well, generally requires its approval. And, on the other hand, this unity is undercut by the EU's sharply limited direct authority to command; the bulk of implementation of EU legislative measures is left to Member State initiative, under constrained circumstances of supervision.

- The Commission's makeup reflects parliamentary rather than republican expectations about executive structure: Its President is chosen by the legislature (at the nomination of Member State governments), not by the people. The Commission acts collegially, but those in charge of its directorate generals (the equivalent of ministers in a parliamentary system) nonetheless hold a quasi-independent authority on which in some sense the President depends.

- A number of elements make the Commission's ostensibly independent policymaking responsibilities for implementation more an element of collective responsibility, contingent both on national and international bureaucratic consensus, than a node of independent institutional power.

    (a) Comitology, a practice internal to the EU that engages national representatives in discussions with responsible Commission staff, is the most directly relevant of these for a discussion of EU procedures.[17]

    (b) Framework legislation is often designated for implementation at the national level under Commission guidance, making this interdependence even more clear.

    (c) Other measures frequently recognize significant standard-setting authority in transnational standard-setting bodies outside the Council-Commission-Parliament trilogy – international organizations like the Codex Alimentarius Commission of the FAO and WHO[18] dealing with food safety issues, independent agencies such as the European Food Safety Authority,[19] and quasi-private standards organizations such as CEN, the European Committee for Standardization.[20]

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17 *See* pp. 25 and 67, below.

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

19 http://www.efsa.eu.int/.

20 http://www.cenorm.be/cenorm/index.htm and *see* pp. [88] and [125], below.

Save perhaps for comitology committees, analogous institutions are not lacking in American experience. State implementation measures adopted under federal supervision are characteristic of many spending (education, welfare) and regulatory (environment, workplace safety) regimes; and at the state level at least organizations like ANSI (the American National Standards Institute) are often entrusted to a significant degree to develop the technical standards underlying public regulation. Yet we are used to thinking of administrative law in simpler ways, not in these terms.

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

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

What has already been said, particularly about the many diversities of the Member States of the European Union, should suggest that considerations of participation and transparency have great importance to any such undertaking. That importance is heightened 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 going to them (or more likely hiring an attorney to go), sorting through them hoping to find what was wanted, and taking notes or making physical copies. Today, sitting at a computer, one 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, are stunning.

- Fifteen years ago, it would also have cost physical effort and the price of a postage stamp for each letter one wrote to Congress or an administrative

> agency commenting on proposed action, and there would have been a postmark to tell the recipient where the letter came from. Neither proposition is true today. Electronic communication is essentially costless and untraceable. 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 the resulting communication possibilities. What to make of an apparent outpouring of public sentiment has become much more problematic.

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

We turn now to a more detailed description of the EU lawmaking institutions and processes.

B. An Introduction To The EU Institutions And Lawmaking Processes

1. The Commission

The EU Commission, effectively the EU Executive, consists (as of 1 January 2007) of a team of 27 senior political appointees chosen by Member States and approved by the Parliament, acting collegially under the leadership of a President.[21] It is charged with representing and upholding the interests of the EU as a whole, and heads a bureaucracy of about 25,000 officials. The chief sub-units of this bureaucracy are Directorates General (DG's), each of which is headed by a senior official named a Director General.

The Commission has an important role in the EU legislative process. First, as a general matter, only the Commission can initiate legislation. The Commission, not the Council or the Parliament, largely governs the initial timing and choice of subject matter to be dealt with, as well as the initial form, structure, content, and legal basis of proposals for legislation.[22] In practice, of course, the Commission is put under various

[21] To date, every Member States has had at least one commissioner. Beginning with the next Commission, this will no longer be true. Article 213 EC Treaty (hereafter "ECT").

[22] One by-product is that EU legislation is drafted initially by Commission bureaucrats, not by legislative staff. This results in more intellectually coherent and sometimes more rational legislation than is found in the US. At least partially because these bureaucrats are normally not lawyers, however, some EU legislation has in the experience of two of the authors frequently been so general and loosely drafted as to impede rigorous implementation and enforcement. While this looseness of language may sometimes result from the necessary political compromises in Council, it is also clear that Member States acting in the Council have had no incentive to discourage loose language, since it has left them with more discretion over the actual applied stringency of such legislation during implementation.

degrees of legislative pressure by the other institutions, the Member States, interested parties and civil society.[23]

Once the Commission has generated a proposal, the Council can directly amend the proposal (in a way that may be contrary to the views of the Commission) only by a unanimous vote. The Commission has, at a minimum, a consultative role during various stages of the EU legislative processes, and thus may shape the final content of legislation by withholding its consent to changes in the legislation in various ways and at various stages. Should the European Parliament propose amendments to a Council-approved measure that is subject to the co-decision procedures of Article 251 ECT, the Commission is responsible to give the Council its views of the proposals; and a negative opinion on at least one amendment will require Council unanimity to accept the Parliament's position. That is, an extraordinary level of concord between Council and Parliamentary is required to overcome Commission disapproval.[24] Finally, it is at least arguable that the Commission can withdraw a legislative proposal from consideration at any point before its final enactment.[25]

These powers lead many to characterize the Commission as the "driving force" of the EU. The Commission's legislation-initiating role, which most approximates the US procedures for notice -and -comment rulemaking, is of most importance in this paper.

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[23] As this millennium began, it was reported that, of all Commission's proposals:

- Between 20 and 25% are a follow-up to Council or European Parliament resolutions or to requests on the part of the social partners or economic operators;
- Around 30% arise from international obligations on the part of the Community;
- Between 10 and 15% have to do with obligations under the treaty or secondary legislation;
- Around 20% are for updating existing Community legislation (*e.g.* adapting it to technical or scientific progress).

Interim Report from the Commission to the Stockholm European Council: Improving and simplifying the regulatory environment. COM (2001) 130 final, weblink: http://europa.eu/eur-lex/en/com/cnc/2001/com2001_0130en01.pdf.

[24] http://ec.europa.eu/codecision/stepbystep/text/index4_en.htm.

[25] The Commission and the Council disagree on how long the Commission has the power to withdraw a proposal during the legislative procedure. There is general agreement on the Commission's power to withdraw or modify a legislative proposal at any time before the completion of the first reading (which is the adoption by the Council of the European Union of a "common position"). The Commission's point of view is that it can also withdraw a proposal after this point in time in theory, but that it chooses to refrain from doing so in practice. It bases this power on the reasoning that the right not to submit a proposal is a corollary of the right of initiative, enabling the Commission to withdraw a proposal at any time. K. Lenaerts and P. Van Nuffel, Constitutional Law of the European Union, Thomson, 2nd edition, 2005, p. 581 ("Lenaerts and Van Nuffel"); *see* the Commission's reply of 23 January 1987 to question 2422/86 (Herman), [1987] O.J. C220/6). According to the Council, the Commission has no such power. To date, this debate has remained theoretical. Finally, there are also two sorts of withdrawals: an "administrative" withdrawal, which is a sort of "cleaning-up" process by the Commission once a year, consisting in withdrawing proposals that have become obsolete, or those for which the discussion are blocked; and a "political" withdrawal, when the Commission disagrees with the amendments introduced by the legislator. This latter type of withdrawal is rare – only 5 or 6 since the beginning of the Community.

In the wake of the adoption of European legislation,, the Commission has an important role in the passage of delegated legislation, that is, of administrative implementing regulation. Finally, the Commission has the tasks of managing and implementing EU policies (important here, since the Commission drafts various general and sectoral action plans) and the budget, and of enforcing European law in the Court of Justice.

2. The Council

The EU Council of Ministers is the EU's senior legislative body, conjoined in the legislature with the European Parliament. The Council is not directly elected, but composed of ministers seconded by the governments of each of the Member States. Its members thus represent their Member State *governments* as such. It has no fixed membership; its composition and thus membership varies with the policy area being acted on. The members of the Council for any given piece of legislation consist of the ministers from each Member State responsible in their own Member State government for the policy area involved. When acting on environmental issues, for example, the Council consists of the Environment Ministers from the Member States, each of whom can commit his government and is accountable to that government.

Votes are distributed among countries largely by population (adjusted in favor of less populous countries). Voting on most issues, including most environmental, health and safety issues, is by "qualified majority." This requires (1) a majority (on some issues, two-thirds majority) of Member States (13 Member States, or 17 in the case of a non-Commission proposal), (2) a minimum of 72.3% of the possible votes (232 votes), and (3) (if a Member State requests it) affirmative votes representing at least 62% of the EU's total population

Each Member State sends a permanent team to Brussels, its "representation" to the EU, to participate in the work of the Council. This "representation" represents the Community, and does not "represent" the Member State of origin.[26] It is headed by a "permanent representative," a senior official who sits on the Permanent Representative Committee ("COREPER") that prepares the work of the Council, assisted by a number of working groups made up of officials from the national administrations (and sometimes also from the EU "representations") of the Member States.

It is important to distinguish this Council of the European Union (also called the "Council of Ministers"), that we consistently call the Council in this essay, from the senior political body of the European Union acting at the treaty level, the "European Council." The European Council is composed of the Heads of State (or Head of Government) of the Member States of the European Union and the President of the Commission, and acquired formal status with the Single European Act. The European Council meets at least once every six months under the chairmanship of the Head of State or Government of the Member State which holds the Presidency of the Council of

[26] Lenaerts and Van Nuffel, p. 821.

the European Union, which rotates twice a year. The Heads of State gathered in the European Council are typically assisted by the Ministers for Foreign Affairs and by a Member of the Commission. Article 4 of the Treaty on European Union provides that it "shall provide the Union with the necessary impetus for its development and shall define the general political guidelines thereof." Thus, the European Council deals with the major political issues relating to European integration, such as amendments to the Treaties and changes to the institutions, declarations on external relations in the context of the common foreign and security policy, etc. It also serves as a forum for top-level political discussion in crisis situations and it endeavors to resolve disagreements between Member States. Following negotiations between the Member States, the European Council, on a consensus basis, can issue:

- Guidelines setting out the European Council's priorities relating to the European Union and implementation of the common policies by the Council of Ministers and the European Commission. Such guidelines may establish timescales and specific objectives.

- Declarations or resolutions, which express the views of the Heads of State or Governments on specific issues.

While these guidelines and declarations are not legally binding, as instructions issuing, in effect, at the treaty level from the highest authority of the Member States, they guide the work of the institutions in all areas of European Union activities at both European and national levels. The EU institutions can be expected to give binding effect to the European Council's products through the regular legislative procedures.

3. The Parliament

The European Parliament is directly elected by EU citizens from the Member States, and is the only EU institution that is composed of directly elected officials. Initially accorded only advisory power over legislation, in recent years it has secured a much more active and powerful role in the evolution of the EU's complex legislative procedures.[27] It now shares with the Council the power to legislate on matters covered by the co-decision procedure, the most often used legislative procedure, and has effective veto power over such legislation. The Parliament also has the power to approve or reject the nomination of the slate of Commissioners, and has the right to discharge the Commission as a whole (through a motion of censure under Article 201 ECT).

[27] The Parliament's power on any particular legislative issue depends on the applicable legislative procedure. For example, under the so-called "co-decision" procedure of Article 251 EC, both the Council and the Parliament must agree to adopt legislation.

4. The Court of Justice

Both EU institutions and individuals have a right of judicial review of certain EU actions in the European Court of Justice, but only EU institutions have broad rights of standing.[28] Except for Commission enforcement actions against Member States concerning their implementation of EU legislation, EU institutions bring judicial review actions sparingly. On those rare occasions, those institutions are usually seeking to vindicate their own institutional interests in jurisdiction and authority. From this perspective, the institutional right to judicial review provides a measure of checks and balances in the EU system, helping to secure the balance of power that separation of powers ideas do in the US. But review generated by an EU institution is ill-suited to perform the function, familiar to American lawyers, of holding EU institutions accountable, challenging the validity, under the EU or EC Treaties, of substantive provisions of EU legislation, or the legal or policy conformity of EU administrative actions with implementing legislation.

Private parties have standing to seek judicial review of "decisions," the products of adjudication, addressed to them.[29] But as a general rule, private parties do not have standing directly to challenge binding EC legislation acts, whether regulations or directives, even to raise claims that these acts violate the Treaty, fundamental rights, or general principles of EU law.[30] Judicial review issues such as standing are dealt with in greater detail in another element of this report; here it may be enough to say that in general, except for the unusual case of a "decision" camouflaged as a "regulation," private parties have standing to secure pre-enforcement review[31] of some generally binding rules only under circumstances meeting the test of the famous *Londoner - Bi-Metallic* distinction in American administrative law – that is, only if they can show that they are both "directly" and "individually" affected by the challenged action.[32]

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[28] Article 230 ECT.

[29] Article 230 ECT. In addition to such traditional, formal legal remedies as it contains, EU law also provides for certain informal "remedies," such as filing a complaint with a national government or the Commission, or with the European ombudsman.

[30] Private parties damaged by failure of Member States properly to implement EU directives can also sue Member States for damages under the *Francovich* case. *Francovich* v. *Italy*, Cases C-6, 9-90, [1991] ECR I-5357. This amounts, in effect, to an indirect form of judicial review of Member State implementation of EU law which can sometimes throw into issue the validity of the EU institutional implementation of EU law. It can be used by a party who has suffered damages to test and deter various forms of Member State failure to implement EU law properly. Its direct purpose, however, is to insure reparation for such damages. The *Francovich* doctrine does not provide for injunctive relief against the government, either alone or in addition to damages.

[31] They can, of course, presumably also choose to violate the law and challenge it during the enforcement process, although this can be both a delayed and a risky way to proceed, particularly if the legislation in question requires, by its terms, some prompt form of up-front challenge to validity.

[32] In *Bi-Metallic Investment Co. v. State Board of Equalization of Colorado*, 239 U.S. 441 (1915), Justice Holmes distinguished the earlier decision in *Londoner v Denver*, 210 U.S. 373 (1908), on the ground that in that case "a relatively small number of persons was concerned, who were exceptionally affected, in each case upon individual grounds." The language of Art. 230 ECT says "of direct and individual concern." A person is not individually concerned if he is affected only as a member of a general class (Hartley, 2003:360-61). To be individually concerned, a person must be affected "by reason of certain attributes which are peculiar to them or by

(continued…)

The situation has not been much changed by the Commission's recently adopted Better Regulation initiatives, discussed below,[33] which tend to deal with the front end of the lawmaking and rulemaking process. These initiatives champion public participation and such concepts as impact assessment, access, transparency, and stakeholder involvement, but except as proposed to implement the Aarhus Convention in the environmental area, they are not legally binding, insofar as they apply to EU institutions. (EU implementation of the Aarhus Convention does create standing in environmental NGO's with regard to judicial review of acts of public authorities that contravene EU environmental law.) Thus, in general, these initiatives do not envision external enforcement via judicial review.

5. The Interplay Among The Institutions

While the structure of EU government does not fully entail the separation of powers, institutional checks and balances are built into the complex interplay among the EU institutions of the legislative and executive branches. The ability of the various EU institutions (including the Member States) to obtain judicial review of the actions of the others in the European Court of Justice, which *is* a "separated" power, provides an additional element of check and balance.

The structural predominance of the Member State governments in the EU legislative and policy processes gives those processes the feel of treaty negotiation among sovereign states, more than the dynamics of legislation in national level parliaments. EC policy is set chiefly through negotiated political deals involving trade-offs of national interests across a wide range of issues.

The Member States are particularly influential, as states, in the Council – although even in that context they are only indirectly accountable to their national publics. Their influence might be seen in legislation that appears to regulate, but is subtly drawn so that it does not, or is hard to implement and enforce, or *de facto* leaves most of the key substantive and procedural issues involved in implementation to the Member States, who are perhaps understandably loath to turn over actual control (as opposed to the appearance of control) of regulatory policy to EU institutions.[34] There are possible implications, as well, for the extent to which EU legislation imposes relatively general standards through directives or regulations, or instead enacts specific,

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reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed." *Plaumann* v. *Commission*, Case 25/62, [1963] ECR 95 at 107. There is a substantial body of European Court of Justice ("ECJ") jurisprudence since the *Plaumann* case on the meaning of "individual concern." *Cf.*, the discussion of the EU implementation of the Aarhus Convention, text at n. 294 *infra*.

While the new EU Constitution would arguably have expanded standing for private parties by creating a right of action with respect to "a regulatory act which is of direct concern to him or her and does not entail implementing measures," Article III-365, ¶4, "regulatory act," however was defined to exclude *legislative* acts. Article I-33 (1).

[33] Text at n. ____ below.

[34] *C.f.,* Krämer, p. 52.

detailed implementing requirements of the sort normally left for implementing rules or other administrative actions in the US system.

State interests, as such, are least evident in the Commission, whose general tendency may be to push for more, and more stringent, legislation than some Member States feel comfortable with. And as Parliament has increased in power, the Commission has been able to win its cooperation; parliamentarians normally represent particular districts, not countries,[35] and there may even be some electoral tendency to send to the EU Parliament representatives from parties other than those that control national governments.

The differences in perspective among Member States are both exploitable and potential sources of limitation in the struggles over the vertical distribution of power in the EU. Thus, in the environmental area, the Commission has been able to draw on the "green" leanings of the Nordic Member State governments and the German government, reflecting the sentiments of their populations, to push more stringent environmental legislation within the Council. Yet the recent addition of Central and Eastern European countries to the EU will likely reduce their leverage, given the lower standard of living of the accession countries and thus their desire for economic development.

6. EU Lawmaking Instruments

As reflected above,[36] textual expressions of EU law can be ordered in a four-part hierarchy – EU and EC Treaty provisions ratified by Member States (called "primary legislation" in Europe), legislation enacted by the Council and Parliament (called "secondary legislation" in Europe), administrative implementing regulation (called "delegated lawmaking" in Europe), and "soft law" instruments that may set policies or control official (but not private) conduct. An additional source of European law, not directly our concern here, is judicial case law. All of these forms of law, in the aggregate, are commonly referred to as the *acquis communautaire*.[37]

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[35] Member States are free to organize European Parliament elections as they see fit, so that whether representatives in fact represent districts depends on national law. Officially, MEPs sit in the European Parliament according to political grouping, although national parties do tend to remain together within the larger European Parliament groupings. P. Craig and G. De Búrca, EU Law: Text, Cases and Materials, Oxford, 2nd edition, 1998, p. 69.

[36] Text following n. 6 above.

[37] It may be useful to point out that there is more than one meaning to this expression. Generally speaking, "acquis communautaire" refers to existing Community law as interpreted and applied by the Court of Justice, but in Article 2 of the EU Treaty, the expression is used to denote the specific institutional and substantive bases of the Community legal order, on which the Union may not go back. When used in the context of enlargement and accession of new Member States to the Union, the expression refers to the whole corpus of Community law which new Member States have to take over, including:

- The Treaties;
- The decisions taken by the EU Institutions pursuant to the Treaties;

(continued…)

The subsidiary terms "directive" and "regulation" are often used to refer to texts adopted at both the secondary and tertiary levels; these terms specify whether the text requires further legislative implementation at the Member State level ("directive") or operates of its own force ("regulation"). The two forms of legislation have the same characteristics whether adopted by the Council and Parliament as secondary legislation, or by the Commission as tertiary implementing measures. It is always necessary, however, to distinguish in references and citations between Council and Parliament regulations and directives on the one hand, and Commission regulations and directives on the other. The draft European constitution would have ended this confusion, designating legislatively adopted "directives" as "European framework laws" and legislatively adopted "regulations" as "European laws."

Article 249 ECT provides that "in order to carry out their task and in accordance with the provisions of this Treaty, the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions." Generally, the EC Treaty does not provide whether to proceed by way of a regulation, directive or decision, but does occasionally prescribe a particular way of legislating.[38]

Either secondary or tertiary legislation, as we are using the term, must be based on specific authority granted with regard to specific sectoral subject matter in the EU or EC Treaties. Under Article 249 ECT, it may take the form of:

(1) Directives, which bind Member States with respect to the legislative objectives to be achieved within a certain time period, while, at least in theory, giving national authorities the freedom to choose how to translate such objectives into national law (*e.g.*, choice of form and means to use),

(2) Regulations, which are directly applicable and binding on the regulated community in all Member States without the need for any national implementing legislation although Member States often do adopt some form of implementing measure,[39]

- The case law of the Court of Justice.

Lenaerts and Van Nuffel, pp. 51 and 359.

[38] *E.g.*, directive (Article 47 ECT); recommendation (Article 149.4 (education) and Article 151.5 (culture) ECT).

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

(3) Decisions, which are binding on those (*e.g.* Member States, enterprises or individuals) to whom they are addressed, and normally do not require national implementing legislation, and

(4) Recommendations and opinions, which are not binding.

Article 249, however, further defines "decisions" as "binding in [their] entirety upon those to whom [they are] addressed." Because they are addressed to named individuals, "decisions" seem best characterized as executive, perhaps adjudicatory, acts rather than measures of general applicability, and will not be further considered here.[40] This report is focused on administrative "rulemaking" in the US sense of the enactment of generally applicable prospective rules, and not with administrative "adjudication." Nonetheless, the reader should be aware that Commission "decisions" may be thought to play a role in the "standards" process of delegated lawmaking.

At the quaternary level, several other non-statutory forms of administrative actions may constitute "soft law" that resembles legislation or is important to or integral in the development of Commission proposals for legislation or its promulgation of administrative implementing regulation – communications, guidance notes, action programs, and resolutions.

(1) The Commission has used "communications" with some regularity. While they could be classed as "opinions," Krämer takes the position that communications are "not expressly provided for in the EC Treaty." He notes that they are not legally binding, but that :

> They are sent from the Commission to the other institutions, in particular the Council or the Parliament, and expose the Commission's position on a particular problem, indicate orientations and discuss options, which the Commission considers possible…. Communications appear under different headings, as strategies, green or white papers, reports or communications. Legally, there is no difference. Communications may be accompanied by a draft for a Council resolution, a directive, or a regulation.[41]

(2) Guidance notes are now used by the Commission to explain how Member States or the regulated community should interpret and apply certain pieces of EU legislation. They are not legally binding (except perhaps on the Commission itself, until changed), and are probably best classified as a form of "communication" or "opinion."

[40] *See* Paul Craig & Grainne De Búrca, EU Law – Text, Cases and Materials 115 (3d ed. 2003); Lenhaerts and VanNuffel, pp. 780-81.

[41] Krämer, p. 55.

Member States tend to resist Commission "guidance," which they believe encroaches upon their freedom to implement.

(3) Action plans, legally taking the form of "communications," have been used by the Commission from the early 1970's. They set out for a period of four-five years the objectives, principles and priorities of Community action which the Commission envisages during this period. At a time when environmental legislation had no express legal basis in the EC Treaty, action plans setting out environmental objectives were found by the European Court not to "contain legally binding or enforceable provisions," and were followed by political resolutions by the Parliament and the Council.

(4) Resolutions are political statements by the Council or the Parliament which have no basis in the EU or EC Treaties.[42] They are frequently in reaction to a Commission communication, are not legally binding, and are adopted by consensus in the Council and by majority vote in the Parliament.[43]

7. The EU Legislative Process

In most areas, only the Commission has the authority to propose legislation, while the Parliament and the Council have the authority to amend and adopt such legislation. As a general matter, the extent to which the Council and the Parliament may exercise their right of amendment and adoption depends principally on the type of legislation involved and the subject matter of the legislation. In other words, legislation dealing with various types of subject matters – various sectors – has different authorizing sections in the EU and EC Treaties.

Thus, the subject matter of the legislation determines the proper authorizing section (the legal base) in the treaty. Each separate authorizing treaty section then generally specifies the legislative procedure applicable to the subject matter in question, and thus the relative powers of the Council and Parliament. For example, most environmental decisions are subject to co-decision, while agricultural measures are normally subject to the consultation procedure. For binding legislative instruments of general validity (*i.e.*, regulations and directives), the types of legislation of most interest in this report, there are at present essentially two types of legislative procedure – the consultation procedure and the co-decision procedure. Of those, the co-decision procedure is the more important.

The co-decision procedure is spelled out in Article 251 ECT. This complex procedure takes place *after* a Commission proposal for legislation has been delivered to

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[42] *Id.*, p. 57.

[43] *Id.*

the Council and the Parliament. It generally allows the Council to act by "qualified majority" voting, allows the Parliament (which acts by simple majority) to interact directly with the Council in the development of the ultimate legislation and gives Parliament an effective veto over the terms of that legislation. The 2006 REACH Regulation, for instance, was adopted pursuant to this co-decision procedure.[44]

Other issues, governed by Article 175 (or possibly Article 94) ECT, call for unanimous voting in the Council and must be subjected to the consultation procedure. Under this procedure, the Parliament must be consulted but it has no direct right to participate in the development of the legislation with the Council and has no veto power. For examples taken from the environmental area, matters that:

- are primarily of a fiscal nature,
- affect town and country planning
- affect quantitative management of water resources or affecting, directly or indirectly, the availability of those resources that affect land use, with the exception of waste management, or
- significantly affect a Member State's choice between different energy sources and the general structure of its energy supply

fall under the consultation procedure of Article 175, ¶2 ECT. Internal market measures that constitute fiscal provisions, provisions relating to free movement of persons, and those relating to the rights and interests of employed persons are also subjected to unanimous voting in the Council and the consultation process by Articles 94 and 95, ¶2 ECT.

8. EU Delegated Lawmaking

One question that might be raised about European legislative acts generally is whether they are prone to leave unsettled questions requiring further lawmaking by inferior authorities. This is, of course, the dominant experience in American administrative law, and the engine of the contemporary interest in and importance of rulemaking procedures. Two decades ago, Ed Rubin underscored the increasing difficulty of the "delegation" problem in American perspective with his observation that Congress had virtually ceased solving problems legislatively – that it had moved, rather, to the habitual creation of regulators through what he styled "intransitive" legislation. As public choice analyses of congressional action are also prone to point out,[45] this is not

[44] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93, O.J. L 396/1 (30.12.2006).

[45] *See*, *e.g.*, David Schoenbrod, Power Without Responsibility (1993).

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 frequently address a particular, relatively detailed subject – for example, the constraints on genetically modified organisms (GMOs) in European agricultural markets – and identify with some precision the "essential requirements" of that subject, that others are required to honor in implementing legislation or regulations. In these situations, they much more closely resemble EPA regulations bearing on state implementation plans (*e.g.*, under the Clean Air Act in the environmental area of regulation) 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, in order that the Member States acting in the Council can be sure that they have controlled the outcome?

Yet EU legislation has other characteristics as well. It is shaped by the constraints of subsidiarity and proportionality, the frequent enough need to find diplomatic formulations capable of accommodating national differences, and the contemporary preference for flexible new governance approaches embodying repeated benchmarking and mutual learning. The result, as mentioned above, may often be in legislation that appears to regulate, but is subtly drawn so that it does not, or is hard to implement and enforce, or *de facto* leaves most of the key substantive and procedural issues involved in implementation to the Member States, All these influences suggest that, for all their seeming detail, EU legislative acts will often leave considerable leeway and discretion,[46] although the penchant for implementation at the national level or through comitology where Member State representatives participate directly in the relevant committees shows that one key objective of the Council is to ensure that Member States can retain control of the result even if there is delegation of important details. Indeed, as earlier remarked, EU implementing measures dominate EU

[46] 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.

Email of 12/21/2004.

legislative acts on a numerical basis, in about the same proportion as regulations dominate statutes in the United States.[47]

One must look to specific authorization in the EU and EC Treaties to determine which institution has, as a matter of law, implementing powers under EU legislation, and on what terms. This is so because EU institutions have only the powers conferred, and because the executive and legislative powers are not conferred exclusively on any one institution. Even so, it is the Commission, as a practical matter, that has the bulk of the implementation authority. It carries out this authority in two main ways – through the comitology process and through the standards process.

Comitology procedures are the means by which the Council (and Parliament) most often implement the terms of Article 202 ECT, which provides that the Council shall:

> confer on the Commission, in the acts which the Council adopts, powers for the implementation of the rules which the Council lays down. The Council may impose certain requirements in respect of the exercise of these powers. The Council may also reserve the right, in specific cases, to exercise directly implementing powers itself. The procedures referred to above must be consonant with principles and rules to be laid down in advance by the Council, acting unanimously on a proposal from the Commission and after obtaining the opinion of the European Parliament.

Although under this provision the Council can and occasionally does reserve and exercise implementing power directly, in the general case it is to give the principal executive role to the Commission, subject to "principles" and "rules" that the Council lays down. These "implementing powers" encompass the authority both to adopt implementing directives and regulations (secondary to, and subject to, EC legislation) and to apply rules to specific cases by individual decisions.[48] The use of implementing powers has been broadly construed by the European Court of Justice. The Commission may in some circumstances be authorized to compel Member States to take temporary measures if the aims of harmonization of national legislation would otherwise be jeopardized; and it may impose penalties on Member States in its implementing provisions, for example, where "designed to secure the proper financial management of Community funds."[49]

Comitology procedures require the Commission to collaborate with legislatively designated committees in exercising its delegated authority. The "comitology" process

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[47] *See* text at n. 7 above.

[48] EU Constitutional Law, ¶14-052. Recall the possibly confusing nature of the "directives" and "regulations" language, text following n. 34 above.

[49] *Id*.

is governed by generic Council Decision; the current such decision is the Comitology Decision of June 28, 1999, amended by Council Decision of 17 July 2006 (2006/512/EC) ("July 2006 Council Decision").[50] Committees are made up of representatives of the Member States, and chaired by a representative of the Commission. The Comitology Decision defines the types of committees, and the procedures each type is to follow. Typically, the Council and Parliament, when legislating, set out in the legislation the nature and extent of the implementing power being delegated to the Commission, reference the Comitology Decision, and select the relevant committee (and by doing so, select also the procedures to be followed). Comitology processes are pervasively used to further elaborate, to set standards under, or to update ("adaptation to scientific and technical progress") legislation over time. Thus they deal with crucially important issues and details of elaboration and implementation. They are further discussed below at page [77].

A second way the Commission handles administrative implementing regulation involves the use of a standard-setting process – what is called the "New Approach" to technical harmonization and the "Global Approach" to conformity assessment.[51] The Council has used this process in some 25 directives since 1987 – chiefly in areas relating to product regulation, where detailed, uniform technical regulatory specifications are needed to ensure freedom of movement of goods in the internal market.[52] The approach is for the legislature to set mandatory general "minimum essential requirements," and to require that all products in a sector be in conformity with those requirements (and generally to show that conformity by qualifying for and displaying a "CE" mark) in order to be legally placed on the EU market. The legislator allows the Commission to delegate to national or Europe-wide private standards organizations the elaboration (pursuant to a Commission "mandate") of more detailed technical specifications to implement the "essential requirements" (such specifications are normally called "harmonized European standards"), and techniques for showing or judging compliance with those requirements (*e.g.*, certification and testing procedures, called "conformity assessment procedures"). These specifications and procedures are then reviewed by the Commission, and if accepted, are published in the Official Journal. Once published, compliance with these standards creates a presumption of compliance

[50] Council Decision 1999/468/EC of 28 June 1999 Laying Down the Procedures for the Exercise of Implementing Powers Conferred on the Commission, 1999 O.J. (L184/23). This Comitology Decision, and its recent 2006 amendment, were both driven by the Parliament's desire to participate in implementation of acts adopted by co-decision. EU Constitutional Law, ¶14-054. They govern the exercise of delegated power by the Commission, when invoked by legislation calling for such delegated action.

[51] In light of the "voluntary" nature of the standards, both as adopted at EU and at Member State level, it might be argued that the standards process is one of soft law only, and thus is not properly termed or considered a process of "delegated legislation." The discussion of standards in this report, p. 88 ff. below, indicates the peculiar nature of their legally binding effect, however, despite their being "voluntary," so we analyze them as a form of delegated legislation. What the process is called may not in any case make much difference for purposes of the analysis. It is not clear that the applicability of the various Commission provisions dealing with access to documents and public participation that are considered in the analysis would differ if the standards were called soft law and not "legislation," delegated or otherwise.

[52] Thus, as the Competition Report indicates, "new approach" techniques are not used in competition law.

with the pertinent directive's "essential requirements," which implies that the authorities will have the burden of proving that a product, despite compliance with the standards, does not meet the essential requirements. If a company chooses not to comply with the standards, which it is free to do, it must demonstrate separately in each Member State that its products meet the essential requirements.

It is worth drawing the reader's attention to the so-called "open method of coordination," which thus far been used only in the employment and social sector (*see* page [ ], below). This "soft law" approach is aimed at identifying goals for mutual pursuit by Member States, rather than setting common obligations for Member State implementation.[53] The approach is one that could be generalized into other areas of Commission activity as well. It is particularly well suited to contexts in which the Community lacks explicit legislative competence or has competence only to define minimum rules, but Member States nonetheless conclude it would be useful to seek unified or coordinated outcomes.

Finally, it may be useful to note a provision for coordination of Commission and Member State action that has considerable importance for protecting the single market. A 1998 Directive, the Standstill Directive,[54] lay down a procedure for the provision of information in the field of technical standards and regulations. Under the Standstill Directive, Member States must provide the Commission with draft national regulations creating technical standards; they must postpone the enactment of these proposals for 12 months if the Commission declares its intention to legislate on the matter at the EU level. One readily understands this a measure to secure the common market against local technical standards that may have a discriminatory effect. In the EU (DG-SANCO) as in the American context, this difficulty has often emerged between the states in the context of ostensibly safety-related regulation of food products. New Approach undertakings, discussed at greater length below, are particularly likely to stem from it. But of course the issue is not limited to the food context. DG Enterprise has established a Technical Regulation Information System (TRIS) website,[55] permitting anyone to

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[53] The original idea behind it was to work towards harmonization in sensitive areas where there was not yet a sufficient common basis for legislative initiatives.

[54] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, O.J. L 204 of 1998. 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 standardization in the framework of European policies and legislation, SEC(2004) 1251 pp. 2 & 4 and an accompanying Commission staff working document, "The challenges for European standardization," express considerable enthusiasm for experience to date, the hope both for exploitation of "room for improvement" and the high desirability of "making use of standards in areas of Community legislation beyond the Single Market." The general question of private standards development, and its relation to governance issues in the EU (and the United States, and international markets generally) is fully explored in Harm Schepel, The Constitution of Private Governance (Hart Publishing 2005). *See* especially *id*. at 50-67 and 101 ff. And a very recent "Communication from the Commission to the Council and the European Parliament" on "Better Regulation for Growth and Jobs in the European Union" (COM (2005)97 Final) strongly suggests that the future lies with increasing reliance on private/public law-generation.

[55] http://europa.eu.int/comm/enterprise/tris/. The Commission's 2003 report discussing this website, n. 241 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

(continued…)

enroll 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.[56]

C. Sector Summaries

1. The Competition Law Sector

The Directorate-General of Competition (DG COMP), through delegation, is the principal Commission element charged with the task of ensuring the creation and maintenance of effective open markets and competition within the EU. In the competition area, both secondary (Commission-Council-Parliament) and tertiary (Commission) standards are normally set by regulation rather than directive, since the European Commission enjoys enforcement authority in respect of behavior of private parties covered by the main EU legislative instruments in this area. Even so, much of the work of DG COMP involves making individual decisions in the competition area, and a good deal of decision-making activity over competition has effectively been moved to the Member States.

DG COMP initiates Council legislation either as a result of internal discussions or studies, or as the result of external influences. In addition to those provisions for notice required by Commission practice, DG COMP uses its Competition Law Newsletter (a policy-focused quarterly) and annual Report on Competition Policy, as well as informal means like speeches to inform the public of its plans. It has often used Green Papers and White Papers for public consultation, and encourages informal contact with the teams it forms to develop policy proposals.

Like its legislative proposals, DG-COMP implementing measures are more often regulations than directives. Although it gives notice of these initiatives to the public in much the same way as for Council Regulations, the possibility of public participation has been much more limited, and its procedures tend to vary case-by-case. In issuing "soft law" Notices or Guidelines, possibly binding on the Commission under the principle of legitimate expectations,[57] but not on the parties, it has been less open to third party influence in initiating a matter, but has often provided extensive notice and consultation opportunities once the process is initiated, usually making public a summary document of the submissions.

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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.

[56] The notices one author has thus far received in several months' 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 week's time; but few notices of an available translation has yet arrived.

[57] Association Internationale des utilisateurs de fils de filaments artificiels et synthétiques et de soie naturelle (AIUFFASS) and *Apparel, Knitting & Textiles Alliance (AKT) v. Commission*, Case T-380/94, 1996 E.C.R. II-2169.

2. The Environmental Sector

The environmental sector, under DG Environment, deals primarily with the regulation of the environmental impacts of industrial and commercial manufacturing plants (including the environmental impacts of industrial accidents) and of the products those plants make. It encompasses regulation of air and water pollution, waste, releases to the environment from industrial accidents and other sources and impacts on special environments such as wetlands, groundwater, and natural areas. Product regulation focuses on ecolabeling and on the harmful environmental impacts of chemicals and use of automobiles, as well as the life cycle of use, reuse, recycling and disposal of products of all sorts. Plant regulation frequently requires implementation by plant specific permits, normally at the Member State level. Product regulation frequently requires implementation through use of EU-level comitology to list products or product types.

The European Environment Agency, located in Copenhagen, Denmark, is a non-regulatory entity that chiefly provides information on the EU environment and coordinates the gathering of basic environmental data.

The EU's treaty authority to legislate in the environment, health and safety areas derives chiefly from two main EC Treaty provisions – Articles 95 ECT (Internal Market) and 175 ECT (Environment) – although others may be invoked under the "integration" provisions of Article 6 ECT. These two main provisions specify use of the co-decision procedure for legislation on environmental issues. Where the consultation procedure may be used for environmental legislation, for example under Article 94 ECT for some forms of environmental taxes, the Council must adopt the measure unanimously. Valid EC environmental legislation pre-empts that of the Member States., but the Treaty and secondary legislation give the Member States some leeway to impose requirements going beyond EU legislation.

In the environmental area, DG ENV acts chiefly through directives, using regulations much less often. This may reflect the wish of Member States to retain freedom of action with regard to issues touching on the environment and natural resources; product-related environmental issues typically involve a more highly centralized EU response. DG ENV frequently uses "soft law" guidance notes to explain how Member States or the regulated community are to interpret or apply certain pieces of EU environmental legislation. From the early 70's, it has developed community environmental action plans, technically "communications" to "set out for a period of four-five years the objectives, principles and priorities of Community action." Under the current (Sixth) Environmental Action Plan, the Commission has also used sectoral action programs.

DG ENV uses the comitology process extensively to further elaborate environmental legislation, to set standards under it, or to update it over time ("adaptation to scientific and technical progress") A recent example can be found in the context of

ecolabeling; the regulation[58] develops ecolabel criteria through a regulatory committee procedure involving a broad-based consultation forum including representatives from industry and ENGOs. The Energy-Using Products Directive will utilize a similar approach for developing eco-design standards for specific product groups.

DG-ENV has also used the "New Approach" to technical harmonization and the "Global Approach" to conformity assessment, in the environmental sector, but only sparingly. The chief examples are in the area of packaging and packaging waste, and to a limited extent in respect of product marking under the Waste Electronics Directive.

The EU now has a relatively developed system of EU environmental policy and legislation. The political importance of the issues dealt with led the promoters of the EU venture to seize on EU environmental policy early on as a vehicle for gaining public support for the EU experiment. A response at the EU level to public concern over the environment was thought to be a good way to popularize and promote the usefulness of EU level regulation. Thus, while EU level policy and legislation has evolved somewhat more slowly than did such policy and legislation in the US, it has played a key role in the evolution of both the EU's governmental architecture and its development of administrative rulemaking procedures.

Indeed, it can be argued that it played a leading and catalytic role in the development of EU administrative law similar to that played by US environmental, health and safety law in the development of US administrative law and judicial review in the US from 1970 to date, in each case for the same reason. As EU environmental policy and legislation has developed an express basis of authorization in the EC treaties, and as its methods of enactment and accompanying rights to transparency and accountability have evolved, its development has at least paralleled, over time, and perhaps importantly influenced, the steady evolution of the treaty architecture of the EU itself. Further, the elaboration of EU environmental policy at the EU level has been the catalyst for some of the most important developments in EU administrative practice, particularly with regard to the EU's European Governance and Better Regulation Initiatives.

3. The Financial Services Sector

Such Financial Services Sector matters as securities regulation, banking regulation, and regulation of other financial institutions like insurance companies and brokerage firms, are the province of DG Internal Market. The relevant Council of Ministers is the ECOFIN. Legislation in this sector is characterized by use of both secondary (Council-and-Parliament) Directives and Regulations, and tertiary (Commission) Directives and Regulations.

[58] REGULATION (EC) No 1980/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 July 2000 on a revised Community eco-label award scheme.

The dramatic changes in financial sector legislation the last 10 years, as the EU has attempted to develop a single integrated financial market to foster economic growth and implemented the Euro, are discussed at some length in the fuller sectoral account below. Here it may be sufficient to note a legislative process that was both extraordinarily efficient and extraordinarily consultative, under the guidance of a committee of independent persons chaired by Baron Alexandre Lamfalussy (dubbed the committee of wise men), to advise with respect to the regulation of securities markets. ECOFIN established the committee in July 2000, given concerns about the need to move to a single securities market even more rapidly than envisaged its earlier, sweeping and ambitious Financial Services Action Plan (FSAP) – and given also some debate as to whether to move to a single EU securities regulator. The committee immediately launched a process of consultation, including an online questionnaire,[59] and meetings with interested parties. The publication of its initial report in November 2000 itself called for a wide debate on its preliminary conclusions, and the committee released its final report in February 2001.[60]

The main conclusion of the Lamfalussy Report, as it is known, was that the principal cause of the problems in the regulation of EU securities markets was the EU legislative process itself. Rather than suggest establishing a European SEC with power to apply a single European rulebook, the committee focused on four levels within the regulatory process.

- EU legislation in the form of directives should state key principles rather than detailed rules. This should speed up the process of agreeing and adopting directives and make them more flexible to deal with changing circumstances.

- A new securities committee, comprising the European Commission and national representatives, should have powers to make and update the technical rules implementing those principles, supported by an advisory committee of national securities regulators. The report effectively envisaged that the Level 1 directives would confer powers on the European Commission, acting in conjunction with the new securities committee, to adopt implementing measures under the "comitology" process.

- There should be enhanced cooperation and networking among EU securities regulators to ensure consistent and equivalent transposition of Level 1 and Level 2 legislation.

[59] The questionnaire is available on the Commission's website at http://europa.eu/internal_market/securities/lamfalussy/index_en.htm.

[60] *See* supra note 3.

- There should be strengthened enforcement of EU rules to ensure greater consistency and timeliness in the implementation of directives.[61]

The Lamfalussy committee also recommended making greater use of regulations, rather than directives, when legislating in the securities area, and a strong commitment to transparency and consultation throughout the rulemaking process. Before it draws up a legislative proposal, the committee recommended, the Commission should consult in an open, transparent and systematic way with market participants and end users, including through the use of open hearings and the Internet. It also recommended making a summary of the consultation process available with the final proposal. In addition, the Commission should continue to consult Member States, their regulators and the European Parliament informally, as early as possible, about forthcoming proposals. Importantly, the committee recommended that this commitment to transparency and consultation should to tertiary as well as secondary legislative acts. Finally, the committee recommended accelerating the timetable for adoption of the FSAP.

The committee's recommendations received widespread support. Within a few weeks of the final report's release, the European Council[62] resolved that the four level approach should be implemented, including the recommendations on transparency and consultation. Three months later, the European Commission established the European Securities Committee (the "ESC")[63] and the advisory Committee of European Securities Regulators ("CESR").[64]

The European Parliament, however, saw in the proposed extension of the comitology process threats to its legislative role, and to the inter-institutional balance among the Parliament, the Council and the Commission. These difficulties were overcome in January 2002 when, after prolonged discussions among the three bodies, the President of the Commission made a solemn declaration in Parliament, supporting an amendment to Article 202 of the ECT to give the European Parliament an equal role with the Council in controlling the Commission in carrying out its executive role.[65] This

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[61] FINAL REPORT OF THE COMMITTEE OF WISE MEN ON THE REGULATION OF EUROPEAN SECURITIES MARKETS, Brussels, 15 February 2001, Chapter II, Regulatory Reform, p. 19.

[62] Resolution of the European Council on More Effective Securities Market Regulation in the European Union Stockholm, Annex 1 to the Presidency Conclusions, Stockholm European Council, 23 and 24 March 2001, available on the Council website at http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/ec/00100-r1. %20ann-r1.en1.html. Recall that the "European Council," composed of the Heads of Member States and the President of the Commission, is to be distinguished from the Council we are chiefly discussing in this report. *See* p. [_], above.

[63] Commission Decision of 6 June 2001 establishing the European Securities Committee (2001/528/EC), O.J. L 216, 13.7.2001, p. 45.

[64] Commission Decision of 6 June 2001 establishing the Committee of European Securities Regulators (2001/527/EC), O.J. L 216, 13.7.2001, p. 43.

[65] *See* Commission press release, Mr. Romano Prodi President of the European Commission "Implementation of financial services legislation in the context of the Lamfalussy Report" Intervention by President Romano Prodi to the European Parliament's plenary session Strasbourg, 5 February 2002 (SPEECH/02/44) and

(continued…)

declaration paved the way for the Council's subsequent call, in April 2002, for a review of the committee architecture for other financial services sectors. After further prolonged discussion,[66] 2004 saw the creation of a parallel architecture of advisory and regulatory committees for the banking and insurance and occupational pensions sectors.[67]

4. The Food Safety Sector

European food safety regulation, aimed chiefly at eliminating barriers to the free movement of food goods, is administered in the Directorate General for Health and Consumer Protection, DG SANCO. It consists mainly of rules related to labeling and approval of substances used in or in conjunction with food. It deals with such things as new foods (known in the EU as "novel foods"), genetically modified foods, food additives, food decontamination, food contact material (packaging), food color, and food flavoring. Originally largely ad hoc, it has been made more uniform in some regards by the adoption in 2002, in response to the BSE crisis, of a general framework Regulation on food law, Regulation 178/2002 (the "General Food Law Regulation").

Increasingly, legislation about food safety is in Regulation rather than Directive format. Most implementing measures concern the pre-market authorization of particular products, which may be accomplished either through the adoption of Commission Regulations or Commission Decisions, using comitology and after substantive participation by the European Food Safety Agency. Some of the older legislation, however, requires authorization through the adoption of Directives. In some situations, the applicable legislation does not specify what form the authorization is to take. While DG SANCO relies heavily on comitology in the food safety sector, it does not use the "New Approach" standards process.

Where the EU acts by Regulations or Directives, whether adopted by the Council and Parliament or by the Commission through comitology, there is effectively no judicial

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Commission press release, Financial markets: Commission welcomes Parliament's agreement on Lamfalussy proposals for reform, 5 February 2002 (IP/02/195).

[66] *See*, *e.g.*, European Commission, Note to the Ecofin Council, Financial Regulation, Supervision and Stability (December 2002), available on the Commission website at http://ec.europa.eu/comm/internal_market/finances/docs/cross-sector/consultation/ecofin-note_en.pdf.

[67] *See* Commission Decision of 5 November 2003 establishing the Committee of European Banking Supervisors (2004/5/EC), O.J. L 003, 07.01.2004, p. 28; Commission Decision of 5 November 2003 establishing the Committee of European Insurance and Occupational Pensions Supervisors (2004/6/EC), O.J. L 003, 07.01.2004, p. 30; Commission Decision of 5 November 2003 amending Decision 2001/527/EC establishing the Committee of European Securities Regulators (2004/7/EC), O.J. L 003, 07.01.2004, p. 32; Commission Decision of 5 November 2003 amending Decision 2001/528/EC establishing the European Securities Committee (2004/8/EC), O.J. L 003, 07.01.2004, p. 32; Commission Decision of 5 November 2003 establishing the European Insurance and Occupational Pensions Committee (2004/9/EC), O.J. L 003, 07.01.2004, p. 34; 2004/10/EC: Commission Decision of 5 November 2003 establishing the European Banking Committee (2004/10/EC), O.J. L 003, 07.01.2004, p. 36; and Directive 2005/1/EC of the European Parliament and of the Council of 9 March 2005 amending Council Directives 73/239/EEC, 85/611/EEC, 91/675/EEC, 92/49/EEC and 93/6/EEC and Directives 94/19/EC, 98/78/EC, 2000/12/EC, 2001/34/EC, 2002/83/EC and 2002/87/EC in order to establish a new organizational structure for financial services committees, O.J. L 079, 24.03.2005, p. 9.

review. As we have seen, legislative actions, whether secondary or tertiary, are not ordinarily reviewable. Where a Decision is issued, however, the regulated entity, but not the general public or other interested parties, can normally obtain judicial review of the action or inaction involved.

A number of EU bodies assist DG SANCO in its work. The European Food Safety Authority (EFSA) is the scientific advisory organ for the Commission on food safety matters,[68] and has a legislatively prescribed role in the consideration of most implementing measures such as individual product authorizations, where it must review the application and issue an opinion to the Commission and the Member States. The EU Food and Veterinary Service (FVO) is a Commission service that conducts inspections on food safety, food and animal hygiene and animal welfare, assisting the Commission in fulfilling its obligation to ensure that Community legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced.

DG SANCO habitually consulted on its actions only with pan-European or international bodies, making transcripts (if at all) and its conclusions available only long after its meetings. Slow to respond to the various Commission initiatives on consultation and transparency, it has recently begun to change. As is typical of all directorates studied, its comitology processes are particularly likely to be opaque to non-participants. Agendas are published on the Commission's homepage usually a few days before (but sometimes also after) the meeting date, and summary meeting reports are available on the Commission's website, but normally only one or two months after the meeting has taken place. DG SANCO's processes have become somewhat more uniform in the wake of the passage of the 2002 General Food Law Regulation and the recent generic Commission Communications on Better Regulation. In cases arising from "decisions," the European Court of Justice has also begun to force the pace of change as to procedures for authorization and it may do so further.

5. The Telecommunications Sector

Telecommunications in the EU has largely been in the hands of State monopolies until relatively recently,. With the introduction and application of information technology in the telecommunications sector, the early 1980's began to see the privatization of some national operators and the introduction of competition, albeit very limited, in some Member States. A 1987 Commission Green Paper then set forth the grounds for a legal framework liberalizing and harmonizing the telecommunications sector. Today, EU telecommunications is mainly privatized and liberalized, with a similar body of rules applying across the EU. However, with few exceptions, the 25 incumbent operators still maintain very strong market position.

[68] It replaced the Scientific Committee for Food on its establishment in 2002 in the General Food Law Regulation.

The European Commission launched three successive stages of legislative intervention to liberalize and harmonize an industry controlled by State monopolies. A 1984 initiative aimed at creating a common ground for development, placing focus on common industry standards, common industry-wide research groups (at the European level), and the development of common European positions in the international telecommunications sector. Then, a 1987 Green Paper on Telecommunications[69] set the stage for a broad debate on the liberalization and harmonization of telecommunications in the EU, that led to "1998 Regulatory Package." Finally, the rapid changes in technology, convergence, and an increasingly competitive and liberalized market, led the Commission to create a new regulatory framework applicable since July 2003 (the "New Regulatory Framework"). The Commission is currently involved in a review of the New Regulatory Framework legislation mandated by the Framework Telecommunication Directive.

Three DGs have competence in the area of electronic communications: DG Information Society and Media; DG Competition; and DG Internal Market. Most Council and Parliament Directives in the telecommunications sector are adopted under Article 95 ECT (Internal Market). At the tertiary level, these DGs use both comitology and "new approach" processes. Comitology committees include the Communications Committee, a mixed advisory and regulatory committee, and the Radio Spectrum Committee, a mixed advisory and regulatory committee. The Commission has also created various new working groups aimed at assisting it in the correct and harmonized implementation of the New Regulatory Framework. The most important of these is the Radio Spectrum Policy Group, established by a Commission Decision which requires that the Group itself consult "extensively and at an early stage with market participants, consumers and end-users in an open and transparent manner."

Because uniform technical specifications are central to the operation of mutual type approval between Member States, and to the development of a single European telecommunications market, telecommunications regulation makes substantial use of New Approach. The most active standards bodies are the European Telecommunications Standardization Institute (ETSI) and the European Committee for Electrotechnical Standardization (CENELEC).

National regulatory authorities (NRAs) have the primary responsibility for implementing and enforcing the EU regulatory framework In the telecommunications sector.

Finally, at the quaternary level, Commission Recommendations are in widespread use in the telecommunications sector, and are often accompanied by an explanatory memorandum. The Commission also uses Guidelines, normally to provide guidance in the application of legislation to a particular industry sector.

[69] Communication by the Commission - Green Paper on the development of the common market for telecommunications services and equipment - Towards a dynamic European economy (COM (1987) 290) of 30 June 1987.

6. The Workplace Sector

The Directorate General for Employment and Social Affairs (DG EMPL) is responsible for legislation relating to employment, social affairs and equal opportunities (hereafter "workplace regulation").[70] This EU sector is almost *sui generis*, due to the express role given to unions and employers in the legislative process. These "social partners" as they are known in European usage, are given special rights as initiators, consultants and implementers of the law regulating them.[71] Reflecting the relative balance of power in this sector between the Member States and the Community, the EU's practice is to use chiefly "directives" establishing "minimum requirements" for "gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States," rather than regulations directly applicable to individuals and organizations, although there are exceptions;[72] and it also uses much soft law and important special soft law processes. This results in great complexity in the lawmaking procedure.

EU legislative procedures in this sector reflect political choices going back to 1985. Article 137 ECT provides for normal legislative processes, but signals the special character of this area of EU law in describing the Community role – it "supports and complements" the activities of the Member States (as opposed, for example, to liberalizing or harmonizing their law and regulation). Directives, not regulations, are to be used, and while co-decision is sometimes provided for, a number of areas of workplace regulation require use of the consultation process (*i.e.*, imposing a requirement of Council unanimity to act) or are outside the scope of Community authority altogether. The very first question in the initiation of legislation is whether Community -level action is appropriate, and Article 138, ¶3 ECT requires that the social partners be consulted on this point ("the possible direction of Community action"). Consultation may extend the Economic and Social Committee (EESC, an institutional assembly of appointed representatives of the various spheres of economic and social activities) the Committee of the Regions (CoR, a Treaty-based consultative committee made up of appointed representatives of local and regional authorities) and advisory

[70] Although DG EMPL has the lead responsibility, other Directorates-General, such as DG MARKT, deal with legislation that directly or indirectly relates to workplace issues. Examples are the rules regarding recognition of professional qualifications, social considerations in public procurement, the law applicable to an employment relationship, and working time for employees in the road transport sector. In addition to employment and social legislation, DG EMPL deals also with legislation on free movement of workers, including pensions, coordination of social security schemes, equality between men and women, and anti-discrimination.

[71] Because of these official roles, Articles 138 and 139 ECT set out rules on the representativeness of the qualifying organizations to address the issues of legitimacy and effectiveness. The *de facto* influence of the social partners, of course, is diminished if they are unable they reach agreement, as has happened on issues such as working time and portability of supplementary pension rights.

[72] For instance, in the area of social security, Regulation (EC) No 629/2006 of the European Parliament and of the Council of 5 April 2006 amending Council Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community and Council Regulation (EEC) No 574/72 laying down the procedure for implementing Regulation (EEC) No 1408/71, *O.J. L 114, 27.4.2006, pp. 1–8*. Regulation 1408/71 on the coordination of social security systems is the key EU law on social security.

committees – none of which are comitology. Rather, all are consultative committees comprised of 3 or 6 members per Member State, and representing the national government, the trade unions and the employers' associations.

DG EMPL appears to have complied with the Commission's 2002 Communication on Consultation in its actions since publication of that communication,[73] and has begun to comply with the Commission's Impact Assessment Communication and Guidelines. Further, in 2005, for the first time, the Commission made available a list of the expert groups divided by DG. For DG EMPL alone, there are some 170 groups and subgroups of experts and advisers.

Rather than comitology, implementation is generally left to the Member States, which in turn may entrust implementation of normal legislation to the social partners, under Article 137, ¶3 ECT. The Member State nonetheless remains responsible for the result.

A "social dialogue" process under Article 139, ¶2 ECT, unique to the labor area, allows the social parties both to develop and to implement legislation and enforceable agreements, independent of whether the Commission has initiated the legislative process and unrestricted as to subject matter. During the consultation process, the social partners can, at either [**check**] point of mandatory consultation with them by the Commission, notify the Commission, under Article 138, ¶4 ECT, that they choose to use the procedure in Article 139, ¶2 ECT to conduct a "social dialogue" at Community level, and within nine months (if there is no extension), to make an agreement among themselves preempting the normal legislative process.[74] This agreement can then result in one of two legal instruments. When it is within the scope of Article 137 ECT, and on the joint request of the social partners, it can be adopted into law as a Council and Parliament Directive[75] on proposal by the Commission; alternatively, it may remain a contractual agreement between the parties (an "autonomous agreement").

Soft law plays a large role in the workplace sector in the EU, given the lack of real power on the part of the Community to force reform and change on the Member States. The major example of soft law in employment is the European Employment Strategy ("EES"), initiated on the basis of the provisions of the Amsterdam Treaty, providing for the principal soft law procedure in labor law. Where the Community does not have legislative competence or where the Community has competence only to define the minimum rules, an EES procedure for generating this guidance, and known

[73] [Check re compliance with full public participation rather than just with social partners during the mandatory consultation with the latter; rendered moot by allowing such public participation by another round of participation, including the full public, ***after*** the legislative proposal was developed?]

[74] In the past, only three organizations were allowed to take part in the European Social Dialogue: ETUC (European Trade Union Confederation), UNICE (Union of Industrial and Employers' Confederations of Europe), and CEEP (European Centre of Enterprises with Public Participation and of Enterprises of General Economic Interest). Currently, over 50 organizations are consulted. For further details *see* note [ ], below.

[75] While Article 139, ¶2 ECT speaks only of a "Council Decision," such decisions have so far been in the form of directives.

as the "open method of co-ordination, is based on five key principles: (i) subsidiarity, (ii) convergence, (iii) management by objectives, (iv) country surveillance, and (v) an integrated approach.

III. The Process By Which EU Rules Are Made

A. Framing legislation

We start, then, with the framing of legislation – "statutes," in the American context; "regulations" and "directives" under the current EU treaties. Previous discussion[76] identified the distinction between a regulation, which may have direct legal effect permitting enforcement by individuals, and a directive, which "shall 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."[77] It would be a mistake, however, to think that "directives" empower only Member States, or that they can in no circumstances be directly enforced against individuals. First, although the quoted language self-evidently creates opportunities for delegation to Member States, the principal source of implementing measures, it may also be 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;[78] 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 the relevant EU authorities, through the comitology process, to revise those parameters as developing technology makes possible. Second, although the language "leav[ing] to the national authorities the choice of form and methods," would appear to create obligations that, at least in formal terms, only the Commission can directly enforce,[79] the European Court may in some situations give directives legal effect in private litigation, even litigation between two private parties. As has been observed, "the distinction between directives and regulations remains salient in political terms even while the legal consequences of their use are complex and confused."[80]

The discussion here will be limited to the framing of proposals for legislation, treating debate and enactment as matters outside the purview of this report. Respecting the latter, it seems sufficient to remark that enactment procedures are

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[76] Recall the discussion at p. 22 above.

[77] Art. 249 (ex 189) ECT.

[78] MARPOL 73/78.

[79] Arts. 226, 228 ECT.

[80] Craig & De Búrca, op cit n. 37 above, at 227; *see* generally *id*., "The Legal Effects of Directives," p. 202 ff.; Sacha Prechal, Directives in EU Law (2005). For example, a directive will often set a time by which compliance is required; after the expiration of that time, private parties may be able to avail themselves of national non-compliance with the directive defensively in litigation with the non-complying nation or its agencies.

themselves set by the relevant treaty provisions. For binding legislative instruments of general validity (*i.e.*, regulations and directives), there are at present essentially two types of legislative procedure – the consultation procedure and the co-decision procedure. Of those, the more important is the co-decision procedure, a complex process that generally allows the Council to act by "qualified majority" voting, allows the Parliament (acting by simple majority) to interact directly with the Council in the development of the ultimate legislation and gives the Parliament a veto over the terms of that legislation. Under consultation procedure, much less frequently used as Parliament has gained in stature, the Council must in most cases (although not, for example, in the field of agriculture) act unanimously, and while the Parliament must be consulted it has no direct right to participate in the development of the legislation and no veto power.

The limitation of this study to the *framing* of legislative proposals may immediately strike American readers as nonsensical. In the American context, the drafting of legislation is not an important, and certainly not a public, procedural context. In formal terms American 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,[81] 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.[82]

The American Constitution empowers the President to suggest legislation to Congress, but the power to make suggestions is not uniquely his, and the fact that he has made a suggestion does not create legislative business. His suggestion must be introduced by a member of Congress, who is formally if not always politically free to decline to do so, or to change its wording in any manner she chooses before doing so. To be sure, the President has put in place internal procedures for controlling the development of legislative recommendations; agencies must secure clearance from the Office of Management and Budget before seeking congressional action, and that obligation is used to effect a very useful coordination across the whole face of the executive branch. But while it is always possible that the administration's friends are engaged in this process, or that for some particular initiative – health care reform, or the creation of an energy policy – the White House will establish a consultative framework to shape its recommendations, none of this is commanded by law. There are no equivalents in statutory development for the internet notices and consultations that mark

[81] http://thomas.loc.gov.

[82] 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.

American rulemaking, now broadly exposed and engageable on the internet. Neither are there American legislative equivalents of the public analytic regimes agencies are required to follow in developing their rulemaking proposals. True, Congress has instructed itself to engage in environmental, economic, and other forms of analysis in connection with legislative work; and one can note in legislative histories assertions that this required analytic work has been done. But participation in and enforcement of these obligations are wholly internal matters; the public, including in this respect the President and executive branch, are not involved.

The European Union, in contrast, operates within a regularized procedural framework for the development of legislative proposals, as established by the EU and EC Treaties. Under the treaties, as would have been continued by the draft European Constitution, essentially all legislative business – that is, all proposals considered by the Council and Parliament for actions that will have the force of law on Member States and/or their citizens – *must* originate with the Commission.[83] The rationale behind entrusting the Commission with such a monopoly is to prevent the submission of legislative proposals inspired by nationalistic interests that would lead to the backsliding of Community legislation. The Parliament and the Council have authority to amend and adopt such legislation (although the Council cannot directly amend a Commission proposal contrary to the views of the Commission),[84] with the precise extent of the authority generally depending on the type of legislation involved and the subject matter of the legislation. But the Commission's monopoly of the right to initiate legislation gives it broad discretion regarding the form, objective, content and the timing of any proposal, and the authority to decide what kind of preparation work should be done before the actual submission of the proposal to the other institutions. The existence of this framework makes treatment of the procedures for developing legislative proposals sensible in a study of European "administrative law."

Of course the political realities[85] give the Council and Parliament – and certainly the European Council of Heads of State – considerable influence over what will emerge as the Commission's proposal. Nonetheless, it must be the Commission that proposes. And while the Commission has felt free to develop its own practices in a non-binding format, that confers no judicially enforceable rights on participants, an understandable

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[83] One of the exceptions to this rule arises in the workplace sector, as discussed in relation to the employment sector, where "social partners" (*i.e.*, unions or employers) can themselves initiate an Article 137 ECT "social dialogue" process, which itself can result in the adoption of legislation. Other exceptions occur in the justice, liberty and security areas.

[84] Article 250 ECT.

[85] Thus, what appears to be a fairly limited and general right of input under the present Treaties has in fact been used "to frame very specific proposals which it [the Council] wishes the Commission to shape into concrete legislation." Craig and De Búrca, n. 37 above, at 69.) The draft Constitution would have made clear an expectation that legislative initiatives could 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). *See* the thoughtful analysis in Paul Craig, European Governance: Executive and Administrative Powers Under the New Constitutional Settlement (2005).

regard for its credibility as an institution has led the Commission to structure the path to legislative proposals in ways that offer considerable transparency and opportunity for public contribution to the process.

B. 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 the European Council, Member States, the Council or the Parliament, lobbyists' suggestions, complaint letters from European citizens, reaction to European Court of Justice rulings, and consideration internal to the Commission and/or its DGs are all possible sources.[86] Although the EC Treaty is silent as to internal processes the Commission must follow before sending legislative proposals to the Council and the European Parliament, the 1999 Amsterdam Treaty Amendments, without explicitly creating private rights of enforcement, added a certain legal obligation to the Commission's political incentives.[87] The Amendments required that:

> For any proposed Community legislation, the reasons on which it is based shall be stated with a view to justifying its compliance with the principles of subsidiarity and proportionality;[88] the reasons for concluding that a Community objective can be better achieved by the Community must be substantiated by qualitative or, wherever possible, quantitative indicators. (…)
>
> Without prejudice to its right of initiative, the Commission should:
>
> — except in cases of particular urgency or confidentiality, consult widely before proposing legislation and, wherever appropriate, publish consultation documents;
>
> — justify the relevance of its proposals with regard to the principle of subsidiarity; whenever necessary, the explanatory memorandum accompanying a proposal will give details in this respect. The financing of Community

[86] In the competition law area, gaps in existing law or a "critical mass" of analysis, suggestions, communications and criticisms with regard to a regulatory topic from the regulated community or others can also be an important trigger to the initiation of the legislative process. External comments are more important in that sector, since a lower than average percentage of the relevant Commission staff deals with policy issues, given the large adjudicatory work load.

[87] *See* Protocol 7 of the Treaty of Amsterdam, 1997 O.J. (C 340) 140 (on the application of the principles of subsidiarity and proportionality) and Interinstitutional Declaration on Democracy, Transparency, and Subsidiarity, Bull. E.C. 10-1993 at 118.

[88] The principles allocating responsibility as between the EU and its Member States – roughly, that the EU may act only to the degree reasonable to secure its limited purposes and even then only in circumstances, and to the extent, that its Member States are incapable by their own actions of achieving them.

> action in whole or in part from the Community budget shall require an explanation;
>
> — take duly into account the need for any burden, whether financial or administrative, falling upon the Community, national governments, local authorities, economic operators and citizens, to be minimized and proportionate to the objective to be achieved; …

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

Preliminary stages may involve the preparation of Commission green papers or white papers exploring policy alternatives – a stage that frequently involves its own consultative processes, as discussed below both in general,[89] and in connection with the just adopted regulation of the chemical industry.[90] The development of legislative proposals is generally assigned to the Directorate General responsible for the subject matter, which will begin informal consultations with Member State experts and others as drafts are prepared.[91] As with rulemakings in the United States, full public engagement begins no later than the appearance of the project on the Commission's work plan and – certainly relative to the time it usually takes to bring a proposal to finality – this brings the project into early public view.[92]

The Commission's work plan is published in numerous formats at its worksite, from a five-year strategic plan to a three month rolling program.[93] Perhaps the most

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[89] *See* p. 60 ff. below.

[90] *See* text at n. 155 below.

[91] In the competition law sector, DG COMP publishes its own Competition Law Newsletter, a quarterly policy-focused magazine. Notice to the relevant public is also given by speeches and articles by DG COMP officials or at conferences in which they participate.

[92] Nonetheless, one encounters suggestions that pre-proposal consultation occur at an earlier stage, and some provision for that by individual DG's. A study by the UK's Better Regulation Task Force, Get Connected: Effective Engagement in the EU 29 (2005), included the following case study:

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

[93] http://ec.europa.eu/comm/off/work_programme/index_en.htm. In the following diagram, the APS is the Annual Policy Strategy, a general policy document that sets out the priorities of the Commission for the following year. It is generally adopted in February of the preceding year and takes the form of a non-binding communication from the Commission to the European Parliament and the Council. Although a Commission document, it takes

(continued…)

useful of these, because they contain contact information within the responsible DG, are the "roadmaps"[94] Commission guidance requires its directorates to develop and publish concerning the proposals adopted as elements of the Commission's Annual Policy Strategy (APS) and Work Program (WP).[95] Like entries in the American regulatory agenda, these roadmaps give a brief account of the matters under development, following a uniform framework for preliminary Impact Analysis (IA).[96] They must

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account of feedback received from the Parliament and the Council, and can therefore be considered to be the result of an inter-institutional dialogue. The annual Commission Work Program, adopted in November of the year preceding the year during which it should be carried out and then published, lays out how and where the Commission will act in order to pursue the priorities and the key initiatives that were announced in the APS. Then each DG establishes an Annual Management Plan (AMP) in order to translate the priority initiatives and the strategic objectives of the Commission into concrete operations, and to provide an instrument enabling the management to plan, follow up and report on all the activities and resources of each DG.

[94] *See* SEC(2004)1175.

[95] *See* SEC(2005)790, putting the guidance document before the Commission as an instrument intended to "clarify" and "reinforce" staff obligations to provide roadmaps, consult widely, analyze impacts and alternatives, etc., and SEC(2005) 791, "Impact Assessment Guidelines" (June 15, 2005).

[96] *E.g.*, the roadmap for 2005/ENTR/019, a Proposal for a Regulation on the authorization, supervision and vigilance of human tissue engineered products, http://ec.europa.eu./comm/off/work_programme/20050128_clwp_roadmaps.pdf p. 10:

> **Lead DG and contact person**: DG ENTR, F/3 - Christian Siebert, Deputy HoU.
>
> **Expected date of adoption**: June-July 2005
>
> **A. Initial impact assessment screening**
>
> **1. What are the main problems identified?**
>
> "Human tissue engineered products" are engineered human cells and tissues developed according to specific processes in order to maintain, restore or improve diseased/injured tissues in the human body. Existing EC legislation does not address these products in a specific and comprehensive manner. Although Directive 2004/23/EC has recently introduced minimal rules on the quality and safety of human tissues and cells, it leaves room for more detailed requirements on manufactured products derived from tissues and cells. In the absence of a fully harmonized regulatory framework, Member States apply different requirements for the manufacture and authorization 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 authorization 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.

(continued…)

provide, among other things, an estimate of the time required for completing the full IA, as well as a brief statement on (1) the likely impacts of each policy option, (2) which impacts warrant further analysis, (3) who is likely to be affected, and (4) an outline of the consultation plan.[97] Of particular importance for interested persons outside the Commission and any groups it may itself invite to participate in consultations, the roadmaps identify contact persons, sometimes including their telephone extensions; this easily permits an outsider early self-identification to responsible bureaucrats as a stakeholder or other interested party. The roadmap identifying numbers, unsurprisingly, correspond to those identified in the work program. While it is hard to assess whether the obligation to produce roadmaps is universally complied with (as one might also say about the Federal Regulatory Agenda that is the American equivalent), the Commission "Guidelines stress the importance of comprehensive and high-quality Roadmaps to allow interested parties to see what the Commission has done and still plans to do,

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> **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 Center's Institute for Prospective Technological Studies (JRC-IPTS) of the European Commission. These studies will analyze the economic, social and environmental impacts of the proposal. Ethical aspects will also be considered in collaboration with the European Group on Ethics in Science and New Technologies (EGE).
>
> The main parties that will be affected by the proposal are tissue engineering companies and, possibly, some hospitals and tissue banks.
>
> **B. Planning of further impact assessment work**
>
> **5. What information and data is already available? What further information needs to be gathered? How will this be done (*e.g.* internally or by an external contractor) and by when?**
>
> The JRC-IPTS has already completed a study on the current European market in human tissue engineered products and its future developments (http://www.jrc.es). The assessment of economic, social and environmental impacts of the proposal is currently under way. Ethical impacts are also being considered. The impact assessment is expected to be completed during the first quarter of 2005 at the latest.
>
> **6. Which stakeholders & experts will be consulted, how and at what stage?**
>
> Extensive consultations have already taken place with Member States and interested parties (consultation on the need for legislation in 2002; public consultation document and stakeholders' conference in April 2004; several consultation meetings with Member States and industry representatives). Discussions have highlighted a fairly broad consensus, in particular amongst industry and governments, in favor of a specific EU regulatory framework for human tissue engineered products. The proposal also responds to requests for harmonization 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).

[97] The Roadmap must also indicate whether an Inter-Service Steering Group will be established. *See* the discussion below of such a group. When a DG does not plan to convene such a group, it must provide reasons.

thereby facilitating the preparation of their input as part of the mandatory consultation process."[98]

C. Impact assessment[99]

Impact assessment, proportionate to the significance (*i.e.*, likely impacts) of the action being undertaken, is a required element of the Commission's development of legislative proposals.[100] For the Commission, as not for the American Congress, this is a seriously considered obligation, underscored by formal commitments it made in 2002 and reinforced in 2005[101] – albeit it is one that like the American counterpart for regulations, E.O. 12,866, is enforced solely by internal means. The Commission maintains a dedicated Impact assessment website with links to all documents,[102] including most impact assessments that have been completed.[103] Effective as of 2005, virtually all secondary legislation items on the Commission's legislative and work program, as well as some less formal actions, require impact assessment. A preliminary assessment appears in the roadmap document; an impact assessment accompanies the proposal to Commission for approval and then to the Council and Parliament. That it is developed in two stages, with the first appearing in the published "road maps" and including contact information, effectively assures interested parties an opportunity to make their views heard.

The scope of action covered by impact assessment includes all legislative and other policy proposals that the Commission chooses to include in its APS or WP, "provided that they have a potential economic, social and/or environmental impact and/or require some regulatory measure for their implementation."[104] These actions include "[a]ll regulatory proposals, White Papers, expenditure programs and negotiating

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[98] SEC(2005) 790 at 3 (emphasis in original).

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

[100] The consideration of impact assessment began in the environmental sector as early as 1985, with the enactment of legislation that required Member States to conduct environmental impact assessments with regard to certain types of projects.

[101] COM(2002) 276 final, "Communication from the Commission on Impact Assessment." Precursor regimes required analysis of budgetary impacts, and impacts on small and medium sized enterprises. Guidance issued during the summer of 2005, n. 99 above, considerably strengthened the analytic requirements involved.

[102] http://ec.europa.eu/governance/impact/practice_en.htm.

[103] http://ec.europa.eu/governance/impact/practice_en.htm. A very few of the statements here are restricted from public access.

[104] Thus, the Commission retains unilateral control over which proposals are subject to IA. This creates opportunities for strategic maneuvering; an independent, quantitative definition of "major initiatives," similar to that used in the US under Executive Order 12866, would reduce this problem significantly. Robert Hahn and Robert Litan, Counting Regulatory Benefits and Costs: Lessons for the US and Europe [forthcoming, Joanne Scott]

guidelines for international agreements (with an economic, social or environmental impact)."[105] The Commission may also decide, "on a case-by-case basis, … to carry out an impact assessment of a proposal which does not appear on the WP."[106]

1. Limits of Coverage

The impact analysis requirement does not extend to all Commission work one might think could benefit from it. Green Papers and proposals for consultation with "Social Partners" are exempted, as are "periodic Commission decisions and reports, proposals following international obligations. The most striking omission, from an American perspective, is that of tertiary legislation, Commission measures deriving from its powers of controlling the correct implementation of EC law and executive decisions."[107] This leaves out entirely the critical area of comitology and other forms of Commission administrative action implementing or interpreting legislation adopted by the Council and Parliament, the setting in which many of the critical regulatory decisions are actually made, and the setting (*i.e.*, administrative rulemaking) in which impact analysis has made its greatest contribution in American practice. Of course, one may argue that the comitology procedure is designed to deal with secondary legislation of a technical or routine nature, must be able to do so efficiently, and involves chiefly technical or scientific issues. Further, where such implementing measures can have potentially significant impacts, the Commission can consider whether a measure should undergo a voluntary impact assessment. The argument can be made that extending impact assessment requirements to all comitology items would put an unsupportable strain on the Commission services.

Yet the contrast becomes the more striking when one considers that the alternative apparently preferred is that of political control. The European Parliament has claimed more than once that the task of implementation should be entrusted completely to the European Commission,[108] as this would enable both the Council of the European Union and the Parliament to supervise the Commission on the basis of their "scrutiny" and Treaty prerogatives. This would be so because if the Council or the Parliament finds that the Commission exceeds its implementing power, they, or any Member State, can bring an action for annulment of Commission measures in the Court of Justice.[109] The Parliament can also hold the Commission accountable on a political level for the manner in which it fulfils its executive role, not only via oral or written questions (Article 197 ECT), but also via the right to pass a motion of censure on the activities of the

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[105] 2005 Impact Assessment Guidelines, p. 6.

[106] *Id*.

[107] *Id*., p. 6. The last category includes "implementing decisions, statutory decisions, technical updates, including adaptations to technical progress, competition decisions or acts which scope [sic] is limited to the internal sphere of the Commission." *Id*., n. 7.

[108] [BACK UP]

[109] *See* for a case successfully brought by a Member State, Case C-393/01: France v Commission [2003], E.C.R. I-5405, ¶¶40-60; a case where the Court found the implementing power not to have been exceeded: Case C-284/94 Italy v Commission [1997] E.C.R. I-3519, ¶¶20-46; Lenaerts and Van Nuffel, p. 618.)

Commission (Article 201 ECT).[110] One could imagine impact analysis undertakings contributing to, rather than detracting from, these controls.

2. The Impact Analysis process

The mechanics of and general adherence to this guidance are, necessarily, works in progress. Prior to the communications of 2002, practice was highly variable from directorate general to directorate general.[111] The new guidelines of June 2005 promise yet more disciplined attention to the process. Under the 2005 Impact Assessment Guidelines, the Impact Assessment process has 6 basic steps:

(1) What is the problem?

(2) What are the objectives?

(3) What are the policy options?

(4) What are the likely economic, social and environmental impacts?[112]

(5) How do the options compare?

(6) How could future monitoring and evaluation be organized?[113]

What the Commission *means* by "impact assessment" differs somewhat from how Americans would understand the process. The Commission published an initial guidance document, "Impact Assessment in the Commission," in the fall of 2002,[114] elaborating the expected processes for developing both preliminary and extended Impact assessments, with models for each. This document made clear that these analyses were seen as aids to a political process, and thus might often be appropriately qualitative in character. It strongly emphasized the obligation of consultation with interested parties and relevant experts. "Consultation with interested parties is an important part of the impact assessment process, and is carried out according to a set of minimum standards."[115] These minimum standards were themselves specified in Commission communications.[116] and the consultations are conducted through the

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110 Lenaerts and Van Nuffel, p. 618 and 394-396).

111 Indeed, it appears from the Financial Sector Report that virtually all of the impact assessment and better regulation initiatives of the Commission were ignored in the adoption of the major Financial Services Action Plan even after 2002, but that the Commission announced in its 2005 White Paper that it would use impact assessment in the future in this sector. A similar result seems to have obtained in the Food Safety sector.

112 This question goes to the concept of "sustainability," which is a cornerstone of impact assessment at the Commission.

113 2005 Impact Assessment Guidelines., pp. 2-3 (Table of Contents).

114 http://ec.europa.eu/comm/secretariat_general/impact/docs/ia_technical_guidelines_en.doc.

115 *See* http://ec.europa.eu/comm/secretariat_general/impact/expert_en.htm.

116 COM(2002) 704 final; *see also* COM(2002) 713 final.

Commission's "your voice" website.[117] "In order to be credible, impact assessment cannot be carried out behind 'closed doors.'"[118]

The 2002 Communication described the desired analysis in terms much broader than might be familiar to American audiences. Impact analysis was presented as a technique for identifying policy options and alternatives by considering the likely forward consequences of a proposed action, as it would also be seen in the United states. Yet for the Commission, these impacts were to be "expressed in economic, social *and* environmental terms," (emphasis added) with no particular emphasis on quantification or cost-benefit balancing.[119] "[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."[120]

American authors have criticized this aspect sharply, urging the EU to "specify[] that the primary objective of regulation is to maximize net benefits."[121] Commission adherents would reply that the Communities' impact analysis guidelines must be more flexible, since they apply to general documents dealing with policy directions (*e.g.*, a draft Communication on the rights of the child) where a full fledged cost benefit analysis or cost effectiveness analysis cannot be done. Further, they may argue that an impact analysis in Europe has no legal status and is essentially destined to assist the EU (legislative) decision-making process (this of course is also formally true in the United States), and that this explains why the Commission has adopted an integrated approach giving equal importance to the likely economic, environmental and social impacts of regulatory and policy proposals. The overall objective, they would assert, is to provide the EU Legislature with a clear picture through which trade-offs (and their likely impacts) are identified and costs and benefits are assessed across a range of different and sometimes conflicting policy objectives. Finally, they may argue that if one strictly applies the statement that "the primary objective of regulation is to maximize net benefits", one might be forced to choose a more costly option with higher net benefits over a more cost efficient option with mostly lower costs but lower "net benefits."

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[117] They can, and probably should, also use the more traditional alternatives as well, since not everyone has access to the internet.

[118] Guidance document at 9.

[119] The EU directives specifically concerning environmental assessment are examined, *inter alia*, in Joanne Scott and Jane Holder, Law and 'New' Environmental Governance in the European Union in […] [PS to supply?] Addressing its procedures requiring provision for public participation at the local level, they find democratizing tendencies supportive of new governance ideas – "a more inclusive, less technicist environmental assessment procedure, with public involvement in decision making expressed in the manner of an entitlement to participate and to access to the courts to enforce its provisions." At 6.

[120] COM(2002) 276 final at 15-16.

[121] Robert Hahn and Robert Litan, Counting Regulatory Benefits and Costs: Lessons for the US and Europe [forthcoming, Joanne Scott]; Kogan, n. 103 above.

One hundred pages of supplementary guidelines and illustrative annexes published in the summer of 2005[122] offered a basis for "*rigorous and comprehensive analysis … easily accessible to the non-specialist*."[123] Yet, like its predecessor, the new guidance does not supply any single, or binding, decision criteria. It notes that Impact Assessment is a decision tool, but that it will not govern the "political" decision of the Commission, much less that of the Parliament or the Council.[124] The new Guidance does, however, go much further than prior guidance both in "screening" to arrive at a shortlist of options (using the criteria of "effectiveness, efficiency, and consistency) and in structuring the consideration and ranking of options. It requires that for all options considered (which must include the "no action" option), the Impact Assessment Report must "consider all the relevant positive and negative impacts alongside each other, regardless of whether they are expressed in qualitative, quantitative or monetary terms."[125] The Commission presents this approach as a "simple multi-criteria analysis," and carefully distinguishes it from the alternative approaches of "cost-benefit analysis, which compares positive and negative impacts expressed in the same units (normally monetary), and cost-effectiveness analysis, which compares the costs of achieving a given objective." In fact, the approach suggested by the Commission seems compatible with what is commonly considered cost-benefit analysis in the U.S., where the term "formal" or "quantified" cost-benefit analysis is reserved for the fully quantified type of assessment.[126]

Bear in mind that we are here discussing the development of *legislative* proposals, matters to be submitted to Parliament and the Council, and that impact assessment is *not* required for the Commission's implementing measures, what Americans would call rulemaking. This choice is perhaps a reflection of where the most important measures will be undertaken, but it is also one of several elements of EU arrangements tending to separate the technical from the political in the development of legislation. Impact analyses, then, operate both to inform and to bulwark the Commission's decisions in the inherently political process of exercising its monopoly powers to propose legislation (the Commission is not democratically elected), and for the control/edification of the external institutions to whom legislative proposals are eventually sent, the Council and the Parliament. Implementing decisions and measures – for example, decisions subject to comitology – do not appear in the Work Program, and are normally exempt from the procedure.

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122 SEC(2005) 791, note 99 above.

123 SEC(2005) 790, *id*., at 2 and 3 (emphases in original).

124 Europeans defend this process by arguing that the relevant decision-makers are not subject to any legally binding decision criteria with the result that the purpose of the IA is only to aid in a well-informed decision.

125 *Id*., p. 39 (emphasis in original).

126 On the other hand, when the Commission defines "multi-criteria analysis" in its Annex at *id*., p. 42-43, it does not require that a "net benefits" hurdle or a "maximizing net benefits" test be used for multi-criteria analysis.

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 legitimizing Commission choices in formulating legislative proposals and informing legislators than for controlling a dispersed bureaucracy, although it does play an important role in giving the President of the Commission more control over the various Directorate Generals in Brussels.

In the United States, impact analysis is less directly 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;[127] and Regulatory Flexibility Act analyses for impact on small business may also involve public consultations. Yet for today's most important form of impact analysis, economic impact analysis made under E.O. 12866, public participation in the process is indirect. Both draft and final regulatory impact analyses are reviewed – and the Executive Order's requirements enforced – in internal dealings between the agency and OMB's Office of Information and Regulatory Analysis [OIRA]. To be sure, the draft analysis, once approved by OIRA, should be available as part of the package submitted to the public during the agency notice-and-comment process, and that opens up the possibility of commenting to the agency about its draft; and one can learn when an EIS has been submitted for review by careful observation of the website OIRA maintains. This posting occurs, however, only after the agency hopes to have completed its analysis; OIRA does not make the documents public or directly invite public participation, and the eventual inclusion of the documents in the agency's rulemaking docket may come too late for effective commentary on it. Disclosure of changes made in the OIRA processes occurs only at agency initiative, and is highly variable.

The EU's guidance documents require those responsible for impact assessment consultations not only to summarize their results, but also to "indicate how the consultation influenced the development of the proposal, and any remaining critical or dissenting opinions."[128] The character of an impact assessment document completed under the initial guidelines can perhaps be appreciated by looking at the report developed for the Commission initiative known as REACH (*R*egistration, *E*valuation, *A*uthorization and *R*estrictions of *C*hemicals),[129] one of the more controversial legislative actions proposed in recent years, which was finally adopted in December 2006, and will enter into force on 1 June 2007. The proposal, captured in six enormous files on the Commission's website,[130] runs about 1200 pages (mostly, to be sure, technical annexes

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127 *See* 40 CFR §§1501.7 (requirement) and 1508.22 (substance to be included).

128 ____ at 26.

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

130 http://eur-europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52003PC0644(01):EN:HTML.

the Commission characterized as not new[131]); the 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 only 33 pages.[132] One could compare the recently adopted American regulation on tire pressure monitoring (a much simpler subject) for which the rule itself comprised seven pages in the Federal Register,[133] and the Final Regulatory Impact Analysis published on the agency website, 249.[134] Under the Commission's 2005 guidance, still, an Impact Assessment Report should be no longer than 30 pages (excluding annexes), following a set format.[135]

D. Stakeholder consultation (and report)

The Commission is committed to extensive consultations with all concerned elements of society as part of its process for developing legislative proposals. It has carried this commitment through in a series of Communications[136] and websites committed in various ways to the process.[137] Although it is grounded in the Amsterdam Treaty Amendments of 1999, the Commission has expressed its commitment in soft law terms that do not create enforceable rights in private parties.[138] Its explanation of this choice both illustrates the importance of soft law in its practice, and the Commission's determination to avoid precise imitation of the accountability inherent in 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

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

132 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.

133 70 Fed. Reg. 18184-91 (April 8, 2005); the statement of basis and purpose accompanying the rule ran 49 pages, *id*. at 18136-84.

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

135 *Id*., p. 14.

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

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

138 *See* the Environmental Sector report for a discussion of the stronger commitments undertaken, in the environmental context only, pursuant to Article 6 and 7 of the Aarhus convention.

> communication (*i.e.* in the form of a policy document) instead of adopting a legally-binding instrument. They argued that this would make the standards toothless and the Commission would be unable to ensure the consistency and coherence of its consultation processes.
>
> However, the Commission remains convinced that a legally-binding approach to consultation is to be avoided, for two reasons: First, a clear dividing line must be drawn between consultations launched on the Commission's own initiative prior to the adoption of a proposal, and the subsequent formalized 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*.[139]

Recall that these are principles developed and, as the contents of the Yourvoice site[140] suggest, most often honored in connection with the development of legislative drafts, not rulemaking.[141]

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[139] COM(2002) 704 final, p. 10 (emphasis added). The guidance documents of June 2005, n. [__] above, are equally forcible about staff obligation; while the increasing stringency of the commitments is clear, empirical data on the extent of compliance with them are hard to obtain.

A September 2005 report of the UK's Better Regulation Task Force, Get Connected: Effective Engagement in the EU, both expressed "surprise[] that the Commission does not publish information about how well individual Directorates General comply with the agreed standards for consultation," thinking that information a part of the citizen's "right to know," and indicated agreement with the soft law approach. "The problem with a legally binding requirement to consult is that it creates an opportunity and perhaps even an incentive for those dissatisfied with a particular policy outcome to challenge proposals in court on the grounds of inadequate consultation …. We want to find ways to help the Commission's consultation process become more effective and efficient, not to slow down the delivery of policy or to enrich the legal profession." At 3, 8 and 25.

[140] 41 N. 138 above.

[141] 42 Indeed, the Commission wholly exempts rulemaking – the comitology process and other forms of exercise of delegated administrative power – from these "soft" consultation procedures, much less any legally binding requirements that might lead to legal accountability through judicial review. Yet, the rationale used by the Commission to justify not using legally binding consultation requirements for the initiation of legislation does not apply

(continued…)

A recent assessment of the Commission's consultation practice welcomed its implementation but questioned whether – particularly in light of the June 2005 impact assessment guidelines[142] – the "principles and standards for consultation should only apply to major policy initiatives."[143] "Even where the general principles and minimum standards are applicable," the report continued:

> they are not binding on the Commission services. While we have found good examples of thorough and extensive consultation, we have also found that many consultation exercises fail to meet the Commission's minimum standards and that compliance is patchy both between and within Directorates General.
>
> We have found it difficult to make a reliable assessment of compliance with the minimum standards, as information is not easily available and some of them are anyway qualitative. Nevertheless, in June 2005 we reviewed all the open and closed consultations on the Commission website and found that nine out of 40 consultations (or 23%) allowed less than eight weeks to respond. Two consultations were barely eight weeks long and took place over the Christmas period. Of the standards other than the period allowed for consultation, the Commission itself acknowledges that it needs to do better in providing reasoned feedback to respondents and in demonstrating how it has taken account of their views.[144]

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

> The problem with a legally binding requirement to consult is that it creates an opportunity and perhaps even an incentive for those dissatisfied with a particular policy outcome to challenge proposals in court on the grounds of inadequate consultation. This would prolong the legislative process and introduce considerable uncertainty over when and how any legislation enters into force …. The United States puts a legal duty on government agencies to consult to a minimum standard on significant proposals. There is

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with nearly the same force to delegated lawmaking. It is precisely such exercise of delegated powers that most needs to be checked and made accountable.

[142] SEC (2005) 791, n. 99 above.

[143] Get Connected, n. 140 above, at 22. Commission adherents may answer that the Get Connected Report (Source: http://www.brc.gov.uk/publications/getconnectedentry.asp) does not clarify that the Impact Analysis Guidelines, which are precisely applicable to all items on the CLWP (except for Green Papers and proposals for consultation with the Social Partners), provide for application of the minimum consultation standards.

[144] *Id.* at 24.

> no equivalent legal duty anywhere in the EU and we do not think it proportionate to introduce one.[145]

Europeans are also quick to point out that the legally minimum binding requirement for rulemaking notice in the U.S., while it allows "stakeholders" to self-select that status, requires only passive notice in the Federal Register, which few people check regularly. The EU minimum standard requires EU bureaucrats to act proactively and to inform those they determine to be stakeholders; while this obligation is "soft law," and thus not legally binding, officials ignoring it are open to criticism. A similar practice characterizes American rulemaking today under the Executive orders.

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.[146] Nor would one wish to suggest that members of Parliament or the Council, who will eventually have to act on Commission proposals (and so wish to maneuver to shape their development), learn their constituencies' views only in this way. Political pressures and lobbying in all its forms are only to be expected.[147] 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

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[145] *Id*. at 25.

[146] Two specific advisory bodies – the European Economic and Social Committee (representing various socio-economic organizations in Member States) and the Committee of the Regions (made up of representatives of local and regional authorities) – as well as Member States are regularly consulted. Consultation with the former is not generally influential; consultation with Member States is.

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://ec.europa.eu/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, invites 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 of April 21, 2005, C 97/02, http://eur-lex.europa.eu/LexUriServ/site/en/O.J./2005/c_097/c_09720050421en00020002.pdf, (and corrigendum at http://eur-lex.europa.eu/LexUriServ/site/en/O.J./2006/c_049/c_04920060228en00580058.pdf), with three seats allocated to the European Consumers Organization "in order to facilitate the representation of European consumers." Unlike the NRA (5 U.S.C. §§561 et. seq), no process external to Commission politics is provided for testing the Commission's success in achieving a representative body; this is no different from many other respects in which EU law eschews formal legalisms; while the Commission's incentives suggest that they might rarely if ever be necessary, one arguable result is to keep advice within an "establishment" community, even if a broadly representative one.

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

[147] *See* p. 68 ff. below.

are treated both by respondents and by the Commission itself, offer a striking contrast to the American framework for legislative development.

Perhaps because these consultations are undertaken at an early stage in the development of proposals for legislation, before a proposal has assumed concrete form, they have a different character than what might be thought the American analog, the "notice" American agencies publish in connection with notice -and -comment rulemaking. In usual American practice, the draft is created first and the public consulted afterwards, and this has a number of consequences. First, it contributes to a certain rigidity and defensiveness on the agency side; the process of creating the draft is itself political – compromises need to be made within the drafting body and stances taken, that may then be difficult to depart from whatever input is received. Relations with OIRA in the pre-notice period can have similar effects. 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,[148] one can find rulemakings with hundreds of thousands of participants, many of whom submit electronic forms with unverifiable identities.[149] 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 that is too structured to manipulate, and then asking particular questions about the matter under study.[150] The result is to require a not insubstantial investment of time in participation and, one imagines, to retard if not entirely defeat computerized response campaigns. This in and of itself may significantly improve the contributions the process makes. But there is a price to pay by having the notifier structure the issues, since such a "straight jacket" makes it harder for the commenter using this form of input to put his own case on both the law and the facts, and to suggest and support in detail his own alternative proposals, particularly when the commenter is opposed to some or all of what the notifier wants to do.

One is not bound to the Commission's structure; self-drafted replies are also allowed. One recent study of American rulemaking reached the conclusion, surprising

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[148] *See* text at p. 16 above.

[149] 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/.

[150] This is particularly the case for consultations undertaken through its approach to "interactive policymaking," http://ec.europa.eu/yourvoice/ipm/index_en.htm, as for example a consultation closing in May 2005 on the sustainable use of pesticides in Europe, http://ec.europa.eu/environment/ppps/home.htm. On the relevant site one finds not only the questionnaire, but links to various documents concerned with it, that may assist in understanding or responding to it.

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."[151] If the tendency of the Commission's approach is to suppress form-based comments, these results suggest, the result will be a more credible and rationalized process - or at least one in which the notifier can more easily control the outcome – one that more easily fits, and is more likely to fit, into the way the notifier himself is thinking about the problem and issues.

The Commission's policies, set out in its consultation documents,[152] require reporting of results and feedback; reports of closed consultations are made in a statistical way on the Yourvoice site.[153]

The REACH process, already encountered,[154] 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."[155] There followed stakeholder conferences on the White Paper in April 2001[156] and May 2002,[157] and a November 2003 workshop[158] 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;[159] it attracted an unusual level of response – again, one thoroughly documented on its website: 968 participants in an Interactive Policymaking tool that

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[151] Schlosberg *et al*, n. 150 above, at _____. 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.

[152] *See* n. 137 above.

[153] *See*, *e.g.*, http://ec.europa.eu/yourvoice/results/services/index_en.htm, "Response statistics for 'The transparency of regulations and standards in the area of services'", 19 July 2004; http://ec.europa.eu/yourvoice/results/4/index_en.htm, "Response statistics for review of the New Approach", 31 March 2002.

[154] *See* text at n. 130 above.

[155] COM(2001) 88 final.

[156] http://ec.europa.eu/comm/enterprise/reach/whitepaper/conferences/conf-2001_04_02.htm.

[157] http://ec.europa.eu/comm/enterprise/reach/whitepaper/conferences/conf-2002_05_21.htm.

[158] http://ec.europa.eu/comm/enterprise/reach/docs/conferences/eia_workshop-2003_11_21.pdf and http://ec.europa.eu/comm/enterprise/reach/eia.htm.

[159] http://ec.europa.eu/rapid/pressReleasesAction.do?reference=IP/03/646&format=HTML&aged=1&language=EN&guiLanguage=en.

was, in part, a structured questionnaire,[160] and a total of 6400 comments of varying length and detail.[161] It seems useful to reiterate here that, in contradistinction to American rulemaking processes of equivalent controversiality, virtually all these comments appear to have spoken to the proposals in knowledgeable detail; even in those relatively rare instances in which a number of people (say, workers at a given chemical plant[162]) are identified as having submitted identical comments, the comments (doubtless supplied by their employer and/or union and likely considered, effectively, as one response by Commission officials) are detailed.[163]

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.[164] Here, very clearly, is an effort at political, not intellectual or technical, influence. Yet the very structure of the declaration's site,[165] 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 – 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 – people with constituencies and votes, not those responsible for technical analysis and drafting. The European process may have succeeded to some extent in severing politics from policy analysis at the legislative level, and having developed an unusually interactive and transparent process for submitting comments to the Commission.

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

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[160] *See* the analysis at http://ec.europa.eu/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://ec.europa.eu/comm/environment/chemicals/pdf/ipm_stakeholder_reactions.pdf.

[161] http://ec.europa.eu/comm/environment/chemicals/consultation.htm; http://ec.europa.eu/comm/enterprise/reach/consultation/contributions.htm.

[162] *E.g.*, 156 identical comments from the workers of Clariant, France, http://ec.europa.eu/comm/enterprise/reach/docs/consultation/others/886_other.doc.

[163] Filling 65 computer screens in this case.

[164] http://ec.europa.eu/comm/environment/chemicals/consultation.htm.

[165] http://www.chemicalreaction.org/.

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. As previously noted, 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' organizations and trade unions). A full list can be found on the European social dialogue - Main joint texts page.[166]

A recent Commission Secretariat document, briefly discussing experience with public consultation and reporting "a growing public consultation culture," seems to suggest more generally that consultations with established partners are preferred.[167] Indeed, those experienced in lobbying in Brussels know that this is the reality insofar as one is concerned with actual effect on legislation, whether the "established partners" are from the business or "public interest" sector. Yet in its inception, as Francesca Bignami has pointed out, the move to "civil society participation," a striking departure from national expectations about lawmaking in Europe, was intended to secure a broad political base, not to reflect established 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

[166] http://ec.europa.eu/comm/employment_social/consultation_en.html, linking to http://ec.europa.eu/comm/employment_social/social_dialogue/index_en.htm.

[167] 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.

> the Community method. This means ensuring that the Commission proposes and executes policy; the Council and the European Parliament takes decisions; and national and regional actors are involved in the EU policy process.[168]

E. Lobbying and its regulation

The Commission has adopted a relatively detailed code of conduct for itself[169] – albeit one that has not prevented the whiff of public scandal[170] – but in other respects the European Union thus far has not been able to adopt more than hortatory measures to deal with lobbying activities. The Commission's Code of Good Administrative Behavior,[171] directed to its staff not to lobbyists, 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.[172] 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 organizations 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.[173]

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168 Bignami, n. 183 below, at 71.

169 *See* http://ec.europa.eu/comm/reform/2002/code_conduct_en.htm.

170 The code provides, *inter alia*, that a Commissioner should not accept a gift valued at more than 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 "a holiday with friends" the Commission's position was that there was no "lack of respect of the code of conduct." "Commission chief's trip raises EU ethics questions," International Herald Tribune, Tues. Apr. 19, 2005, p. 1 and 3.

171 http://ec.europa.eu/comm/secretariat_general/code/index_en.htm.

172 http://ec.europa.eu/comm/reform/2002/chapter06_en.htm#1.

173 Journal C 348/70 (1999).

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

> Special interest groups are best placed to establish and enforce codes of conduct. The Commission therefore invites the sectors concerned to draw up such codes, which should include certain minimum requirements.[174]

Those requirements are stated in quite general terms – advising, for example, that a group should not "offer any form of inducement to Commission officials in order to obtain information or to receive privileged treatment," but giving no concrete detail about the propriety of hosting luncheons, sending holiday gifts, or providing golfing trips to Scotland for dear friends.[175]

The European Parliament, too, has what may best be described as minimal rules on the subject, requiring accreditation of lobbyists and quite general standards of proper behavior.[176] Its website carries an extensive list of accredited lobbyists,[177] making evident that lobbying the Parliament is a major activity.[178] In late April, 2005, it appeared that political pressures were growing to create more formal structures,

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[174] http://ec.europa.eu/comm/secretariat_general/sgc/lobbies/communication/annexe2_en.htm#public.

[175] The reference is to a distinctly American scandal; *see* Philip Shenon, "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. [__] above.

[176] Rules of Procedure of the European Parliament 9(2) and Annex IX.

[177] http://www2.europarl.eu.int/lobby/lobby.jsp?lng=en.

[178] 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 organize 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://ec.europa.eu/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 Organizations (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 behavior.

including an independent watchdog organization, in the wake of embarrassing disclosures of vacations taken with friends who were also persons highly interested in the EU's affairs.[179] That appearances of conflict of interest might arise from genuine friendships in political circles is hardly unknown.[180]

F. The Commission's internal processes

This does not seem an appropriate place to explore in detail the Commission's internal processes, which in any event are (appropriately, to the extent they are truly internal[181]) not open to public view. One characteristic, however, seems appropriate to underscore for persons seeking comparisons, however implicit, with American institutions – that the Commission is fundamentally a collective. Its President (as a prime minister) may be *primus inter pares*, but the group takes 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 apparent objectivity in its dealings with the outer world.

As Francesca Bignami so persuasively argues in the context of the Union's procedural development generally,[182] the structure of the EU may be such as to make its actors – and perhaps especially the Commission – sensitive to the expectations of its more demanding members. The incentives for Europe's bureaucrats are quite different to those American agency staffs might experience – not only that consensus should be achieved on the particular matter they are proposing, but also that Member States and their populations on an ongoing basis perceive EU processes as attentive to their concerns:

> Notwithstanding that procedural rights emerged in different historical periods and that they were informed by different cultural traditions and supranational interests, they display one striking

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[179] *Id.*; Bennhold, n. 171 above.

[180] *E.g.*, Justice Antonin Scalia's opinion refusing to recuse himself in a case involving Vice President VP Cheney, from whom he had accepted the gift of air transportation when they were both invited to duck hunting in a distant venue. For a similar, if understated, view, *see* Get Connected, n. 140 above, at 61.

[181] 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.

[182] Francesca Bignami, "Creating 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://eprints.law.duke.edu/archive/00000705/01/bignami_Creating_rights_10.04.pdf.

> 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 is not led by a popularly elected official, as are executive branches at the national level … [but] by a College of Commissioners, headed by a President, that is appointed by common consensus among the Member States, with some input from the European Parliament. In no way can the Commission be said to enjoy an electoral mandate when it undertakes its mission.[183]

Thus, one could believe, to earn credibility the Commission's impulse must be to a highest rather than the lowest common denominator, although this can by no means be achieved in many cases once Member State interests are sorted out.[184]

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

In 2002, the Commission issued guidelines defining core principles and guidelines for collecting and using the advice of experts outside the responsible Commission DG.[185] These require it, in the first instance, to maintain a level of in-house expertise enabling it to act as an 'intelligent customer' when organizing and acting on external expertise. The use of internal resources is preferred. If outside help is to be sought, the scope and objective of the experts' involvement, and the questions they will address, are to be set out clearly. Both mainstream and divergent views are to be considered, and departments are to maintain a record of the process including the terms of reference and the main contributions of different experts or groups of experts. The experts themselves, and also the Commission, are made responsible for monitoring any possible conflict -of -interest issues that could jeopardize the quality of the advice. And transparency is also a central consideration: experts must highlight the evidence (*e.g.* sources, references) upon which they base their advice, as well as any persisting uncertainty and divergent views; within the framework of freedom of information legislation, the principal documents associated with the use of expertise – in particular

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183 [*Id*. at ___?]

184 *See also* 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.

185 COM(2002)713.

the advice itself – are to be made available to the public as quickly as possible;[186] and departments are encouraged to permit public attendance at expert meetings, particularly on sensitive policy issues. Finally, departmental proposals for Commission decision are to be accompanied by discussion of the expert advice (whether or not it has been followed) and this information is generally to be made public when the Commission's proposal is formally adopted.

G. Explanation

The obligation to explain proposals is treaty-based. Intended to inform the subsequent political processes (and thus generally met by preambular material in legislative proposals rather than separate explanations of "basis and purpose"), it is subject principally to political enforcement – by the Council or Parliament rather than the courts. Article 253 ECT requires that all *regulations*, *directives*, *and decisions* adopted by the Parliament and Council jointly, by the Council alone, or by the Commission, "shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained by this Treaty."[187] This treaty requirement is normally thought to be satisfied by the recitation of "whereas" clauses at the beginning of EC legislation.[188] Such recitals, however, only set out seriatim a set of relevant facts or factors, and do not explore trade-offs or the real reasoning of the decision.

In addition, the Commission accompanies its legislative proposals with explanatory memoranda setting out the results of consultations, and available in all languages. As characterized in the recent UK Better Regulation Task Force report,[189] these memoranda typically run to about eight pages and, by the Commission's own account, often do little to reveal how responses to public consultations were taken into account.[190] They are not the kind of explanation American courts have long demanded as an adequate reasoned explanation of a rulemaking decision.[191]

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[186] Regulation (EC) No 1049/2001 of May 2001 regarding public access to European Parliament, Council and Commission documents.

[187] [Note also the disposition in proposed EU Constitution].

[188] [Cite relevant EC authority].

[189] Get Connected, n. 140 above at 39.

[190] The Get Connected Report refers to the Commission's 2004 Better Lawmaking Report; its more recent 2005 Better Lawmaking Report asserts: "Overall compliance with the minimum standards for public consultation has been good. Experience has shown that there is room for further improvement in (1) providing general feedback on how comments were taken into account in a proposal or why they were discarded; and (2) ensuring that comments received are systematically published." http://www.cc.cec/sg_vista/cgi-bin/repository/getdoc/COMM_PDF_COM_2006_0289_F_EN_ACTE.pdf.

[191] *See*, *e.g.*, *Independent US Tanker Owners Committee v. Dole*, 809 F.2d 847 (D.C. Cir.), cert. den. 484 U.S. 819 (1987).

IV. Creating implementing measures

Legislative measures frequently establish general, rather than detailed, requirements. Their doing so is encouraged by contemporary preferences to have requirements that are imposed on the private economy formulated as standards to be met, rather than detailed, prescriptive rules to be obeyed – the thought being that private actors will be best able to find the most efficient means of compliance. Any such measures will normally require some form of further elaboration and implementation by other governmental institutions like the Commission in the EU or administrative agencies in the EU and the US, or by subordinate jurisdictions like Member States in the EU or the States of the Union in the US. The legal characterization of such further elaboration and implementation at the EU level – as either delegation of legislative or lawmaking power, or delegation of interpretative or implementing power only – bears importantly on the legal justification for such implementing measures. Further, the more general the legislative measures are, the more detail must be subsequently supplied. The level of detail in legislation is, as noted above,[192] governed by a number of factors, some of which are related to efficiency in regulating the particular subject matter and some of which stem from the incentives that legislators face.

Actions corresponding to American agency rulemaking take a variety of forms. When the EU has issued a "directive," setting framework standards that require implementing measures, these measures are commonly – but not invariably – taken by Member States subject to EU controls for their adequacy. Because the procedures for creating these implementing measures are set by national law, they will not be addressed here; nonetheless one considering the means by which law is shaped in Europe must always consider that national implementation is a major element, and the procedures and expectations operating at that level inevitably shape the European experience. Even if in the first instance it is for Member States to exercise the freedom of approach that "directives" intentionally leave, however, it may be necessary to adjust the dimensions of that freedom from time to time, as experience develops; and it will be necessary to reach judgments over time as to what approaches do and what do not honor the directives' essential requirements. And EU "regulations" creating law directly applicable to private individuals may also require or at least permit subordinate forms of lawmaking. At least three contexts for implementing measures directly involve procedures at the EU level, predominantly in the Commission but to some degree in coordination with external international or pan-European bodies – comitology, "new approach" standards, and other forms of reference to external international or pan-European bodies.

A. Delegation Doctrine In The EU

In the EU as in the United States, "legislative power," as such, cannot be delegated, but nonetheless executive authority *may* validly be invested with the

[192] *See* text at nn. 42-44 above.

authority to create texts having the force of law. Such a paradoxical statement creates difficulties of theory in both places; in Europe, resolution is achieved by characterizing the powers thus conferred as involving the power of "implementation." The EC Treaty permits investing the Commission only with power to *implement* EU legislation adopted by the Parliament and the Council, or the Council alone. Just as American caselaw insists, at least as a matter of form, that legislation conferring regulatory authority on an agency provide standards sufficient to permit assessment whether the regulator has acted with legality, the EC treaties and EU caselaw insist that Commission implementation powers be demonstrably subsidiary to, and measurable against, legislatively created norms.

The draft European Union Constitution, after clarifying the nomenclature,[193] would have stated these constraints in some detail. Article I-33 provided for a "European regulation," which it characterized as a *non-legislative* act of general application for *implementation* of legislative acts and of certain provisions of the Constitution" (emphasis added), which could have had either the effect of a current regulation (direct effect in the Member States) or of a current directive ("binding as to the result to be achieved … but [leaving] to the national authorities the choice of form and methods"). Article I-35, ¶1 was then explicit that the "essential elements of an area shall be reserved for the European law or framework law and accordingly shall not be the subject of a delegation of power." It also required bounding the delegation, stating that the "objectives, content, scope and duration of the delegation of power shall be explicitly defined in the European laws and framework laws." It went on to require that the delegation be conditioned, providing that:

> European laws and framework laws shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows:
>
> (a) the European Parliament or the Council may decide to revoke the delegation;
>
> (b) the delegated European regulation may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the European law or framework law.

Article I-36 spelled out the framework under which the Council and the Parliament could have delegated to the Commission "the power to adopt delegated European regulations to *supplement* or *amend* certain *non-essential elements* of the *law* or *framework law*." (Emphasis added) Finally, Article I-37 provided for a second type of "delegated" European regulation, European "implementing regulations."[194] Like Article I-35, it would

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[193] P. 22 above.

[194] Article I-37, ¶1, would have required that Member States "adopt all measures of national law necessary to implement legally binding Union acts." Article I-37, ¶2 would have permitted delegation by the Council (continued…)

have required that "European laws shall lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers."

B. The Delegated Powers of the Commission

Article 202 ECT provides that the Council "shall" "confer on the Commission, in the acts which the Council adopts, powers *for the implementation* of the rules which the Council lays down."(Emphasis added) The Council "may impose certain requirements in respect of these powers." The Council "may also reserve the right, in specific cases, to exercise directly implementing powers itself." Finally, "[t]he procedures referred to above must be consonant with principles and rules to be laid down in advance by the Council, acting unanimously on a proposal from the Commission and after obtaining the opinion of the European Parliament."

The process of adopting implementing measures takes place at the EU level in two main ways – through the so-called comitology process under Article 202 ECT and through the so-called standards process.[195] The Council has provided for different "principles and rules" to govern the process in each case, as discussed below. Little of this subordinate lawmaking is developed with the detail of either American rulemaking or, for that matter, Commission preparation of legislative proposals. Although examples of a process similar to that used for legislative measures can be found within the EU DGs themselves,[196] on the whole implementation measures are much less in public view, or committed to public participation, than are legislative acts. The UK Task Force for Better Regulation characterizes comitology, the first and perhaps most prominent of these practices, in a way that echoes through the whole of the literature:

> The main concern we have about the comitology procedure is one of transparency. The comitology database that lists the committees and their agendas is welcome, but information is often posted too late for stakeholders to influence the discussion. With participation

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and the Parliament to the Commission (and in "duly justified specific cases) … of "*implementing* powers" to enact "European implementing regulations" where "*uniform conditions for implementing* legally binding Union acts are needed." (Emphasis added).

[195] Implementation by Member States, chiefly of Directives, is beyond the scope of this Report.

[196] For example, the Commission has created, in association with DG Internal Market's Financial Services bureau, two committees, the European Securities Committee[ESC] and the Committee of European Securities Regulators[CESR], and it sometimes issues mandates to them in connection with the implementation of its work. *See*, *e.g.*, http://ec.europa.eu/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://ec.europa.eu/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://ec.europa.eu/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). And *see* the discussion of the European Air Safety Agency, p. 87 below.

> in the committees restricted to Member State representatives and institutional actors, together with little public information, the process can seem a complete mystery to many people.[197]

Thus, as Bignami also reports,[198] the pattern of consultation in the EU is quite the reverse of that in the United States. The following pages discuss in turn comitology, "new approach" standards, and other forms of reference to external international or pan-European bodies. The very recent revisions in comitology practice, discussed in the following pages, while enhancing the role of Parliament, do not appear to have addressed these concerns. Even the draft Constitution, which essentially would have made Parliament a political equal to the Council in supervising Commission proposals for implementing measures, specified no greater degree of public participation in the adopting of those measures than currently exists.[199]

C. Comitology

For the Commission itself, implementing measures are most frequently the product of a process known as "comitology," a process characterized as a means for consulting Member States, and carefully structured by the Member States acting in the Council to ensure that they *are* consulted.[200] As required by Article 202, third indent, of the EC Treaty, this process is given some structure by the so-called comitology decisions.[201] These decisions are designed to allow Member State and, increasingly, Parliamentary control over the process, but do not yet significantly involve public notice or participation. Essentially, they commit Commission proposals for implementing

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[197] Get Connected, n. 137 above, at 19.

[198] Francesca Bignami, The Challenge of Cooperative Regulatory Relations After Enlargement, n. above, at 90-91:

> … 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.

[199] 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 _____.

[200] http://ec.europe.eu/comm/civil_society/apgen_en.htm p. 4, visited April 12, 2005, updated as of March 15, 2005.

[201] Decisions 87/373/EEC and 1999/468/EC, as further modified by Council Regulations 806(2003) (qualified majority) and 807(2003) (unanimity), and by Council Decision 2006/512/EC. 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. ___ above, pp. 185-215.

measures to the active oversight of committees of experts drawn from Member States, with the results to be reported to the Council, and in some cases the Parliament, before they can become effective. We discuss, first, the practice itself; and then the increasingly complex supervision relations with the Council and Parliament.

Comitology practices vary, depending on the legislation involved, on the functional needs of implementing measures, and on the competencies given to the Community in one sector compared to another. Most closely supervised by individual DGs, the frequency with which comitology is used also varies considerably from place to place within the Commission; some Directorates (for example, Employment) employ comitology hardly at all, where others (Agriculture, Enterprise, SANCO) report hundreds, even thousands, of annual events. The Commission Secretariat maintains a Register of Comitology covering comitology documents from January 1, 2003.[202] Here one can occasionally find notice of agendas in advance of meeting,[203] together with an indication who is invited (Member-State representatives and, if useful, member-state designated experts, but not the public); drafts may be available *if* Members of Parliament will enjoy a right of scrutiny, but not otherwise.[204] Given the variation and this general lack of transparency, a report like this one can do little better than scratch the surface; while the attached sectoral reports attempt specific examples in their contexts, one is well advised to consult the particular practice of particular DGs in the current moment.[205] Comitology procedures have changed considerably over the years, particularly as Parliament's place has strengthened, and for this reason early studies[206] are of uncertain continued relevance.

Comitology committees consist of Member State representatives qualified in the particular field, chaired by a non-voting representative of the Commission.[207] Their meetings may or may not be preceded by public notice, but in any event they will be

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202 http://www.ec.europa.eu/comm/secretariat_general/regcomito/registre.cfm?CL=en.

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

204 It may be possible to request them, *see* the report on transparency, but notice does not often appear in advance of meeting, and in any event such requests often will not be fulfilled in a time consonant with the committees' actions. COM(2005) 554 final, the annual report for 2004 on the operation of committees, characterizes as Commission policy that "draft implementing measures should normally become publicly accessible *after the vote in a committee has taken place*," – that is, when the committee has concluded its work but before the final adoption of the measures by the College of Commissioners at 4.

205 Many committees used by DGs for advice or similar functions are not Comitology Committees exercising the powers or subject to the procedures established by the Comitology Decisions. These non-comitology groups may or may be not set up by official Commission decisions; some further development about them may appear in the sectoral reports. *See*, as one example, the Commission Decision of 25 March 2003 setting up a consultative group, to be known as the 'Experts Group on Trafficking in Human Beings,'(2003/209/EC).

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

207 This description draws on ¶¶14-054-061 of Lenaerts and Van Nuffel, pp. 614-19.

held in small venues, to which only the members and a limited number of "experts" seconded by members will be invited. The Commission presents a proposed draft of its intended action (for our purposes, an implementing measure) to the committee which, after deliberation, delivers an opinion on the proposal. The committee acts on the draft by qualified majority under one of five regimes; the committee denomination that invokes these regimes will be specified in the secondary legislation in relation to which the committee is formed:

- If a committee is denominated "advisory," its actions are simply advisory in character; while the Commission is expected as a political matter respond to negative advice in a final instrument taking action, as a legal matter its resolution may take effect without further formalities.

- If a committee is denominated "management," the style most likely in agricultural matters or matters with large budgetary implications, failure of the committee to approve the Commission's draft (or a revised draft) by a qualified majority must be communicated to the Council, which has three months in which to take a different position by qualified majority. Unless it does so, the Commission draft enters into force.

- If a committee is denominated "regulatory," control may rest in the Council alone or, as is more likely under current practice and in light of new procedures adopted in July, 2006,[208] in the Council *and* Parliament. As the most demanding of the ordinary forms of comitology, "regulatory" comitology is the principal concern of the following discussion.

    (a) If the draft measure in question is not considered "quasi legislative," the Commission's proposal will come into force routinely if it secures qualified majority support from the committee *or*, failing that, if it secures support from the Council within three months – again, by qualified majority. The Council can amend the Commission's proposal only by unanimous vote. Should a qualified majority of the Council *oppose* the Commission's draft, the Commission must submit a revised proposal (or seek legislative action) to effect an implementing measure. However, the Commission proposal will take effect, even if not approved in committee, if three months expire without either qualified majority support or qualified majority disapproval being expressed in Council. If, as is now usual, the underlying legislative act

[208] Council Decision on 17 July 2006 (amending Council Decision 1999/468/EC; *See* Thomas Christiansen and Beatrice Vaccari, "The 2006 Reform of Comitology: Problem Solver or dispute postponed?" forthcoming in EIPASCOPE Vol. 2006, No. 3. The political quid pro quo for the new procedure was that the Parliament had to agree not to exercise its power to require "sunset" provisions in legislation allowing the Commission "implementing powers."

was adopted by co-decision, drafts are also transmitted to Parliament; Parliament then has a month in which it may adopt a resolution informing the Commission of its view that the draft exceeds the Commission's delegated powers. Should this happen, the Commission is obliged to reexamine its draft and to report, with reasons, the action it intends to take. Resubmission to such parliamentary review is provided whenever the Commission substantially modifies its action from an earlier draft, if the underlying legislative act was adopted by co-decision.

(b) If the draft measure in question is considered "quasi legislative," the July 2006 amendments to the comitology decision outlined a new "regulatory procedure with scrutiny" procedure. "Quasi legislative" measures are those "measures [implementing co-decided basic acts] of general scope designed to amend non-essential elements [of the basic act] *inter alia* by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements."[209]

The new procedure is complex, but the basic thrust is to give the Parliament, in most respects, the same power of review and disapproval of quasi legislative measures as the Council has.

Even if the relevant committee agrees with the Commission's proposal, new Article 5a requires that both the Parliament and the Council must be given copies of the draft measure, and each can disapprove the measure (the Council by a qualified majority, and the Parliament by an absolute majority), in which case the Commission has to either amend its proposal or seek legislation. Not only is the Parliament given the right to disapprove (if the draft measure is not "quasi legislative," it can only "inform" the Council of its position), but its disapproval, like the Council's, may be based on the conclusion that "the draft is not compatible with the aim or the content of the basic instrument or does not respect the principles of subsidiary or proportionality." For measures that are not "quasi legislative," it can "inform" the Council only as to its views with regard to an "excess of implementing powers."

[209] *Id*.

When the committee disagrees with the Commission's draft measure, or renders no opinion, then the Parliament has the same power to disapprove, on the same grounds, but can only exercise this power sequentially, after the Council "envisages adopting" (rather than opposing) the measure or has not acted within two months. If the Council agrees with the committee's refusal to agree to the Commission's draft, then the Council can unilaterally oppose the measure and the Commission must amend it or seek legislation, without regard for what the Parliament may think.

- The final style, "safeguard," is a rarely invoked amalgam.

As appears from the Commission's most recent reports on the working of committees,[210] the elaborate comitology provisions regarding Council and Parliament review were rarely invoked in the period before the recent revisions, and most committee contributions were, at least on the surface, minor. Parliament has now enacted a resolution characterizing a draft as beyond Commission authority, with regard to the implementation of the RoHS Directive in the environmental sector, but in 2004 as in 2003 it did not formally invoke its authority. The great bulk of Commission DG proposals are ratified without significant change or opposition by the committees – and as a result, the Council is rarely consulted, at least formally. There were 17 referrals to the Council in 2004,[211] *no* referrals to the Council in 2003; seven, in 2002. Of course one may say, as the Commission does,[212] that the relative imbalance of DG and committee or Council work reflects the sensitivity of DG staff to committee and Council preferences. The claim is very hard to evaluate in the absence of transparency in the comitology process, however. The drafts the Commission submits to comitology committees are not published outside the committees; committee agendas are usually reported (if at all) after the fact of meeting; and minutes of committee meetings are quite summary.[213]

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[210] COM(2003) 530 final (concerning 2002), COM(2004) 860 final (concerning 2003), and COM(2005) 554 final (concerning 2004).

[211] "Although the total figure represents only 0.5% of the total number of implementing measures adopted by the Commission under the management and regulatory procedures, it is the highest figure in absolute terms since the beginning of regular reporting in 2000 (which yielded a high concentration [12/17] in the Environment sector)." COM(2005) 554 final at 6. The report goes on to speculate that enlargement may be making it hard to reach consensus, perhaps especially in the sensitive environmental field. *Cf.* the final paragraph of "The Interplay Among the Institutions," p. 21 above.

[212] *Id.* at p. 5 (both).

[213] *See*, *e.g.*, http*://ec.europa.eu/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 these two recent reports:[214]

DG	2001-04 committees[215]	2001-04 regulatory procedures[216]	2001-04 meetings[217]	2002-03 opinions[218]	2002-03 instruments[219]
ENTR	33	18	200	1126	1012
EMPL	8	3	52	32	5
AGRI	30	4	1383[220]	4147	4147
TREN	45	24	157	108	79
ENV	35	26	219	179	119
INFSO	13	4	128	125	105
MARKT	12	7	120	27	23
TAXUD	10	4	443	148	135
SANCO	22	9	443	1228	988
JAI	10	1	83	86	48
TRADE	13	2	119	168	150
AIDCO	9	2	158	527	502
OLAF	1	1	6	1	0
TOTAL[221]	**256**	**100**			**7313[222]**

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 well over seven thousand comitology acts would generally fail to attract Parliamentary correction, and involve the Council only 24 times, may reflect Commission caution;[223] but it certainly also suggests Commission initiative and the application of successful political acumen. In the more active DGs, the number of instruments significantly outnumber the number of (generally half-day) meetings; the length of SANCO agendas[224] 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 so meetings per instrument, suggesting that at least in these

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214 A similar analysis of earlier experience appears in Josef Falke, Comitology: From Small Councils to Complex Networks, Andenas and Turk, n. 6 above, at 331, 343 ff.

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

216 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.

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

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

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

220 Predominantly management meetings

221 May include DGs without *any* regulatory procedures

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

223 McNollgast on police alarms/fire alarms [full cite needed]

224 N. 215 above.

contexts the committees can be rather deeply engaged with Commission proposals. Again, direct opportunities for external knowledge and participation are limited. Occasional accounts one can find in the literature – for example, of the handling of the BSE crisis[225] – 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.[226] And one general account of comitology practice in ENV, under prior regimes and thus now perhaps outdated, suggests not only the problems with its "secret life," but quite specifically that, relative to its committees, and as a matter of practical politics, the Commission is in "quite a strong position."[227]

In the circumstances, the consistent observation that transparency and citizen involvement are missing at the level of comitology suggests at least the possibility that engaged oversight is absent because it is ill-informed. This possibility 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."[228] The "your voice" site, again, references few if any consultations about implementing measures. Individual DG websites seem little better. And the Secretariat-General's Register of Comitology, as earlier noted,[229] is also quite limited in the access it provides.

The pharmaceuticals unit of DG Enterprise (ENTR) – one of the more active DGs so far as implementing measures are concerned – publishes a not inconsiderable list of implementing measures for Directive 2001/20/EC (pharmaceuticals).[230] No link for consultations appears on its web site. By consulting the "news" link that is there,[231] one can find invitations to comment on draft guidance documents, coordinated with the European Medicines Agency site,[232] but no information about comitology activities. ENTR consultations link[233] is no more informative. The comitology process, mild as it may be, is hidden from view.

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225 Gunther Shafer, Linking Member State and European Administrations – The Role of Committees and Comitology, in Andenas and Turk, n. 6 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.

226 *Id*. at 22; *see* n. 205 above.

227 Christoph Demmke, Comitology in the Environmental Sector, Andenas and Turk, n. 6 above, 279, 285, 287.

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

229 Text at note 203 above.

230 http://pharmacos.eudra.org/F2/pharmacos/dir200120ec.htm.

231 http://pharmacos.eudra.org/F2/pharmacos/new.htm.

232 http://www.emea.eu.int/; *see* n. 246 below.

233 http://ec.europa.eu/comm/enterprise/consultations/list.htm.

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.[234] For Europe, in particular:

> "the great enemy of successful … transnational regulation … appears to be the selfish pursuit of particular national interests by the Member States or rather by their democratically elected, political leaders responding to their particular domestic constituencies with electoral clout. Transnational regulatory technocrats become the transnational regulatory heroes in pursuit of the transnational general interest …. The nationality requirement [of comitology committee membership] is a bow to Member State political control … [but] in most instances, the shared professional or expert standards, practices, values, assumptions and agreed truths of the particular specialized expertise shared by committee members is likely to overwhelm national differences or indeed any political considerations."[235]

Shapiro, one might add, is a person not impressed with the virtues of technocracy, of "government regulation of what we eat by the deliberation of nutritionists."[236]

D. European Agencies As Actors

Comitology is a process that develops implementing measures through the Commission itself. One might also imagine – and to a limited extent find – European legislation creating agencies that, like American independent regulatory commissions,

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[234] Some Free Associations on Administrative Judicial Review, draft paper presented at the University of San Diego January 20, 2005, p. 3. A similar analysis appears in print as Martin Shapiro, "Deliberative, "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?, 68 Law & Contemp. Prob, 341 (2005). [**Peter – This title does not look correct.**]

[235] "Some Free Associations" at 3-4. The great example to the contrary, however, is the success of the Member States in stopping use of GMO's dead in its tracks for years under existing legislation, with no legal basis for doing so, under the rubric of a political use of the "precautionary principle" driven by public fears whipped up by environmental NGO's.

[236] *Id.* at 5.

would be empowered to enact implementing measures in a delimited field of action. The power of the European agencies to enact implementing measures, however, is very limited. Only a few of them have any power of taking technical decisions, and that power where found is circumscribed. Some of them have certain functions in a regulatory process, but many of them have only consultative functions.

One reason for the relative unimportance of the "independent agency" as a source of what Americans would call regulations lies in the Commission's vigorous defense of what it considers its role as Europe's "unitary executive."[237] (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.[238]) Accepting that regulatory agencies may be created at the EU level, the Commission has asserted that "[t]he main advantage of using [them] is that their decisions are based on purely technical evaluations of very high quality and are not influenced by political or contingent considerations"; while they "can be granted the power to take individual decisions in specific areas, [such agencies] cannot adopt general regulatory measures" and "cannot be granted decision-making powers in areas in which they would have to arbitrate between conflicting public interests, exercise political discretion, or carry out complex economic assessments."[239] 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."[240]

The EU's central website for European agencies[241] identifies eight as having regulatory functions – the Office for Harmonization in the Internal Market,[242] the Community Plant Variety Office,[243] the European Medicines Agency,[244] the European

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[237] COM(2002) 718 final, at 2.

[238] *Cf.* p. 13 ff. above.

[239] COM(2002) 718 final at 5, 8; *see also* http://ec.europa.eu/comm/governance/governance_eu/decentral_en.htm.

[240] 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.

[241] http://ec.europa.eu/agencies/index_en.htm. Each assesses fees for its services, and thus is essentially self-supporting.

[242] http://oami.eu.int/. Concerned with Community trademarks and design registration; its 2004 annual report is devoid of mention of "rulemaking" or "implementing measure," and one finds no evident links from its website to such matters.

[243] http://www.cpvo.eu.int/index800.php. Essentially a Community patent office for plant varieties, in 2004 the CPVO adopted administrative guidelines for determining plant varieties, pursuant to authority granted in

(continued…)

Food Safety Authority,[245] the European Maritime Safety Agency,[246] the European Aviation Safety Agency,[247] the European Network and Information Security Agency,[248] and the European Railway Agency.[249] 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,"[250] that engages in a process strongly resembling American notice-and-comment rulemaking[251] to generate standards on a variety of subjects (including, in contradistinction to Commission practice, an apparent disposition to draft its proposals *prior* to initiating

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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.

[244] http://www.emea.eu.int/. Formerly the European Agency for the Evaluation of Medicinal Products, this agency (connected with the pharmaceuticals unit of DG Enterprise and Industry) is the European equivalent of the American FDA. It appears to engage in active generation of guidance documents and standards for both human and veterinary medicine following consultations that are not obvious from the front page of its site, but presumably are well known to stakeholders. *See* 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.eudra.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.

[245] http://www.efsa.eu.int/. Given particular impetus by "mad cow disease," this agency offers subscriptions for news highlights and notices of consultations on its front page. Its principal responsibilities concern risk assessment, and it is not clear that any of its products have the force even of soft law.

[246] http://www.emsa.eu.int/. EMSA, like EASA, is an adjunct to DG Energy and Transport, but unlike that agency, discussed in the text following, no "rulemaking" unit or activity is readily discernable on its website.

[247] http://www.easa.eu.int/home/.

[248] http://www.enisa.eu.int/, established in March, 2004.

[249] http://www.era.eu.int/, the EU's newest agency, under formation as an adjunct to DG Energy and Transport, there to join the Maritime Safety and Aviation Safety agencies. *See* http://ec.europa.eu/comm/transport/rail/era/index_en.htm, http://ec.europa.eu/comm/dgs/energy_transport/home/organigram/doc/organi_en.pdf (DG organization chart).

[250] http://www.easa.eu.int/home/rulemaking_en.html.

[251] 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.

public consultation).[252] Like the Commission, it maintains a published rulemaking program[253] 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.

There are a plethora of other agencies that have no regulatory powers. The European Environment Agency, a good example, is limited to developing information and data on the state of the European environment.

E. Delegation Out – International Bodies and European Standards Organizations

The Commission and expert bodies act together in the formulation of norms in at least two other contexts worthy of mention, but not elaborate discussion, although both raise fundamental issues of legitimacy, accountability, and perhaps even legality in lawmaking and implementation because they involve apparent delegation of sovereign power to non-state actors.[254] In both of these settings, in contrast to comitology, it appears that one can secure advance notice of the matters to be discussed, and perhaps seek to influence the discussion.

The first arises where other international bodies are ultimately responsible for the generation of standards (as for example the Codex Alimentarius Commission that the FAO and WHO have jointly created to develop standards, guidelines and related texts concerning food purity[255]). Here, the Commission may use a committee format to develop joint positions with Member States on matters to be considered on forthcoming

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[252] *See* Art. 13 of EC Regulation 1592 (2002), O.J. 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.

[253] http://www.easa.eu.int/doc/Regulation/Docs/decision_ED_2004_09_RM_annex.pdf.

[254] *See also* n. 147 above, concerning the use of advisory committees early in the legislative drafting process.

[255] http://www.codexalimentarius.net/web/index_en.jsp.

agendas. And for these committees (not comitology committees), agendas and discussion papers may be noticed and made available in advance of meetings.[256]

Second, some Commission directives employ what it has denominated the "new approach" in matters affecting the single European market – that is, in American terms, where one might fear that Member States could be tempted to use national safety or similar concerns to mask favoritism to domestic industry. As already noted,[257] Directive 98/34/EC establishes a procedure under which EU Member States are obliged to notify the Commission and each other of all draft technical regulations and voluntary standards concerning products and information society services before they are adopted in national law. Directive 98/34/EC becomes important in the context of New Approach directives, because Article 6 of the Directive provides that the Commission can submit communications and proposals to the Directive's Article 5 Standing Committee, which consists of representatives of the Member States and is chaired by a Commission representative. The Standing Committee, upon consultation, can propose that the Commission request the European standards organizations to draw up a European standard within a given time limit. This prior consultation ensures that the Commission's mandate to the European standards organizations provides them with a strong indication of the expectations of the public authorities concerned.

The New Approach technique is extensively used in the telecommunications sector, which involves much technical integration, and has been used to a much lesser degree in the environmental sector where the regulatory choices are much more political and value laden. Commission directives qualifying for the New Approach, in themselves, define only the "essential requirements" of regulatory controls in technical fields – say, safety standards for toys, or for pressurized containers – and not particular means of achieving compliance with these requirements. They also create Commission mandates to European standards organizations (rather than "comitology" committees) to identify 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) public enquiry period.[258] It is by this means that, it is hoped, the wheat of genuine protection can be winnowed from the chaff of favoritism to industry.

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[256] Thus, on April 20, 2005, one could find at http://ec.europa.eu/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. Few issues of SANCO-news subsequently received carried any advance notice of comitology meetings, or links to documents to be discussed at them, in conformity with Commission policy. N. 205 above.

[257] *See* n. [**4 on p. 42?**] above.

[258] *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.

If they are accepted by the Commission and officially published, the standards establish presumptively valid means of satisfying the essential requirements the directives define. Thus, the adoption of technical standards has the effect of soft, not hard law[259] – essentially the same as an American business would experience if it followed "guidance" an agency had issued describing in detail particular actions it would accept as complying with its regulations. Such assurance is particularly important where, honoring contemporary preferences for maximizing the initiative left to regulated industries, hard law instruments have set standards to be met ("essential requirements," what qualities a safe toy should have) rather than specified exact behaviors that are required (exactly how a toy must be built). Thus, 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. National implementation of the same directives is to honor these standards once created.

One can get the misimpression that standardization work is uniquely done by *national* standard-setting organizations acting in coordination with *national* authorities from the Commission's published guide and 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)[260] "following consultation with the Member States,"[261] to develop Union-wide harmonized standards;[262] elsewhere, it lists 27 mandates issued 1999-2001.[263] The CEN website gives, sector by sector, elaborate reports on the progress of mandated standards through its processes.[264] In doing so it makes evident that it, too, proceeds very largely by committee action.[265] And a recent "Communication from the Commission to the Council and the European Parliament" on "Better Regulation for Growth and Jobs in the European Union" strongly suggests that the future lies with increasing reliance on this private/public mechanism for law-generation.[266] Recently the

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[259] Technical standards "cannot replace a legal text or change what the legislator has provided." Guide, n. 260 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.

[260] http://www.cenorm.be/cenorm/index.htm.

[261] *See* Guide, n. 260 above, Table 4/1, p. 28.

[262] N. 260 above at 40-43.

[263] *Id*. at p. 12. Tables in Schepel, n. 259 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.

[264] 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.

[265] Schepel, n. 259 above, describes CEN and its processes at p. 101 ff.

[266] SEC(2005) xxx at 9; and see the Commission documents and Schepel, cited in n. 241 above, *passim.*

EU has experimented with use of the standards process in areas like packaging waste and other environmental areas where value judgments have more relevance than simple technical determinations. As noted in the environmental Sector Report, this has proved controversial, and the Commission has not widely extended the practice.

V. Guidance and Other Forms of "Soft Law" – Giving reliable advice

It remains to address the realm of "soft law," settings in which the Commission or its delegates seek to develop what in the American context would fall within the realm of general statements of policy, interpretive rules, or staff manuals intended to structure staff behaviors. In American practice these matters, that might be lumped together under the rubric "guidance documents" or "publication rules," are generally free of procedural requirements; the one clear procedural constraint respecting them is that an agency is permitted to rely upon them to the detriment of a member of the public only if they have previously been published and indexed, or specifically brought to the member's attention.[267] Generally, such publications are adopted with the purpose of governing an agency's subordinate staff, by committing it to act in the predicted manner when identified facts are presented or found; but while they doubtless influence public behaviors through awareness of this intent and their consequent predictive value, they do not, in themselves, create any obligation on members of the public. Hence, "soft law."[268]

Enough has already been said to indicate that the Commission is often itself a source of soft law documents, and that – as in the "New Approach" directives – it 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,[269] although one confidently supposes that strong political incentives as well as these formal obligations underlie it.

Here, too, these steps are preliminary and tend to be quite structured and pointed – the Commission exposes the questions on which it wishes public commentary, and does not present its policy choices until after this consultative process

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[267] 5 U.S.C. §552(a)(1,2); Peter L. Strauss, Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element, 53 Ad. L. Rev. 803 (2001).

[268] Although, given the court-imposed requirement that European institutions comply with their own guidance, it may only be the lack of effective judicial review that separates "soft" law from "hard" law here. [**Cite**]

[269] *See* the "overview 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. ___ above however, this site is explicit that "the consultation standards do not apply to comitology consultation," nor presumably to actions of agencies or to "new approach" decisions by international or standardization entities.

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.[270]

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 individually to public consultations, but the small and overworked EU staff tends to pay less, sometimes much less, attention to individual company or union input, particularly if, *e.g.*, the company commenting is not an EU company.) 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. Such official but *de facto* "appointment" as "gate-keepers" controlling effective access to the EU political entities raises serious issues of democracy, protection of minority interests, fairness and accountability with regard to the internal structure of those organizations. Individual companies, for example can be seriously disadvantaged in the "political" processes within a trade association, and companies from particular countries can be disadvantaged within EU-level trade associations effectively controlled by strong companies in the industry in question from certain countries (*e.g.*, as to some major industries, like Germany), particularly if they are non-EU companies.

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.[271] 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

[270] A notable exception is the FDA, which by statute and internal regulation is committed to "good guidance practices" producing similar levels of notice and engagement. *See* 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.accessdata.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.

[271] EC(2000) 60. *See* http://ec.europa.eu/comm/environment/water/water-framework/index_en.html.

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."[272] 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 working groups responsible for implementing environmental regulations and directives.[273] 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;[274] the library includes, in particular, a several hundred page document[275] 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.[276] As is common, however,

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[272] *See* http://ec.europa.eu/comm/environment/water/water-framework/implementation.html. The strategy is discussed at some length in Scott & Holder, n. 120 above, at 12 ff, remarking on the flexibility and reflexivity of the results.

[273] http://forum.europa.eu.int/Public/irc/env/Home/main.

[274] 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.

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

[276] 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 program 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.

(continued…)

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.[277] 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, however, 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, one of the authors of this study applied for observer membership in the WFD site (and also for one other, for working groups for the Noise Directive also located on the CIRCA site). He informed both groups that he was "a university professor in the United States researching issues about public participation in American and EU law, and would greatly appreciate access to the CIRCA materials on …."[278] 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 program. On the basis of the information that you provided, we were not convinced that a private or economic interest could be excluded. For your information, the following activities fall under this criterium:
>
> — consultancy work for other institutions other than the Commission
>
> — university studies and projects
>
> — individual industry representatives.

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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.

[277] Annex III to the Guidance on Public Participation in the WFD, n. [__], above, reported the working process of the group responsible for developing it. "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.

[278] Email of April 9, 2005

> In conclusion, we had to refuse your application for full access to the WFD CIRCA system.[279]

No recourse was stated or evident.

The WFD undertaking is extraordinarily complex and demanding, and both economic and national stakes are high. The wish to exclude "a private or economic interest" is not hard to appreciate, and one may believe too that within the engaged framework of NGO participants and observers there exists rich opportunity for knowledgeable critique.[280] 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.

One other area of "soft" law to note is the new promotion by the Commission of informal groups of national regulators, such as the IMPEL group of national enforcement regulators in the environment sector. Given the extent of delegation of implementation in the legislation of some sectors like environment, the Commission has found it useful for national officials to develop vehicles for cross-Member State communication and coordination of implementation and enforcement. Such ties develop in the US at national level "trade associations" of state and local officials, which have yet to develop in the same way in the EU. The IMPEL group has been so successful that a new group of national legal advisors in the environmental area is now developing.

VI. EU Institutions And Lawmaking Processes By Sector – The Details

A. The Competition Law Sector

As earlier mentioned, the Directorate General for Competition (DG COMP) has principal responsibility for the task of ensuring the creation and maintenance of effective open markets and competition within the EU. DGCOMP is, organized into both cross-cutting Directorates: A (Policy); C (Information, Communication and Media); D (Services); and G and H (State Aids) and industry-specific ones (B (Energy, Basic Industry, Chemicals and Pharmaceuticals); E (Consumer Goods);and F (Cartels). The industry-specific Directorates are responsible for both merger control and agency investigations in the respective industries.

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[279] 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.

[280] *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.

Articles 81 and 82 ECT set out the competition law principles for the Community, and Article 83 ECT grants the Council and Parliament authority to legislate with regard to them. Article 202 ECT grants authority to the Council to delegate to the Commission the power to adopt implementing measures. In the competition area, both the Council and the Commission use directives less frequently than regulations. Council and Parliament Directives, based on Article 95 ECT or other articles but not on specific competition law authority, have addressed the liberalization of formerly monopolistic national markets such as electricity, gas, and telecoms (although for liberalization of the airspace sector, Council regulations have been used). Commission Directives, adopted pursuant to a special grant of competition law surveillance authority to the Commission over Member State public companies by Section 86 ECT, have been used to supervise Member State public companies or companies to which a Member State has granted special or exclusive rights. The two main Council regulations are the so-called Modernization Regulation and the Merger Regulation. Commission Regulations fall into two main areas – Implementing Regulations that specify the procedural rules for the Council Regulation to which they refer, and Block Exemption Regulations that set out the conditions under which categories of merger and other agreements between private corporations can be considered compatible with EU competition law.

Besides lawmaking, much of the work of DG COMP involves making individual decisions in the competition area. Both the principle of subsidiarity and the workload of DG COMP has resulted in more authority in the competition sector being moved to the competition law authorities of the Member States, limiting the scope of Commission action to those cases where EU level action is necessary.

DG COMP may initiate Council legislation either as a result of internal discussions or studies, or as the result of external influences. In the competition sector, the Commission tends to intervene either when it is confronted with certain gaps in the existing legislation or when it is confronted with a "critical mass" of analysis, suggestions, interventions and criticisms on a certain topic, which can in this sector result from decisions of the European Court of Justice or the Court of First Instance. Further, the percentage of DG COMP staff doing policy work is lower than the 55% average for the Commission, because so many DG COMP staff are employed in making individual decisions. This heightens the importance of external comments in contributing to and stimulating the internal DG COMP debate.

Besides the normal forms of notice for the initiation of the lawmaking process used by the Commission, DG COMP publishes a Competition Law Newsletter, a quarterly policy-focused magazine. Further, DG COMP discusses the issues it plans to take up in the Annual Report on Competition Policy, speeches and articles by DG COMP's officials or Commissioner, and in conferences in which it participates. For public consultation, DG COMP has used Green Papers, designed to stimulate debate and to launch a process of consultation at the EU level for particular topics, for such initiatives as the new Merger Regulation. It has used White Papers to solicit public comment for such areas as the modernization of EU antitrust rules. DG COMP used a four month and three month comment period, respectively, in these cases and received

and posted to its web site over 100 comments in each, along with a DG COMP report in the last.

In the early stages of the legislative process, DG COMP normally forms a team of officials to handle the matter, involving officials from Directorate A (Policy) as well as officials of any industry specific Directorate if the measure involves a specific economic sector. One can informally contact members of the team as a matter of course, or submit comments to other participating Commission services such as the Legal Service. Since the views of the national competition authorities (NCA's) are carefully considered, concerns can also be conveyed to the DG COMP team through them. Other vehicles for input are the European Parliament *rapporteurs*[281] and the Economic and Social Committee (EESC), which intervened in the legislative process for adoption of the Merger Regulation and Regulation 1/2003.[282]

As in the case of competition law legislation, Commission implementing measures in the competition sector are more often regulations than directives. With the exception of Commission regulations adopted under Article 86 ECT dealing with surveillance of the public companies of Member States, Commission Regulations in the competition sector are adopted pursuant to rulemaking powers delegated from the Council, using the Advisory Committee Procedure.[283] Thus, in the case of a Commission Implementing Regulation, the first step in its adoption is normally the adoption of the Council Regulation to be implemented, where the basic decision to adopt a Commission Regulation has already been taken.

Notice to the public about proposed implementing measures occurs in much the same way as in the pre-legislative process for Council Regulations. For implementing measures, however, public participation is much more limited than for Council Regulations, on the grounds that they contain mainly procedural rules and are of a technical nature. Once an internal draft is ready, that draft is published on the Commission's web site and a consultation procedure is initiated, but frequently with a significantly shorter consultation period than in other situations.

In the case of Block Grant Commission Regulations, the decision to initiate the process is normally taken internal to DG COMP, in light of its own experience in the application of competition law generally and of Article 81 ECT specifically, although public comments and articles can play a role. Public participation in the development of Commission Block Grant Regulations is of key importance to the Commission, since

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[281] As established in the Rules of procedure of the European Parliament, supra note 14, Art. 42 and ss., the Committee on Economic and Monetary Affairs of the Parliament is in charge of following all the procedures relating to antitrust, mergers and state aid and is responsible for preparing the Parliament's opinion on proposals from the Commission.

[282] In the context of competition policy, the EESC is regularly consulted in the course of the legislative process of Council Regulations.

[283] Two Advisory Committees are involved with EC competition policy, the Advisory Committee on Restrictive Practices and Dominant Positions, and the Advisory Committee on Concentrations.

such regulations have a significant impact on the conduct of business by private corporations. Thus, formal consultations will be opened and interested parties will have the opportunity to participate starting early in the process. Indeed, the Commission is under a formal obligation to consult following the publication of a draft Block Exemption Regulation.[284]

DG COMP does not follow a standardized procedure when adopting Commission Regulations, proceeding case-be-case instead. It has shown great flexibility in its choice of methods for consultation, and regularly consults with the competition authorities of nations outside the EU, as indicated by the examples in the Competition Sector Report with regard to the new Technology Transfer Regulation, a Commission Block Exemption Regulation for technology transfer agreements.[285] Because the Commission must work through the [_____] Advisory Committee, whose members are representatives of the NCA's, input to the process may be had by comment to the NCA's as well as directly to DG COMP.

DG COMP also adopts Notices or Guidelines, forms of "soft law" documents that are not binding on the regulated community but are on the Commission under the principle of legitimate expectations.[286] Notices may be of a general nature or specific to particular areas such as mergers, antitrust or State aid. They may provide guidance on the implementation of substantive rules or deal with procedural issues. Because Notices express the Commission's own interpretation and application of competition law, third parties may have difficulty influencing the initiation of a Notice; but normally DG COMP provides extensive notice and consultation opportunities, and voluntarily considers the views of interested third parties, usually making public a summary document of the submissions. There are no legal explanation or publication requirements, but notices are published in the O.J. series C and make available in other ways. Notices are not normally subject to judicial review, but where they have a *de facto* normative content or create new rights and obligations, they may be reviewed.[287]

B. The Environmental Sector

The environmental sector deals primarily with the regulation of the environmental impacts of industrial and commercial manufacturing plants (including the environmental impacts of industrial accidents) and of the products those plants make. It encompasses regulation of air and water pollution; waste (*e.g.*, waste, hazardous waste, waste shipment, waste oil, and PCB's), especially waste releases to the environment from

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284 [**Cite?**]

285 [**Cite Competition Sectoral Report**; Commission Regulation 772/04.]

286 Association Internationale des utilisateurs de fils de filaments artificiels et synthétiques et de soie naturelle (AIUFFASS) and Apparel, Knitting & Textiles Alliance (AKT) v. Commission, Case T-380/94, 1996 E.C.R. II-2169.

287 *See France v. Commission*, Case C-303/90, 1991 E.C.R I-5315.

industrial accidents and other sources; and regulation of impacts on special environments such as wetlands, groundwater, and natural areas. Product regulation focuses on eco-labeling and life cycle regulation of the harmful environmental impacts of chemicals, packaging, batteries, electrical and electronic equipment, products containing genetically modified organisms, and automobiles. Environmental regulation also covers such subjects as environmental impact of major public or private development and other projects, eco-management and auditing, and legal liability for environmental damage. Plant regulation typically requires implementation by plant specific permits, normally issued at the Member State level. Product regulation frequently requires implementation by listing of products or product types through EU-level comitology, much as in the field of food safety.

The chief regulatory institution at the EU level is DG Environment, located in Brussels and employing about 550 staff. It consists of the Office of the Director-General and seven Directorates covering such matters as Communication, Legal Affairs & Civil Protection; Climate Change & Air; and Water, Chemicals & Cohesion.

The European Environmental Agency, a relatively new agency with about 150 employees and an annual budget of about 31 million Euros, is located in Copenhagen, Denmark. It became operational in 1994, and is a non-regulatory entity that provides environmental information to the Commission, other EU institutions, national governments, and the public. The Agency's mandate is to help the Community and Member States make informed decisions about environmental issues, and to coordinate the development and integration of compatible environmental data across the EU through the European Environmental Information and Observation Network (Eionet). The Agency regards itself as an independent source of environmental information that analyzes and assesses that information and builds bridges between science and policy through networks involving the EU governments and UN and other international organizations. It deals with the state of the environment and trends, pressures on the environment and the driving forces behind them, policies and their effectiveness, and outlooks and scenarios. It provides a number of reports, briefings, and publications. It also disseminates best practice in environmental protection and technologies and information on the results of environmental research. Its membership extends beyond the EU to include EU candidate countries (Bulgaria, Romania, and Turkey), European Economic Area countries (Iceland, Norway and Lichtenstein) and Switzerland.

The EU'S treaty authority to legislate in the environment, health and safety areas arises principally under Articles 95 ECT (Internal Market) and Article 175 ECT (environment). When it does so its law pre-empts that of the Member States,[288] although the Treaty and secondary legislation give the Member States some leeway to impose requirements going beyond EU legislation (*e.g.*, through a so-called "safeguard"

[288] The pre-emptive effect of EU law is founded on a line of Court of Justice rulings establishing that all national authorities, including regional and local subdivisions of the national governments, and publicly owned companies, regardless of the national constitutional structure, must implement and apply Community law.

clause pursuant to which Member States, under certain conditions, may temporarily restrict activities permitted by EU legislation).[289]

The sources of authority for EU environmental law govern the legislative procedure used. The co-decision procedure is used for the bulk of environmental legislation. Such legislation stems primarily from three EC Treaty provisions – Articles 175 (1) ECT governing environmental measures as such, Article 175 ¶3 ECT governing environmental action programs, and Article 95 ECT governing internal market measures. By force of the "integration" requirements of Article 6 ECT, environmental or environmentally related measures may also be adopted under other EC Treaty provisions dealing, for example, with agriculture (Article 37 ECT) and transport (Article 80 ECT), each with its special requirements.[290] Articles 95 and 175 each specify that the legislative procedure of Article 251 ECT, the co-decision procedure, is to be used, which requires qualified majority voting in the Council.

Environmental matters that:

- are primarily of a fiscal nature,
- affect town and country planning
- affect quantitative management of water resources or affecting, directly or indirectly, the availability of those resources,
- affect land use, with the exception of waste management, or
- significantly affect a Member State's choice between different energy sources and the general structure of its energy supply,

fall under the consultation procedure of Article 175 ¶2 ECT. Internal market measures that have environmental implications, but that constitute fiscal provisions, provisions relating to free movement of persons, and those relating to the rights and interests of employed persons are subjected to unanimous voting in the Council and the consultation process, by Articles 95 ¶2 and 94 ECT.

In the environmental area, for the reasons noted earlier, the EC acts chiefly through directives, using regulations much less often. Recently, however, more use has been made of regulations – *e.g.*, with regard to the proposed new EC chemicals legislation entitled "REACH," which deals with products, requires a Community wide

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289 *See*, *e.g.*, Article 95(10) and 174(2), ECT.

290 Because this paper does not deal with the legislative process itself except in passing, those will not be discussed. Nor will we discuss (1) aspects of Articles 175 ¶2 or 95 ECT that deal, in different ways in each provision, with the extent to which Member States may undertake more stringent measures, or (2) the more uniform requirements of those provisions with regard to whether and how various other EC bodies must be consulted, since these aspects are not directly material to the process by which the Commission develops proposals for legislation or promulgates implementing administrative regulation.

system and creates a Community agency. Non-binding guidance notes are also used by the Commission to explain how Member States or the regulated community are to interpret or apply certain pieces of EU environmental legislation – for example the BREF's to spell out by industry category the "best available techniques" for manufacturing plant or other environmental controls.

The Commission uses normal processes of legislation to develop environmental legislation for proposal to the Council and Parliament, but the process has of late been marked by extensive use of consultation procedures, impact assessment, and other forms of "better regulation." As previously noted, the environmental sector has been a bell-weather in the early development of these techniques in the EU.

Community environmental action plans have been used from the early 1970's, and are technically "communications". They set out for a period of four-five years the objectives, principles and priorities of Community action. Sectoral action programs can be used, and have been by the Commission under the current Sixth Environmental Action Plan.

DG-ENV uses comitology processes used extensively, as for example in the implementation of the Waste Framework Directive and the WEEE and RoHs Directives.[291] Comitology processes are pervasively used to further elaborate, to set standards under, or to update environmental legislation over time ("adaptation to scientific and technical progress"). Thus they deal with crucially important issues and details of elaboration and implementation. Comitology in the environmental area, in particular in the implementation of the RoHS Directive, has been the focus of clashes between the Commission and the Parliament over Parliamentary power over, and rights to participate in, the comitology process.

The "New Approach" to technical harmonization and the "Global Approach" to conformity assessment are also used, but sparingly, in the environmental sector, the chief examples being in the area of packaging and packaging waste, and to a limited extent in respect of product marking under the Waste Electronics Directive. Ecolabeling, as noted above,[292] is not based on the New Approach but develops ecolabel criteria under comitology procedures. The use of the New Approach in the packaging waste area has been marked by controversy.

As previously noted,[293] EU environmental legislation has anticipated many elements now common throughout EU administrative law. It imposed "impact assessment" requirements as early as 1985 (chiefly environmental impact) to case-by-

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[291] The WEEE Directive requires that manufactures of certain electrical and electronic products take-back these products when they become waste and ensure that they are reused or recycled. The RoHs Directive prohibits or restricts the use of certain toxic substances in the manufacture of such equipment or its components.

[292] *See* p. [_], above. [in DG-ENV summary pp.]

[293] [**Cross-ref to general discussions**]

case Member State action with regard to certain types of public and private projects[294] The same Directive had provisions requiring specific forms of public participation, and written reasons for decision Later environmental legislation, like the Integrated Pollution Prevention and Control (IPPC) Directive, contained similar requirements for public access to permit information and right to participate with regard to Member States taking case-by-case permitting actions, although it did not provide rights against EU institutions themselves.[295] By 2003, a directive, implementing the Aarhus Convention, had given the public the right to participate in the adoption of certain specific Member State governmental projects, plans and programs relating to the environment.[296] Similarly, access to information principles and requirements also first developed in the environmental area, with a 1990 environmental Directive applicable to the Member States and not limited to specific case-by-case contexts.[297]

The "cutting edge" of progress may still be found in the environmental area. Implementation of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the "Aarhus Convention") has required the Commission to introduce more specific and detailed procedural provisions in many areas of environmental regulation. The Commission's implementation of that Convention has been grudging, however, and it has chosen not to grant the same rights outside the environmental area. The Aarhus Convention also has access to information provisions, applicable to the environmental area, that are broader in scope and more detailed and far-reaching than those of the existing generally applicable EU Regulation (EC) No. 1049/2001.[298]

C. The Financial Services Sector

The financial services sector covers such matters as securities regulation, banking regulation, and regulation of other financial institutions like insurance companies, brokerage firms, etc. The Directorate General involved is DG Internal Market. The relevant Council of Ministers is the Ecofin ("ECOFIN").

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[294] Council Directive 85/337 on the Assessment of the Effects on Certain Public and Private Projects on the Environment, 1985 O.J. (L 175) 40, as amended by Council Directive 97/11/EC of 3 March 1997, O.J. (L 73) 5, 14.3.1997 (EIA Directive).

[295] Council Directive 96/61 Concerning Integrated Pollution Prevention and Control, art. 15(1), 1996 O.J. (L 257) 26.

[296] Council/Parliament Directive 2003/35 Providing for Public Participation in Respect of Certain Plans and Programs Relating to the Environment, 2003 O.J. (L 56/17).

[297] Council Directive 909/313 on Freedom of Access to Information on the Environment, 1990 O.J. (L 158) 56, repealed and replaced by European Parliament and Council Directive 2003/4/RC of 28 January 2003 on Public Access To Environmental Information 2003 O.J. (L 41) 26 (FOIA Directive). [**Compare the chapter of this report on information access**.]

[298] Proposal for a European Parliament and Council Regulation On The Application of the Provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to EC Institutions and Bodies (COM(2003) 622 – C5-0505/2003 – 2003/0242(COD)).

Legislation in this sector is characterized by use of both Council and Parliament Directives and Regulations, and of Commission Directives and Regulations. Financial services legislation is critical both because the firms involved are themselves major economic enterprises, but also because financial markets are important in optimizing the allocation of capital and facilitating access to equity finance and risk capital for small and medium sized companies ("SME's") and start up companies.

Financial sector legislation has undergone a dramatic change over the last 10 years as the EU has attempted to develop a single integrated financial market in order to foster economic growth. The legislation of the late 1980's and the early 1990's, the 1992 program, was designed to harmonize the essential elements of the authorization and prudential regulatory systems in the Member States with regard to the securities, banking and insurance sectors, with a view to achieving the mutual recognition of those systems. The idea was to give firms authorized in one Member State a "passport" to operate throughout Europe on the basis of their authorization in their "home Member State" without the need for further authorization in other Member States. Nonetheless, it became clear that the financial markets in the EU remained segmented. Further, the introduction of the Euro as the single currency of 11 Member States on 1 January 1999 created an impetus to readdress the issue of financial sector integration.

The Commission instituted in the mid-1990's a new round of reform that was quickly picked up and backed politically by the European Council and the Parliament. Through a Green Paper and a Communication by the Commission, invitations and support by the Council, and the use of a new advisory group, the Financial Services Policy Group ("FSPG") (consisting of representatives of ECOFIN ministers and the European Central Bank, under the chairmanship of the European Commission) to assist it in selecting priorities, the Commission launched a consultation process that culminated in a May 1999 communication. This communication contained a work program for financial sector reform, with a sweeping and ambitious Financial Services Action Plan (FSAP) in an Annex. The Commission proposed to adopt 42 individual legislative and non-legislative measures by 2005, most of which have now made it through the legislative process – a remarkable achievement.

The context in which the Commission undertook this effort included rapid and major changes in industry and market structure and in national regulatory structures. It also included discussions in international fora on a new capital adequacy framework for internationally active banks and investment firms (being developed by the Basel Committee on Banking Supervision, and known as "Basle II,"), and on other policy initiatives by such bodies as the International Accounting Standards Board, the International Organization of Securities Commissions, and the Financial Action Task Force, as well as discussions with regulators in other national jurisdictions like the United States. There were also severe market shocks during this period, including the technology stock boom and bust, the terrorist attacks on the US on 11 September 2001, corporate scandals in the US and Europe, and a broader international regulatory and industry debate on such subjects as market abuse, money laundering and terrorist finance, and corporate governance.

Faced as it was with a gargantuan legislative task and limited time, the Commission proposed to initiate a change in the process by which financial services legislation was developed. The resulting process is almost *sui generis*, but was largely successful and stands as a monument to how the EU institutions can manage large scale legislative change when there is a political will and they set their mind to the task. Specifically, the Commission sought to identify mechanisms which would avoid a piecemeal and reactive approach, protracted decision making processes and inflexible and overly prescriptive legislative solutions. The Commission indicated that it would seek to consider steps to update priorities and identify future challenges, using a forum group like the FSPG as well as a high level forum to take soundings from principal interest groups, working with the national regulatory bodies and industry experts to develop technical solutions and seeking to implement agreed solutions speedily, to speed up the legislative process and to develop legislative drafting techniques to minimize inflexibility.

In short, implementing the FSAP by 2005 represented a major challenge. The Commission gave the FSAP a new mandate to work with the Commission, to develop consensus between national ministries and to monitor progress on the FSAP implementation. FSAP discussions were made the subject of public communications. The Commission also regularly published progress reports to the Council and Parliament, again serving as a means of public communication. The Commission early on formed "Forum Groups" of market experts to assist the commission in identifying imperfections and practical obstacles in the functioning of specific areas in the single market, such as market manipulation, information for purchasers of financial services, barriers to retail financial services, and cross border corporate financial services.

The Commission reports to the Council and Parliament mention a range of different techniques for managing the FSAP implementation process:

- European Council and ECOFIN engagement through receiving reports and issuing guidance and resetting priorities.

- Continuous Commission identification of slippage, and resetting of priorities and of specific steps and timetables for meeting them.

- Setting up of a high level group (the "2005 Group")to help improve institutional co-ordination between the Commission, the Council, and the European Parliament. The informal group consisted of the chair of the Economic and Monetary Affairs Committee, representatives of the then current and incoming presidencies, and the Commissioner in charge of financial services.

- Interim stocktaking, in particular through a mid-term review in February 2002 in which public input was sought from, and dialogue held with, industry and user representatives on progress to date.

- A number of reports, such as the Economic and Financial subcommittee's report on financial stability and a research paper by London Economics, an independent consultancy, to demonstrate the economic benefits of financial integration.

The most important factor in successful implementation, however, was the Lamfalussy report. Given concerns about the need to move to a single securities market even more rapidly than envisaged in the FSAP (and given also some debate as to whether to move to a single EU securities regulator), ECOFIN on 17 July 2000 set up a committee of independent persons, dubbed the committee of wise men, chaired by Baron Alexandre Lamfalussy, to advise with respect to the regulation of securities markets.

That committee launched a process of consultation, including an online questionnaire,[299] meetings with interested parties and the publication of its initial report in November 2000, which itself called for a wide debate on its preliminary conclusions.

The committee released its final report in February 2001.[300] Its main conclusion was that the principal cause of the problems in the regulation of EU securities markets was the EU legislative process itself. The system was too slow and too rigid. It led to inconsistent implementation and was overly reliant on inflexible and ambiguous EU directives, which failed to distinguish between essential principles and day-to-day implementing rules.

The committee did not suggest that the solution was to set up a European SEC with power to apply a single European rulebook. Instead, the committee's proposed approach focused on four levels within the regulatory process:

- EU legislation in the form of directives should state key principles rather than detailed rules. This should speed up the process of agreeing and adopting directives and make them more flexible to deal with changing circumstances.

- A new securities committee, comprising the European Commission and national representatives, should have powers to make and update the technical rules implementing those principles, supported by an advisory committee of national securities regulators. The report effectively envisaged that the Level 1 directives would confer powers on the European Commission, acting in conjunction with the new securities committee, to adopt implementing measures under the "comitology" process.

[299] The questionnaire is available on the Commission's website at http://ec.europa.eu/comm/internal_market/securities/lamfalussy/index_en.htm.

[300] *See supra* note 3.

- There should be enhanced cooperation and networking among EU securities regulators to ensure consistent and equivalent transposition of Level 1 and Level 2 legislation.

- There should be strengthened enforcement of EU rules to ensure greater consistency and timeliness in the implementation of directives.

The Lamfalussy committee also recommended that the EU should make greater use of regulations, rather than directives, when legislating in the securities area, although at present the Treaty requires use of Directives in this area. In addition, the committee also said that there should be a strong commitment to transparency and consultation throughout the rulemaking process. The committee recommended that the Commission should, before it draws up a legislative proposal, consult in an open, transparent and systematic way with market participants and end users, including through the use of open hearings and the Internet. It also recommended that a summary of the consultation process should be made available when the final proposal is made. In addition, the Commission should continue to consult Member States and their regulators on an informal proposal as early as possible and inform the European Parliament on an informal basis of forthcoming proposals.

Importantly, the committee recommended that this commitment to transparency and consultation should also apply at Level 2. The advisory committee of securities regulators should involve market practitioners and end users at every level in a continuous process. In the case of complex issues, the advisory committee should consult first on the basis of a concept release, followed by a draft proposal once a regulatory approach is decided. The committee should use hearings or roundtables, as well as the Internet, and a summary of the public comments should be appended to the final recommendations. Recognizing the need for speed the Lamfalussy committee recommended that the maximum comment period should be three months.

Finally, the committee recommended accelerating the timetable for adoption of the FSAP. The EU should adopt key parts of the FSAP for securities markets by the end 2003.

The committee's recommendations received widespread support. The European Council, at its meeting at Stockholm in March 2001, resolved that the four level approach should be implemented, including the recommendations on transparency and consultation.[301] The European Commission moved quickly to establish the European

[301] Resolution of the European Council on More Effective Securities Market Regulation in the European Union Stockholm, Annex 1 to the Presidency Conclusions, Stockholm European Council, 23 and 24 March 2001, available on the Council website at http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/ec/00100-r1.ann-r1.en1.html.

Securities Committee (the "ESC")[302] and the advisory Committee of European Securities Regulators ("CESR").[303]

The ESC was formed as a regulatory committee with the task of advising the European Commission on policy issues and draft legislative proposals. The ESC is composed of high level representatives of Member States, mainly representatives of finance ministries, and is chaired by a representative of the European Commission.

CESR effectively replaced the former Forum of European Securities Commissions ("FESCO"), an informal grouping of national securities regulators. CESR's stated task was to act as an independent advisory group with the role of advising the Commission, either at the Commission's request, within a time limit laid down by the Commission, or on CESR's own initiative. In particular, it was envisaged that CESR would advise the Commission on draft implementing measures. CESR is composed of high level representatives of national securities regulators and is chaired by one of its members. The Commission attends its meetings and can participate in its discussions. CESR is based in Paris and has its own secretariat. CESR adopted its own charter[304] and, after a period of consultation, a public statement of consultation practices.[305]

However, the proposal to make wider use of the comitology process ran into difficulties with the European Parliament. Most EU legislation in the securities area is adopted by the co-decision process under Article 251 ECT, where the European Parliament acts as the co-legislator with the Council of Ministers. In contrast, the European Parliament has no formal role in the adoption of implementing measures under Article 202 ECT.[306] Thus, the extension of the comitology process created a perceived threat to the legislative role of the European Parliament and the inter-institutional balance between the Parliament, the Council and the Commission.

This resulted in prolonged discussions between the Commission, the Parliament and the Council which led to the President of the Commission making a solemn declaration in the European Parliament in January 2002, confirming that the Commission favored an amendment to Article 202 ECT to give the European

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[302] Commission Decision of 6 June 2001 establishing the European Securities Committee (2001/528/EC), O.J. L 216, 13.7.2001, p. 45.

[303] Commission Decision of 6 June 2001 establishing the Committee of European Securities Regulators (2001/527/EC), O.J. L 216, 13.7.2001, p. 43.

[304] Charter of the Committee of European Securities Regulators, which took effect on 11 September 2001, available on the CESR website at http://www.cesr-eu.org/.

[305] CESR, Public Statement of Consultation Practices, December 2001 (CESR/01-007c), available on the CESR website at http://www.cesr-eu.org/.

[306] The Stockholm resolution envisaged that the Parliament would be kept informed of the ESC's proceedings and would receive all documents and, if the Parliament considers that the draft implementing measures would exceed the powers conferred by the relevant directive, the Commission would re-examine its proposals expeditiously. *See* paragraph 5 of the Resolution of the European Council on More Effective Securities Market Regulation in the European Union, *see supra* note 36.

Parliament an equal role with the Council in controlling the Commission as it carries out its executive role.[307] In the meantime, the declaration indicated that the Commission was in a position:

- "To note Parliament's intention to include a four year "sunset clause" in all legislation conferring implementing powers on the Commission;
- To ensure that Parliament is given three months to examine any proposed implementing measure;
- To ensure full transparency to Parliament throughout the whole procedure for adopting implementing measures and to ensure that there is wide public consultation before implementing measures are drawn up;
- To support Parliament's wish to see CESR form an advisory market participants' group;[308]
- To reaffirm its commitment "to take the utmost account of the Parliament's position and any resolutions that it might adopt with regard to implementing measures exceeding the implementing powers provided for in the basic instrument and the Commission's aim of reaching a balanced solution in such cases".

This declaration broke the logjam which had held up the practical implementation of the Lamfalussy proposals. It paved the way for the Council's subsequent call in April 2002 for a review of the committee architecture for other financial services sectors, which led, after further prolonged discussion,[309] to the creation, in 2004, of a parallel architecture of advisory and regulatory committees for the banking and insurance and occupational pensions sectors.[310]

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[307] *See* Commission press release, Mr. Romano Prodi President of the European Commission "Implementation of financial services legislation in the context of the Lamfalussy Report" Intervention by President Romano Prodi to the European Parliament's plenary session Strasbourg, 5 February 2002 (SPEECH/02/44) and Commission press release, Financial markets: Commission welcomes Parliament's agreement on Lamfalussy proposals for reform, 5 February 2002 (IP/02/195).

[308] CESR announced its formation of its market participants consultative panel on 10 July 2002. *See* press release CESR/02-111.

[309] *See*, *e.g.*, European Commission, Note to the Ecofin Council, Financial Regulation, Supervision and Stability (December 2002), available on the Commission website at http://ec.europa.eu/comm/internal_market/finances/docs/cross-sector/consultation/ecofin-note_en.pdf.

[310] *See* Commission Decision of 5 November 2003 establishing the Committee of European Banking Supervisors (2004/5/EC), O.J. L 003, 07.01.2004, p. 28; Commission Decision of 5 November 2003 establishing the Committee of European Insurance and Occupational Pensions Supervisors (2004/6/EC), O.J. L 003, 07.01.2004, p. 30; Commission Decision of 5 November 2003 amending Decision 2001/527/EC establishing the Committee of European Securities Regulators (2004/7/EC), O.J. L 003, 07.01.2004, p. 32; Commission Decision of 5 November 2003 amending Decision 2001/528/EC establishing the European Securities Committee (2004/8/EC), O.J. L 003, 07.01.2004, p. 32; Commission Decision of 5 November 2003 establishing the European Insurance and Occupational Pensions Committee (2004/9/EC), O.J. L 003, 07.01.2004, p. 34; 2004/10/EC: Commission Decision of 5 November

(continued…)

As the FSAP was implemented in the Level 1 process, the political direction of the Member States was crucial. Consultation was also critical, and the extent and depth of the consultation process evolved considerably during the process, with a shift from use of Green and White papers to widespread use of expert groups, which themselves sometimes carried out consultations. In addition to open hearings, the Commission also held conferences and discussion forums. Even so, it was still relatively unusual for the Commission to publish the full text of a proposed directive for consultation at any stage before it made its formal legislative proposal.

The transparency of the consultation process has also changed over the course of the FSAP. The Commission now, as a matter of routine, publishes its financial services proposals and consultation documents on the Internet. In some cases, it will also publish on the Internet feedback statements summarizing the responses to the consultation, as well as copies of the responses received. It also uses the Internet to publicize proposed public hearings as well as reports on meetings of key bodies involved in the management of the process. It has established a specific website, *Your Voice in Europe*,[311] as a single access point to a wide variety of consultations, not just for financial services.

The Commission has also sought to address concerns that the financial services industry, rather than end-users of financial services, predominate in the consultation process. In 2004, it established FIN-USE, a panel of ten experts with knowledge of financial services selected by the Commission from among consumer protection and small business experts, academic researchers and staff from major consumer and small business organizations.[312] Its mandate is to strengthen the role of consumers and small businesses in the evolution of the EU financial services sector, by providing responses to the Commission's requests for consultation.[313] However, its own assessment is that there is a regrettable absence of "meaningful research on consumers' experience of financial services in the markets across Europe" and that there still need to be

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2003 establishing the European Banking Committee (2004/10/EC), O.J. L 003, 07.01.2004, p. 36; and Directive 2005/1/EC of the European Parliament and of the Council of 9 March 2005 amending Council Directives 73/239/EEC, 85/611/EEC, 91/675/EEC, 92/49/EEC and 93/6/EEC and Directives 94/19/EC, 98/78/EC, 2000/12/EC, 2001/34/EC, 2002/83/EC and 2002/87/EC in order to establish a new organizational structure for financial services committees, O.J. L 079, 24.03.2005, p. 9.

311 http://ec.europa.eu/yourvoice/index_en.htm.

312 *See* European Commission press releases, Financial services: Commission to set up expert forum to look at policies from users' point of view (FIN-USE), IP/03/1119, 25.7.2003 and Financial services: new group will give consumers and SMEs a stronger voice in EU policy making, IP/04/450 2.4.2004, available on the Commission website at http://ec.europa.eu/comm/internal_market/finservices-retail/finuse_en.htm.

313 *See* the FIN-USE website at http://ec.europa.eu/comm/internal_market/fin-use_forum/about/index_en.htm.

improvements to the consultative process to achieve the "inclusion and participation of users and other stakeholders in financial services".[314]

Additionally, as has been seen, the FSAP placed strong emphasis on the importance of publicly scheduling actions and fixing deadlines as a means of seeking to create an impetus towards completion. These more specific actions are then reflected in the Commission's general action work program which is published on the Internet.[315]

For the most part, there is no legal mandate requiring consultation and the Commission's developing practices reflect policy decisions by the Commission rather than legal requirements. However, in some cases, the directives include review clauses which specifically require the Commission to engage in consultation.

Impact assessments have not formed a major part of the rulemaking process in the FSAP. Each legislative proposal is accompanied by an explanatory statement and in many cases is accompanied by a formal, albeit relatively short, impact assessment statement.[316] However, these are generally not detailed reviews of the likely impact of alternative policy options and do not contain substantive cost benefit analysis of the proposals. They are also not the subject of prior consultation.

Nevertheless, there have been some efforts to carry out specific evaluations of policy initiatives forming part of the FSAP, over and above the use of general studies such as the London Economics research paper already mentioned.[317]

The Commission's 2005 White Paper on financial services policy 2005-10 contains a commitment that impact assessments will accompany any new Commission proposal, focusing on costs and benefits and, where appropriate, the impact on financial stability, proper functioning of markets and consumer protection.[318] Indeed, the White Paper itself includes an impact assessment presenting the parameters that influenced the choices set out in it.[319] The White Paper also indicates that assessment methodologies will be shared, prior to publication, with stakeholders, although it is unclear whether this will include prior consultation on the results of the application of those methodologies. All this reflects a growing emphasis on evaluation in the rulemaking process, illustrated by the Commission's 2002 Communication on Impact

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[314] Financial Services, Consumers and Small Businesses, A User Perspective on the Reports on Banking, Asset Management, Securities and Insurance of the FSAP Stocktaking Groups, FIN-USE Forum, October 2004, available on the FIN-USE website, *see supra* note 76.

[315] *See*, *e.g.*, Commission Work Program for 2005 COM(2005) 15 final 26.1.2005.

[316] *See*, *e.g.*, Proposal for a Directive of the European Parliament and of the Council on the harmonization of transparency requirements with regard to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC COM(2003) 138 final, 26.3.2003.

[317] *See supra* note 25.

[318] *See supra* note 6, p. 5.

[319] *See* Annex II to the Commission White Paper, *supra* note 6.

Assessment[320] and its publication of revised guidelines for impact assessments in 2005.[321]

As for implementation of financial services legislation at Level 2, Level 1 measures have to identify whether the Commission is required to adopt implementing measures or whether this is optional.[322] They vary significantly as to the extent to which they prescribe parameters within which the Commission must act.[323] Further, the use of Commission Regulations to implement some directives has the potential to significantly limit the flexibility of Member States to take divergent approaches to national implementation.[324]

The normal process for comitology is illustrated by Commission implementation of the four Lamfalussy style directives adopted so far, and is initiated by the issuance of a Level 2 mandate by the Commission to the CESR calling for advice on the content of implementing measures.[325] On receipt, CESR publishes the mandate as a "call for evidence" seeking initial contributions from interested parties, usually setting a comment period of one month. It may also at that stage set out its expected work program for the particular mandate. CESR publishes the responses received on its website.

Based on these initial responses and following informal discussions with interested parties, CESR produces its reasoned consultative proposals. This may take the form of a concept release, rather than detailed proposals. Typically, CESR allows three months for consultation on the proposals[326] and will often organize a public hearing on the proposals during that period. Again, at the end of the period, CESR publishes the responses received.

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[320] Communication from the Commission on Impact Assessment, COM(2002) 276 final 5.6.2002. *See* also and Commission Staff Working Paper, Impact Assessment: Next Steps, In support of competitiveness and sustainable development, SEC(2004)1377 21.10.2004.

[321] European Commission, Impact Assessment Guidelines, SEC(2005) 791 15.6.2005

[322] *Compare* Article 4.1(2) MiFID, *supra* note ___, which states that the Commission "shall" determine the scope of certain provisions by adopting implementing measures, *with* Article 4.2 MiFID which provides that the Commission "may" adopt implementing measures to clarify other definitions.

[323] *Compare* the relatively high degree of flexibility given with respect to the implementation of the conduct of business principles in Article 19 MiFID, *supra* note ___, under Article 19.10 MiFID *with* the relatively limited level of choice allowed with respect to the implementation of the Article 27 rules on systematic internalization under Article 27.7 MiFID.

[324] *See*, *e.g.*, Commission Regulation (CE) 809/2004 of 29 April 2004 implementing Directive 2003/71/EC of the European Parliament and of the Council as regards information contained in prospectuses as well as the format, incorporation by reference and publication of such prospectuses and dissemination of advertisements, O.J. L 149, 30.4.2004, p. 1.

[325] While all the existing Lamfalussy directives concern securities markets and thus the consultation processes adopted by CESR, both CEBS and CEIOPS have adopted similar procedures.

[326] CESR aims to allow a three month consultation period on significant issues. *See* ¶3(b)(v) CESR, Statement of Consultation Practices, *supra* note 35.

After considering the responses, CESR will then often consult for a second time on its proposed advice or aspects of its proposed advice (providing preliminary feedback on the initial round of consultation), but will usually set a shorter period for comment on this stage (perhaps as short as one month). It may hold a second public hearing during this period. Again, CESR publishes the responses received.

Finally, following consideration of the responses to any second round of consultation, CESR will publish its final advice to the Commission, together with feedback on the consultation (and copies of all responses received but not yet published). In practice, the process can take about one year from the time of the mandate to the issue of formal advice.

Following receipt of the CESR advice, the Commission informally consults with interested parties and then prepares its draft legislative text of the implementing measures. It then publishes that text on its website for consultation.[327] This is followed by an iterative series of meetings of the Commission with the ESC, in the light of which (and further input from interested parties) the Commission refines its proposed text, revisions of which are periodically exposed to public comment through the Commission website. At the end of this process, the Commission publishes its formal draft proposal to start the three month period within which the European Parliament can consider the proposal. At the end of that period, the ESC votes on the proposal; it has unanimously approved the implementing measures so far proposed under these directives.

In addition to their role at level 2, CESR and the other committees of supervisors also play an important role at Level 3 in coordinating implementation of the directives and developing regulatory policy more generally. For example, CEIOPS has consulted on a protocol for the implementation of the insurance mediation directive,[328] CEBS has consulted on a number of issues associated with the implementation of the proposed capital requirements directive[329] and CESR has consulted on the cross-border notification procedure for UCITS funds under the UCITS directive[330] and on the implementation of the market abuse directive.[331]

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[327] The Commission has stated that in future it will assess, on a case-by-case basis, whether it should prepare an impact assessment for level 2 measures. *See* Commission White Paper, Financial Services Policy 2005-10.

[328] Consultation Paper No. 8, Protocol Relating to the Cooperation of the Competent Authorities of the Member States of the European Union in Particular Concerning the Application of Directive 2002/92/EC of the European Parliament and of the Council of 9 December 2002 on Insurance Mediation CEIOPS-CP-05/05, available on the CEIOPS website at http://www.ceiops.org/media/files/consultations/consultationpapers/cp_0505.pdf.

[329] Consultation Paper on the recognition of External Credit Assessment Institutions (CP07), 29 June 2005, available on the CEBS website at http://www.c-ebs.org/pdfs/CP07.pdf.

[330] CESR's guidelines for supervisors regarding the notification procedure according to Section VIII of the UCITS Directive CESR/05-484 (October 2005), available on the CESR website at http://www.cesr-eu.org/.

[331] CESR consultation paper, Market Abuse Directive, Level 3 – preliminary CESR guidance and information on the common operation of the Directive CESR/04-505 (October 2004), available on the CESR website at http://www.cesr-eu.org/.

As in other areas, the Commission has sought on a number of occasions to achieve its objectives without a formal legislative proposal, through use of Recommendations or Guidelines. Thus, for example, the Commission has issued recommendations on the subject of corporate governance, rather than proposing new legislation.[332] The Commission did consult publicly on these measures (although it only allowed a short one-month comment period).

The history of the FSAP is a reminder of the daunting timescale in which the EU operates. A ten year process presents particular challenges for industry and other interested parties, even if there is a fully transparent and open approach to policy formation and rulemaking. Further, there has also been concern that the acceleration in pace as the FSAP deadlines became imminent led to a sacrifice in the quality of legislation.[333] Similarly, the breadth and range of the FSAP and the complexity and iterative nature of the process has given rise to concerns about "consultation fatigue."[334]

What is clear is that the effect of the FSAP and the rulemaking process under it has moved the EU from the periphery to the centre of financial services regulation. This seems unlikely to change in the near future, even if no further steps are taken in the direction of setting up an EU wide regulatory agency. The 2005 white paper aims at "dynamic consolidation" rather than a new action plan on the scale of the original FSAP, but still lists 72 concrete tasks and activities for the Community institutions over the next five years, some of which will only come to fruition long after that.[335] Even if there is no new FSAP, these tasks and activities will continue to test the quality of the EU's rulemaking processes.

D. The Food Safety Sector

Food safety is the general responsibility of the Directorate General for Health and Consumer Protection (DG SANCO). European food safety regulation is adopted under the general Co-Decision legislative procedure of Article 251 ECT. Usually drawing on the authority of Articles 95 ECT (internal market), 153 ECT (consumer protection), or 152 ECT (public health), it deals with a large range of matters relating to the regulation of foods, including new foods (as "novel foods"), genetically modified foods, food additives, food decontamination, food contact material, food color, and food flavoring. The implementation of food safety legislation uses the comitology rather than its

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[332] Commission Recommendation of 14 December 2004 fostering an appropriate regime for the remuneration of directors of listed companies (2004/913/EC) O.J. L 385 29.12.2004 p.55, and Commission Recommendation of 15 February 2005 on the role of non-executive or supervisory directors of listed companies and on the committees of the (supervisory) board (2005/162/EC), O.J. L52 25.2.2005, p. 51.

[333] *See*, *e.g.*, Inter-institutional Monitoring Group, Third Report Monitoring the Lamfalussy Process, 17 November 2004, p.14, available on the Commission website at http://ec.europa.eu/comm/internal_market/securities/docs/monitoring/third-report/2004-11-monitoring_en.pdf.

[334] *See*, *e.g.*, European Commission, FSAP Evaluation, *supra* note 46, pp. 16-17.

[335] Commission White Paper, Financial Services Policy 2005-10, Annex I, *supra* note 6.

alternative. National draft regulations notified to the Commission under the 1998 Standstill Directive are an important source for DG SANCO's food safety initiatives.[336]

The older Council and Parliament legislation includes. In 2002, the Council and Parliament adopted the General Food Law Regulation 178/2002 to set common principles and responsibilities for all food law applicable to all foods and food ingredients, including food packaging; this legislation also established the European Food Safety Agency. Prior legislation, such as the 1997 Novel Foods Regulation, the 1989 Framework Directive on Food Additives, and the 1995 "Miscellaneous" Food Additives Directive, and implementing measures adopted on their authority are to be adapted no later than January 1, 2007, to comply with the new general principles.

The General Food Law seeks to assure both a high level of protection of human life and health, and protection of consumer interests, including fair practices in food trade, protection of animal health and welfare, plant health and the environment. The statute seeks to assure a high level of protection of human life and health through a requirement of risk analysis (except where this is not appropriate to the circumstances or the nature of the issue). Risk assessment is to be based on the available scientific evidence, and undertaken in an independent objective and transparent manner. Risk management is to take into account the result of the risk assessment, other factors legitimate to the matter, and the precautionary principle.

Most food safety legislation takes the form of Regulations, although some early legislation uses the Directive format. Most implementing measures, in turn, involve pre-market authorization of individual products, normally by adding the product to lists in Annexes to the applicable legislation. DG SANCO normally effects these authorizations through the sponsorship of Commission Regulations implementing the framework in the 2002 General Food Law Regulation or Commission Decisions (in the case of the 1997 Novel Foods Directive and parts of the 2003 Genetically Modified Foods Regulation),[337] using comitology. Some of the older legislation (*e.g.*, the 1989 Food Additives Directive), however, requires authorization through the adoption of Council and Parliament or Commission Directives. In some situations, the applicable legislation does not specify what form the authorization is to take (*e.g.*, the 2004 Food Contact Material Regulation, the 2004 Food Hygiene Regulation; and the 2000 Food Labeling Directive).

[336] Directive 98/34/EC of the European Parliament and the Council, of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations, O.J. L 204 of 1998. As discussed above, [ca. p. 33], the Standstill Directive requires Member States to postpone the enactment of national legislation for 12 months if the Commission declares its intention to legislate on the matter at the EU level.

[337] Interestingly, in the case of the 2004 Smoke Flavorings Regulation, affirmative Commission action (including authorization limited by conditions) is taken by a regulation, but any refusal to authorize is issued as a decision, so that the disappointed applicant has the right of judicial review.

Traditionally, consultation on new legislation by DG SANCO has taken place in Brussels only, in various fora[338] which are called on by DG SANCO on a largely ad-hoc and as needed basis. These usually involve only European level participants, with no consultation organized via the web or at Member State or regional level.[339] The conclusions and transcripts of the consultations have only sometimes been made publicly available, and then normally only a long time after the meetings. A new development is the use of Advisory Groups or Platforms (such as the new European Platform for Action on Diet, Physical Activity and Health)initiated by DG SANCO on an ad hoc or as needed basis. While these groups largely consist of the normally consulted EU-level groups, representatives from individual companies have sometimes been included.

In general, DG SANCO seems to have been slower than most DGs in responding to the Commission's recent generic Communications on consultation, impact assessment, public participation, and legislation on public access to documents. With the exception of its 2002 internet consultation evaluating the Novel Foods Regulation 258/97, DG SANCO did not organize wide-range public consultations until very recently (2006). Consultations still were organized on an ad-hoc and as needed basis and the number of invitees was usually limited to the European industry, trade, consumer organizations, other NGOs and semi-governmental organizations. In the Novel Foods consultation, for the first time, DG SANCO made stakeholder comments available on the Commission's homepage. Within the past year, however, DG SANCO's practices have changed significantly, and in 2006, DG SANCO launched nine food related internet consultations.[340] On major policy initiatives, such as the revision of food labeling legislation currently under review, DG SANCO is now systematically organizing internet consultations.

DG SANCO's comitology processes use a regulatory committee, the Standing Committee on the Food Chain and Animal Health (SCFCAH),[341] and involve substantive participation by the European Food Safety Agency. In 2002, DG SANCO had the fifth largest number of comitology committees among the DG's, the second highest number of meetings, and the third highest total output in opinions and instruments. Roughly half

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[338] Fact-finding proceeded by use of an external consultant, conferences by the Commission or other bodies, inspections by national or EU (*e.g.*, the EU FVO) institutions, or reliance on work by international organizations such as the UN's World Health Organization (WHO) or the Food and Agriculture Organization (FAO). The drafting was preceded or accompanied by the organization of one or more stakeholder consultation meetings.

[339] Participants are normally invitees and are limited to the European industry, trade, consumer organizations, other NGO's and semi-governmental organizations (*e.g.*, the European Network on Nutrition and Physical Activity; the European Network for Public Health, Health Promotion and Disease Prevention).

[340] http://ec.europa.eu/food/consultations/index_en.htm.

[341] The Committee and its sections consist of the national chief administrators in each relevant particular subject area. For example, the section on Animal Health consists of the national Chief Veterinary Officers. The meetings of the Standing Committee and its sections are closed and not open to the public. Agendas are published on the Commission's homepage usually a few days before (but sometimes also after) the meeting date, and summary meeting reports are available on the Commission's website, but normally only one or two months after the meeting has taken place.

of these involved food safety issues. Since adoption of the 2002 General Food Law Regulation, the number of committees in the food safety area has been reduced; but when the Commission started to process files on genetically modified foods in 2004, after a six year moratorium, no qualified majority could be secured in the relevant Regulatory Committee. The resulting political impasse resulted in many more referrals to Council, but then also blocked action there. These files have been passed back to the Commission which has adopted them.

Note that, without regard to process, the form that an implementing authorization action takes is a matter of great significance. As noted earlier, direct judicial review of legislative actions like Regulations or Directives is generally unavailable, whether they are adopted by the Council and Parliament or by the Commission through comitology; and little effective indirect judicial relief is available. Where a *Decision* is issued, however, the regulated entity can normally obtain direct judicial review of the action or inaction involved. The general public and other possibly interested parties have no such remedy, however.

The European Food Safety Authority (EFSA) is the scientific advisory organ for the Commission on food safety matters,[342] and has a legislatively prescribed role in the consideration of most implementing measures; for individual product authorizations, for example, it must review the application and issue an opinion to the Commission and the Member States. The EU Food and Veterinary Service (FVO) is a Commission service that conducts inspections on food safety, food and animal hygiene and animal welfare, assisting the Commission in fulfilling its obligation to ensure that Community legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced.

As is the case in other Directorate generals, comitology in DG SANCO entails considerably less consultation, both in terms of the number of events and the number of participants. For implementing measures to be adopted under the comitology rules, the minimum rules on consultation do not apply and there is therefore less consultation both in terms of the number of events as well as the number of participants than for legislation to be adopted under the Article 251 ECT procedure. The Commission will usually only consult once a draft text has been elaborated, and then only with those stakeholders it has previously identified as having an interest in the subject, most of the time a limited number of EU industry trade and consumer organizations. Consultations will not be launched via the Internet, but by fax or mail, usually with short notice (2 to 4 weeks). Revised drafts may not be subject to consultation.

The main implementing actions are authorizations of individual products, which follow procedural paths that are specific to the specific legislation involved, but which have the same basic functional steps and are somewhat more uniform in the wake of the passage of the 2002 General Food Law Regulation and the recent generic

[342] It replaced the Scientific Committee for Food on its establishment in 2002 in the General Food Law Regulation.

Commission Communications on Better Regulation. The main steps are as follows. Applications are filed either at the Member State level (the normal case) or with the Commission (*e.g.*, food additives and additive purity criteria). An initial scientific assessment is then done, either at the national level (*see* novel foods) or at the Community level by the EFSA (the more common case[343]) to determine whether the application is complete, whether it meets the relevant substantive tests in the legislation, and whether the product's use should be conditioned or restricted in light of those tests. There are provisions in some of the legislation for the adoption of guidelines with regard to various parts of this process, but in some cases no such guidelines are now in effect, or the guidelines are in existence but not formally adopted and only in English.

Thereafter, the Commission prepares a draft proposal[344] that would proceed through the comitology process for consideration by the Regulatory Committee, the SCFCAH and then adoption by the Commission unless the matter were sent to the Council under the comitology process (except, for example, in the case of food additives, where it is the Council and the Parliament that must act in the first place, not the Commission). In the case of food safety, this normally takes between one (exceptional cases) and five years, with the majority of cases in the two to three year range.

The newer legislative instruments adopted under the framework of the 2002 General Food Law Regulation usually provide deadlines for the scientific assessment and most of the following administrative procedure, which can be suspended for various reasons. Some, for example the 2003 Smoke Flavorings Regulation, also require that certain non-confidential information with regard to the application[345] be made public in accordance with the general 2001 Regulation on access to information. The Smoke Flavorings Regulation also limits the authorization to 10 years, subject to renewal. Even more recent regulations under the framework of the 2002 General Food Law Regulation also provide for an administrative review by the Commission of action and inaction by EFSA, "on its own initiative or in response to a request from a Member State or from any person directly *or* individually concerned."[346]

The net result is that there are a large variety of procedures used for implementing authorizations in the food safety sector, but the more recent pieces of legislation, especially those adopted after the 2002 General Food Safety Regulation, set out procedures in more detail[347] and establish deadlines,[348] a major improvement in the

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[343] The Scientific Committee for Food is [or was?] also involved in the case of food additives. [**Cite**]

[344] In some of the more recent legislation, such as the 2004 New Food Contact Material Regulation consolidating and updating the existing food contact legislation, the Commission must give reasons if it chooses not to prepare a draft specific measure despite a favorable opinion by the EFSA.

[345] The Regulation specifically provides that information of direct relevance to the assessment of safety and to the analytical method cannot be considered confidential.

[346] Article 14, New Food Contact Material Regulation 1935/2004 (emphasis added).

[347] Even in the more recent legislation, however, no details are provided on the interaction between applicants on the one side and the EFSA and the Commission on the other, once an application is filed – for

(continued…)

clarity of procedure.[349] Notwithstanding these developments, however, even these legislative instruments leave the availability of judicial review of action or inaction on the authorization up in the air, since they do not specify whether those decisions are to be taken in the form of a regulation or a decision. Further, the criteria applicable to the scientific review are not legally binding on the EFSA, and the non-binding criteria that are used are not available in all EU languages. The European Court of Justice may force the pace of change as to procedures for authorization. An Advocate General (Geelhoed) recently challenged the validity of the Directive on food supplements, Directive 2002/46, on procedural grounds. After stressing the impact of prior approval processes on the manufacturer of products, he said that such "legal instruments must be designed with prudence and precision." He concluded that the Directive was seriously deficient in three respects, two of which raise crucial general issues:

> "There is no mention, in the text of the Directive itself, of the substantive norm which the Commission must follow as a guiding principle in exercising its powers under Articles 4(5) and 13 of the Directive. The Directive thus contains no standard for assessing whether the Commission has, in taking decisions concerning modifications of the positive list, remained within the limits of its legal powers;
>
> …
>
> On the supposition that private parties are indeed able to submit substances for an evaluation with a view to inclusion in the positive lists, there is no clear procedure for this purpose which provides minimum guarantees for protecting those parties' interests.
>
> The first deficiency is a particularly serious shortcoming, because it relates to the substantive norm governing the exercise by the Commission of the most far-reaching power provided for in the Directive, namely the decision to add to the as yet incomplete positive lists. The way in which this power is exercised determines the scope for interested parties to exercise their existing economic activities, as well as the restrictions to which they will be subject in

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example, whether the applicant is entitled to comment on an EFSA opinion or on a draft Commission measure. Nor are rules provided for interaction between the applicant or third parties and the regulatory committee, nor any rules on public consultation of any draft measure. In all of these areas, the current practice of informal consultation by applicants of the Commission will likely continue. It is not at all clear, however, that this will be true of contacts with EFSA, which is more formalized in its dealings with applicants than were the scientific committees which it replaced.

[348] Even so, there remain steps in the administrative process for which no deadlines are set, such as the time allowed to the regulatory committee to make a decision, and sometimes also the time for the Commission to prepare its own draft measures.

[349] It is important to note, however, that even some recent legislation fails to provide any detailed rules on the procedure for adoption of an authorization decision. *See*, *e.g.*, the approval of decontaminant products for fresh meat, under Regulation 853/2004.

the future. Even if we take as a basis only the minimum requirements of the legal certainty necessary in economic relations, it is indispensable that the legislative instrument should itself lay down a substantive standard. Without such a standard there is no basis for effective legal protection.

…

Although the preamble to the Directive, at recital 5, provides a certain substantive point of reference for the decisions on the composition of the positive lists, where it states that 'the products that will be put on the market must be safe', such a recital in the preamble does not constitute a substitute for a standard which should appear in the corpus of the Directive.

…

[A]n 'interested party' never gets beyond the EFSA's front door. It must patiently await the 'scientific opinion' of this body, following which, under Article 13 of the Directive, a decision is taken by the Commission or the Council in accordance with the so-called regulatory procedure of the Comitology Decision. Once they have submitted their application with the accompanying dossier, interested parties have no right to be heard. Nor are they given the opportunity to express their views on the EFSA's (draft) 'scientific opinion'. According to the 'Administrative Guidance' an applicant must consult the EFSA's website to learn of the EFSA's final judgment. If this judgment is favorable, the Commission remains free to decide whether to follow it up by submitting a proposal to the Standing Committee on the Food Chain and Animal Health, which acts as the regulatory committee referred to in Article 5(1) of the Comitology Decision. Neither the Directive nor the Administrative Guidance obliges the Commission to inform the interested party of its decisions and the reasons on which they are based.

In short, this procedure, in so far as it may exist and in so far as it may deserve this title, has the transparency of a black box: no provision is made for parties to be heard, no time-limits apply in respect of decision-making; nor, indeed, is there any certainty that a final decision will be taken. The procedure therefore lacks essential guarantees for the protection of the interests of private applicants.

At the hearing, the representative of the Council, responding to a question, remarked that the decisions on the composition of the positive lists are of general application and that it was not necessary, therefore, to accord procedural rights to individual

interested parties at the preparatory stage. That position, it would appear to me, is based on a misunderstanding. Even though decisions relating to the extension or the shortening of the positive lists have effect erga omnes, plainly they may also affect the vital interests of individual parties. In order to ensure that these interests are taken into account in the decision-making process in a manner which is open to judicial scrutiny, the basic legislative act ought for that purpose to provide for the minimal guarantee of an adequate procedure. The Community legislature recognized this requirement in, *e.g.*, Regulation (EC) No 384/96 which provides, in precise terms, for guarantees for balanced decision-making in the procedure leading to the adoption of protective anti-dumping measures. Those measures, too, are generally applicable.

The claimants in the main proceedings in this case observed, in both their written and their oral submissions, that preparing an 'admissible' application within the meaning of the 'Administrative Guidance' is a costly matter and that the final decision – or the lack of such a decision – may have the consequence that the company concerned will have to cease (part of) its economic activities. These observations were not contradicted. In this light, the Community legislature in drafting a legislative act may at least be expected to act with such care as to make express provision for minimum conditions of prudent decision-making in that legislative act. The fact that these conditions were not included in Directive 2002/46 is in itself sufficient to conclude that the Community legislature has failed in this respect. The Directive does not comply with essential requirements of legal protection, of legal certainty and of sound administration, which are basic principles of Community law. Thus, lacking appropriate and transparent procedures for its application, the Directive infringes the principle of proportionality. It is, therefore, invalid.

I would make one further observation on the Interinstitutional Agreement of 22 December 1998…. The mutual obligations which the institutions entered into in respect of the quality of drafting of Community legislation are not intended primarily to achieve the linguistic aestheticism dear to legislative draftsmen. In a Community of law, such as the European Union, which is governed by the principles of the Rechtsstaat, there are two aspects to a legislative act as an expression of the legislature's will. On the one hand, it is an instrument for pursuing and, if possible, achieving justified objectives of public interest. On the other hand, it constitutes a guarantee of citizens' rights in their dealings with public authority. Qualitatively adequate legislation is characterized by a balance between both aspects. The wording and the structure

> of the legislative act must strike an acceptable balance between the powers granted to the implementing authorities and the guarantees granted to citizens. Directive 2002/46 does not comply with this essential quality requirement of proper legislation.[350]

In its resulting judgment of July 12, 2005,[351] the ECJ upheld the Directive, but laid down rules for the Commission in future cases. The ECJ ruled, in particular, that:

> [A] measure which, like that at issue in the main actions, includes a prohibition on marketing products containing substances not included on the positive lists laid down in the applicable legislation must be accompanied by a procedure designed to allow a given substance to be added to those lists and the procedure must comply with the general principles of Community law, in particular the principle of sound administration and legal certainty. Such a procedure must be accessible in the sense that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorized substances may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts."[352]
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> … It would, no doubt, have been desirable, as regards the stage between the filing of a dossier seeking modification of the positive lists, and the time when the matter is brought before the committee…for the Directive to have included provisions which in themselves ensured that that stage be completed transparently and within a reasonable time. The absence of any such provisions cannot, however, be regarded as such as to jeopardize the proper functioning of the procedure for modifying the positive lists within a reasonable time. It is none the less the responsibility of the Commission, by virtue of the implementing powers conferred on it by Directive 2002/46 concerning, *inter alia*, the way the procedure is operated, to adopt and make accessible to interested parties, in accordance with the principle of sound administration, the measures necessary to ensure generally that the consultation stage

350 [**Cite** AG Opinion in Joined cases C-154/04 and C-155/04].

351 [**Cite** ECJ judgment].

352 Para. 72 and 73.

> with the European Food Safety Authority is carried out transparently and within a reasonable time. By providing for the procedure established in Article 5 of Decision 1999/468 to apply, Article 4 (5)[353] of Directive 2002/46 also ensures that an application for inclusion on the positive lists of a vitamin, a mineral or a vitamin or mineral substance can be rejected only by a binding legal act, which may be subject to judicial review."[354]

E. The Telecommunications Sector

Until relatively recently, telecommunications in the EU was essentially characterized by State monopolies. This began to evolve in the early 1980's with the privatization of some national operators and the introduction, albeit very limited, of competition in some Member States. Such competition was triggered essentially by the introduction and application of information technology in the telecommunications sector. In 1987, the Commission issued a Green Paper setting forth the grounds for a legal framework liberalizing and harmonizing the telecommunications sector. Today, EU telecommunications is mainly privatized and liberalized, with a similar body of rules applying across the EU. However, with a few exceptions, the 25 incumbent operators still maintain very strong market position in many markets.

This wide-reaching achievement was built upon successive legislative interventions, primarily launched by the European Commission, that mainly sought to liberalize and harmonize an industry controlled by State monopolies. The opening up of the market remains largely based on the following three pillars: (1) progressive liberalization of a former monopoly sector, (2) accompanying harmonization measures, and (3) the application of competition rules.

The liberalization and harmonization process has undergone three successive stages:

- A first stage, beginning in 1984, aimed at creating a common ground for development, placing focus on common industry standards, common industry-wide research groups (at the European level), and the development of common European positions in the international telecommunications sector.

- The second stage, triggered by the release of the Commission's Green Paper on Telecommunications[355] (the " 1987 Telecommunications Green Paper") in June 1987. This Green Paper set the stage for a broad debate

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353 [Comitology].

354 Para. 81 *et seq*.

355 Communication by the Commission - Green Paper on the development of the common market for telecommunications services and equipment - Towards a dynamic European economy (COM (1987) 290) of 30 June 1987.

on the liberalization and harmonization of telecommunications in the EU and resulted in the liberalization of all telecommunications services by 1 January 1998 through the "1998 Regulatory Package".

- The third stage, initiated by rapid changes in technology, convergence, and an increasingly competitive and liberalized market, led the Commission to create a new regulatory framework for electronic communications, which has applied since July 2003 (the "New Regulatory Framework").

The Commission is currently involved in a review of the New Regulatory Framework legislation mandated by the Framework Telecommunication Directive.

Three DGs have competence in the area of electronic communications: DG Information Society and Media; DG Competition; and DG Internal Market. Most Council and Parliament Directives in the telecommunications sector are adopted under Article 95 ECT (Internal Market). Early in the process of breaking up national monopolies, the Commission used its powers under Article 86(3) ECT to "ensure the application" of Article 83 ECT by addressing "appropriate directives or decisions to Member States." While use of this legal basis to abolish monopolies was unprecedented, the Commission felt that it was necessary to do so in order to liberalize the telecommunications markets in a time frame consistent with the technological developments and with similar reforms in other parts of the world. It did so with the widest possible dialogue with other Union institutions, Member States and interested parties. Even so, its use was challenged by a number of Member States in the European Court of Justice, but was upheld on all grounds. More recently, however, the Commission has not used this legislative tool.

In July 2000, the Commission proposed a package of measures for a new regulatory framework for electronic communications networks and services. The New Regulatory Framework is intended to provide a coherent, reliable and flexible approach to the regulation of electronic communication networks and services in fast moving markets. The directives provide a lighter regulatory touch where markets have become more competitive, yet seek to ensure that a minimum of services are available to all users at an affordable price and that basic consumer rights continue to be protected.

The package consists of five proposed EP and Council directives under Article 95 ECT, one Commission directive to be adopted under Article 86 ECT, and one proposed Commission Decision on a regulatory framework for radio spectrum. In addition, the Commission proposed an EP and Council Regulation for unbundled access to the local loop, which was adopted by the EP and Council in December 2000, entered into force on 2 January 2001.[356] The main directives are the Framework

[356] Regulation No 2887/2000 of the European Parliament and of the Council of 18 December 2000 on unbundled access to the local loop [2000] O.J. L336/4.

Directive, the Access Directive, the Universal Service Directive, and the Authorization Directive.

Commission Recommendations are in widespread use in the telecommunications sector, and are often accompanied by an explanatory memorandum. The Commission also uses Guidelines, normally to provide guidance in the application of legislation to a particular industry sector.

During the comitology process, the Commission works with a number of committees in the telecoms sector, including:

- The Communications Committee, a mixed advisory and regulatory committee, and

- The Radio Spectrum Committee, also a mixed advisory and regulatory committee.

The Commission also has also created various new working groups aimed at assisting it in the correct and harmonized implementation of the New Regulatory Framework. The most important of these is The Radio Spectrum Policy Group, established by a Commission Decision which requires that the Group itself consult "extensively and at an early stage with market participants, consumers and end-users in an open and transparent manner." This Group provides a platform for Member States, the Commission, and stakeholders to coordinate the use of radio spectrum.

The telecommunications sector makes wide use of the New Approach standards process. Uniform technical specifications are central to the operation of mutual type approval between Member States and to the development of a single European telecommunications market. To develop a truly competitive market in telecommunications services, infrastructure and termination equipment must operate on the same specified technical standards. The standards bodies most active in the telecommunications sector are:

- The European Telecommunications Standardization Institute (ETSI), which was created in 1987 by the CEPT[357] in order to enhance and complement the Community's policy on telecommunications and information technology standards and to promote open international standardization. Standards approved by the ETSI are known as European Telecommunications Standards (ETS).

[357] CEPT stands for "*Conférence Européenne des Postes et Telecommunication*". CEPT was established in 1959. Since 1992, CEPT has been composed of national authorities. It is to consider, in a European context, public policy and regulatory matters relating to posts and telecommunications and to foster the harmonization of regulations.

- The European Committee for Electrotechnical Standardization (CENELEC), created in 1973. Its mission is to prepare voluntary electrotechnical standards to promote the Single European Market for electrical and electronic goods and services by removing barriers to trade, creating new markets and cutting compliance costs. CENELEC is developing and achieving a coherent set of voluntary electrotechnical standards as a basis for the creation of the Single European Market/European Economic Area without internal frontiers for goods and services.

Since mid-1997, the Commission has issued a series of implementation reports assessing the state of implementation of telecommunications legislation in each Member State. Those reports not only monitor the transposition of the various directives into national law, but also assess the state of competition in national markets. They provide an excellent overview for the private sector of the regulatory positions in the various Member States. In the context of the preparation of such reports, the Commission has extensive contacts with Member States and operators, providing opportunities to the latter to bring concerns about the proper transposition of EU legislation into national law.

In the telecommunications sector, national regulatory authorities (NRAs) have the primary responsibility for implementing and enforcing the EC regulatory framework. Thus, NRAs play a major role in the new regulatory regime, alongside the national competition authorities. They also play an important role in ensuring that rules are consistently applied in all Member States, in cooperation with other NRAs and the Commission. NRAs, in particular, must assess the level of effective competition in relevant markets, and determine the regulatory obligations to be imposed on players with significant market power.

One of the cornerstones of the continued liberalization of the telecommunications sector is the increased introduction of competition analysis principles in the telecommunications regulatory environment. The 1998 Regulatory package gave little space to the NRAs for policy and implementation. NRAs were legally constrained in imposing regulatory obligations to the extent that (1) the relevant market, (2) the operators concerned (static criterion of 25% market share), and (3) the remedies were identified and set by the applicable legal framework.

The New Regulatory Framework, however, leaves considerably more scope for regulation by the NRAs. In this regard, NRAs must (i) define relevant markets; (ii) designate certain operators and service providers as having significant market power ("SMP") on these markets; and (iii) impose regulatory requirements (remedies) on these SMP operators, where such remedies could affect trade between Member States.

This decentralization of regulatory powers, however, raises harmonization concerns. The new framework sets out to address an important and difficult challenge: reconciling the seemingly contradictory aims of (i) harmonizing the regulatory framework across the EU and therefore strengthening the Single Market, while (ii) allowing for a

much-needed degree of flexibility to reflect national particularities. To meet these concerns, the EU Regulatory Framework empowers the Commission to oversee the national regulatory measures by way of consultation and transparency procedures provided under Article 7 of the Framework Directive.

Article 7 of the Framework Directive requires NRAs to carry out market analyses to establish the state of competition in relevant communications markets and to identify any providers with SMP in these markets. Once an operator is deemed to have SMP, NRAs must identify the specific obligations that are appropriate to impose on such operator. Obligations can vary according to the nature and the source of the competition problem, which, combined with the wide range of potential remedies, allows for a high degree of tailor-made solutions to specific circumstances.

NRAs must, however, conduct a 'national' and a 'Community' consultation on the measures they intend to take. The Commission has certain "veto powers" over the result. The Article 7 consultation procedure is a decision-making procedure between authorities at national and Community level (NRAs and Commission). It does not provide for any formal means of participation by mobile operators or other concerned entities. Nonetheless, operators and other concerned parties are often given the opportunity to express their views on the draft measures at both national and EU-level.

The Article 7 procedure implies the use of considerable resources and puts a heavy administrative burden on the Commission, given the strict deadlines set out in the new framework for carrying out such assessments. To manage the Community consultation, the Commission has established two Article 7 Task Forces, one in the Competition DG and another one in the Information Society DG, to carry out the duties that the new framework places on the Commission. Key responsibilities include the review and analysis of draft regulatory measures ('cases') notified by NRAs under the Community consultation. The Task Forces work very closely together and establish joint case teams in each case in order to meet the tight deadlines of the Article 7 consultation mechanism.

An additional implementation mechanism is the European Regulators Group for electronic communications networks and services ("ERG"), created by Commission Decision 2002/627/EC.[358] The ERG is an informal body which is not subject to the rules on committees. It is composed of the representatives of the NRAs and chaired by one of the representatives. The ERG aims at ensuring a consistent application of the New Regulatory Framework on the ground, through informal coordination of the actions of the various national NRAs.

[358] Decision 2002/627/EC of 29 July 2002 establishing the European Regulators Group for Electronic Communications Networks and Services [2002] L200/38, as amended by Commission Decision of 14 September 2004 (2004/641/EC) [2004] L293/30.

F. The Workplace Sector

The term "workplace regulation" is a broad term, devoid of connotations of a particular national jurisdiction, and should be considered as covering all potential legal aspects of the workplace. It pertains to legislation relating to employment, social affairs and equal opportunities, which are also the subject matters dealt with by the Directorate General for Employment and Social Affairs (DG EMPL) of the European Commission. In particular, it includes:

- Legislation on employment, quality of work, productivity and approximating of Member States' national legislation regulating the labor market;

- Legislation on social protection and social exclusion, with the aim of reinforcing co-operation between Member States, drawing up legislation and running programs to counter discrimination, promoting fundamental rights and enhancing the integration of disabled people;

- Legislation on equality between men and women, including all the legislation aimed at improving equal opportunities for women and men and ensuring that the gender issue is taken into account in all fields of Community action.[359]

The EU sector of workplace regulation is almost *sui generis*, due to the express role given to unions and employers in the legislative process. These "social partners" as they are known in European usage are given special rights as initiators, consultants and implementers of the law regulating them.[360] While this deeply modifies the normal institutional balance in the decision process, their role remains subject to Commission guidance. Reflecting also the relative balance of power in this sector between the Member States and the Community, the Community uses Council directives (which, under Article 137, ¶2(b) ECT can establish "minimum requirements," but only for "gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States"),[361] not regulations, and much soft law and important special soft law processes. This results in great complexity in the lawmaking procedure.

EU legislative procedures in this sector reflect political choices going back to 1985. At that time, various federations and unions representing both employers and employees (private and public sectors) (the "social partners") first decided to launch a

[359] Article 141 ECT provides a further basis for legislation in this area.

[360] Because of these official roles, Articles 138 and 139 ECT set out rules on the representativeness of the qualifying organizations to address the issues of legitimacy and effectiveness.

[361] As the Article specifies, such directives are meant to avoid imposing constraints which would hold back the creation and development of small and medium-sized undertakings. An example of such a directive is Council Directive 94/45/EC of 22 September 1994 on the establishment of a European Works Council or a procedure in Community-scale undertakings and Community-scale groups of undertakings for the purposes of informing and consulting employees ([1994] O.J. L254/94; Lenaerts and Van Nuffel, p. 302).

dialogue which could bring about progress through broad agreements, paving the way to the adoption of the Agreement on Social Policy which was adopted on October 1, 1991 and constituted the most important decision-making reform in European labor law. It was subsequently integrated into the Protocol on Social Policy, which was itself annexed to the Maastricht Treaty. It was signed by 11 of the then 12 Member States of the European Community. The non-signatory was the UK government which decided to "opt out" of the Social Chapter,[362] arguing that its provisions constituted unnecessary and damaging intervention into the operation of the labor market and the relationships between employers and employees, a position it changed in 1997 and signed up to it. The social dialogue provisions of the Agreement were incorporated into the Amsterdam Treaty, and, upon ratification, became part of the ECT as Articles 138 and 139 ECT. With this text, social partners were given an advisory role (Article 138 ECT), plus a role as initiators (Article 139 ECT) in workplace rulemaking. On this latter point the text provides that agreements negotiated by the European social partners could be given legal effect by a Council decision and transposed into the national legislation of the Member States.

The normal legislative processes are provided for in Article 137 ECT, but the special character of this area of EU law is signaled at the outset by the language used to describe the Community role – it "supports and complements" the activities of the Member States (as opposed, for example, to liberalizing or harmonizing their law and regulation). The use of directives, not regulations, is provided for, and while some of the areas regulated use the co-decision process, a number require use of the consultation process (unanimity).[363]

Initiation of legislation by the Commission can happen either through its formal agenda setting process, or as a result of complaint letters from European citizens or written questions from European Members of Parliament (MPs). In DG EMPL, Directorate F (Social Dialogue, Social Rights, Working Conditions and Adaptation to Change) and its units F2 (Labor Law) and F3 (Working Conditions and Adaptation to Change) are most involved in the legislative and policy issues involved here.

The first question in the initiation of legislation is whether Community level action is appropriate,[364] and Article 138, ¶2 ECT requires that the social partners be consulted on this point ("the possible direction of Community action"). If action is to be taken, a consultation process is initiated which involves mandatory consultation of the social partners (this time, on the content of the initiative) and the Economic and Social Committee (ESC), an institutional assembly of appointed representatives of the various spheres of economic and social activities – employers, employees, and various other

[362] In 1991, the UK opted out of the Agreement on Social Policy. In 1997, however, the UK did sign the Amsterdam Treaty.

[363] Unanimity voting in the Council does not always go together with mere consultation of the Parliament. Under Article 42 ECT, co-decision and unanimity voting in the Council are required.

[364] In some areas, EU legislation is not an option at all (*e.g.*, social exclusion and social protection, *Cf.* Article 137(1), under j and k).

interests. The Committee of the Regions (CoR), a Treaty-based consultative committee made up of appointed representatives of local and regional authorities is also consulted.[365] Finally, an advisory committee can be consulted, in such areas as health and safety at work, vocational training, equal opportunity, freedom of movement for workers, and social security for migrant workers.

None of these committees has been established through the comitology procedure. In broad terms they are comprised of 3 or 6 members per Member State, which represent the national government, the trade unions and the employers' associations. The exception to that is the advisory committee on equal opportunities, whose members, for trade union and employer association domains, are representatives at a European and not a national level. The work of these advisory committees is accessible on their relevant webpages, usually a subpage of DG EMPL. There is no central register, contrasted to the Commission's web-based comitology register.

DG EMPL appears to have complied with the Commission's 2002 Communication on Consultation in its actions since publication of that communication,[366] and has begun to comply with the Commission's Impact Assessment Communication and Guidelines. Further, in 2005, for the first time, the Commission made available a list of the expert groups divided by DG. For DG EMPL alone, there are some 170 groups and subgroups of experts and advisers, according to the following typology:

- Advisory Groups (14 groups and sub groups) Example: Advisory Group on the Equality of Opportunity between Women and Men
- Permanent Expert Groups (95 groups and subgroups) Example: European Network of Employment Services
- Temporary Expert Groups Example: Group on Workplace Rights and Conditions

Implementation is normally committed to the Member States, which under Article 137, ¶3 ECT, may in turn entrust implementation to the social partners. In this sector, the Directive normally requires that Members States inform the Commission, within a stated period, about implementation progress. In some cases, the Commission then prepares a report on implementation, which is published on its web site. Whether or not a Member State relies on social partners, it remains responsible for the result.

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[365] Article 137, par. 2, ECT. This provision requires consultation of the ESC and CoR.

[366] [**Check re compliance with full public participation rather than just with social partners during the mandatory consultation with the latter; rendered moot by allowing such public participation by another round of participation, including the full public, after the legislative proposal was developed?**]

DG-EMPL does not much use implementation through the comitology. The latest Commission statistics for 2004 show that in the employment and social policy sector, only six comitology committees have been appointed, which delivered a total of 6 favorable opinions in 2004, based on a total of 10 meetings (with no instrument being adopted in 2004).

The "social dialogue" process under Article 139, ¶2 ECT, allows the social parties both to develop and to implement legislation and enforceable agreements. During the consultation process, the social partners can, at either [check] point of mandatory consultation with them by the Commission, notify the Commission, under Article 138, ¶4 ECT, that they choose to use the procedure in Article 139, ¶2 ECT to conduct a "social dialogue" at Community level, and within nine months (if there is no extension), to make an agreement among themselves preempting the normal legislative process.[367] This agreement can then result in one of two legal instruments. When it is within the scope of Article 137 ECT, and on the joint request of the social partners, it can be adopted into law as a Council and Parliament Directive[368] on proposal by the Commission. It may also remain a contractual agreement between the parties (an "autonomous agreement").

It is important to note that the social partners can also themselves *initiate* an Article 139 ECT social dialogue, independent of whether the Commission has initiated the legislative process. In this case, they are not restricted to any specific subject matter (*e.g.*, they are not restricted by the language of Article 137 ECT). This process is one of the rare times under EU law that legislation has the possibility to be initiated by someone other than the Commission.

Implementation of an Article 139 ECT agreement can take place in one of two ways. First, if the agreement has been made incorporated into a Council and

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[367] In the past, only three organizations were allowed to take part in the European Social Dialogue:

- ETUC (European Trade Union Confederation): established in 1973, the ETUC currently groups together 77 member organizations in 35 European countries, as well as 11 European industry associations of trade unions, and has a total of 60 million members. Other trade union structures, such as Eurocadres (representing managerial staff) and FERPA (European Federation of Retired and Older People) operate under the auspices of the ETUC.
- UNICE (Union of Industrial and Employers' Confederations of Europe): established in 1958, it groups together the employers' organizations of 27 European countries, and represents the interests of European industry and business circles vis-à-vis the European institutions. Another structure, the UEAPME which represents small and medium-sized companies participates in the European Social Dialogue as part of the UNICE delegation.
- CEEP (European Centre of Enterprises with Public Participation and of Enterprises of General Economic Interest): created in 1961, it deals with the activities of enterprises with public participation and enterprises of general economic interest.

Currently, over 50 organizations, which are selected on the basis of representativeness, are consulted. *See* http://www.ec.europa.eu/employment_social/social_dialogue/represent_en.htm.

[368] While Article 139, ¶2 ECT speaks only of a "Council Decision," such decisions have so far been in the form of directives.

Parliament Directive, the normal responsibility for transposition and implementation lies with the Member States (although the social partners can choose to implement normal legislation themselves under Article 137, ¶3 ECT, and because an "agreement" is involved, may be able to do so under Article 139, ¶2 ECT as well, the process next to be described[369]), even in cases where the provisions are implemented through collective bargaining by the social partners. The Member States associate the social partners in their transposition at national level. Responsibility for monitoring these agreements lies with the Commission, although the management and labor organizations which have signed the agreement are systematically consulted by the European Commission on implementation reports.

Second, autonomous agreements can be implemented "in accordance with the procedures and practices specific to management and labor and the Member States."[370] In this case, it is the social partners themselves who are responsible for implementing and monitoring these agreements. Effective implementation and monitoring is important in the case of agreements of this kind, particularly if they have been negotiated subsequent to a Commission consultation under Article 138 ECT. Article 139(2) ECT states that the Community level agreements "shall be implemented" (emphasis added), which implies that there is an obligation to implement these agreements and for the signatory parties to exercise influence on their members in order to implement the European agreement. The Commission has signaled some concern with the level of monitoring and enforcement with this method of implementation.[371]

Given the lack of real power on the part of the Community to force reform and change on the Member States, soft law plays a large role in the workplace sector in the EU. This may embrace such matters as regulation by planning, monitoring, examination and re-adjustment, coordination, voluntary agreement, exhortation, publicity and shaming, and other techniques that do not depend on legally effective instruments backed up by court enforcement. The major example of soft law in employment is the European Employment Strategy ("EES"), initiated on the basis of the provisions of the Amsterdam Treaty providing for the principal soft law procedure in labor law.

Under the EES, European Employment Guidelines are decided each year by the Council following a proposal from the Commission. These Guidelines have to be taken into account in National Reform Programs (National Action Plans until 2005), which are assessed through the Joint Employment Report from the Commission and Council, with a view to setting the next guidelines. Since 2000, the Council, following a proposal from the Commission, issues specific Recommendations to Member States, in order to complement the Employment Guidelines. From 2005, the employment guidelines are

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369 [**Check**]

370 Article 139, ¶2 ECT.

371 *See* The Commission proposal for a Council decision establishing a Tripartite Social Summit for Growth and Employment of June 26, 2002, COM (2002) 341 Final.

integrated with the EU's macroeconomic and microeconomic policies and are set for a three year period.

The EES initiated a new procedure at Community level, which has become known as the "open method of co-ordination." A tool for coordinating employment policies priorities to which EU member states should subscribe, this method shares with "directives" the characteristic of addressing Member States rather than individuals; but its fundamental characteristic is one of soft law – identifying goals for mutual pursuit rather than setting common obligations for Member State implementation. It is based on five key principles: (i) subsidiarity, (ii) convergence, (iii) management by objectives, (iv) an integrated approach, and (v) country surveillance. First, as to subsidiarity, the method is aimed at achieving an "equilibrium" between European Union level co-ordination in the definition of common objectives and outcomes, and Member States' responsibilities in deciding the detailed content of action. The definition of the means and conditions under which programs and policies are implemented is left to a large extent to individual Member States. Second, as to convergence, the strategy strives to achieve commonly agreed employment outcomes through concerted action, where each Member State contributes towards raising the European average performance. Third, management of the EES is by objectives, in that the strategy relies on the use of quantified targets. It leaves Member States free, however, to choose the means to achieve them. As a related matter, to foster mutual learning and build knowledge, one of the core objectives of the open method of co-ordination is exchanging good practices and experience. Fourth, reflecting an integrated approach, the EES is not limited to active labor market policies but extends to social, educational, tax, enterprise and regional policies. Fifth, in terms of country surveillance, because the strategy relies on the use of quantified measurements, targets and benchmarks, proper monitoring and evaluation of progress is facilitated.

The original idea behind the open method was to work towards harmonization in sensitive areas where there was not yet a sufficient common basis for legislative initiatives, but it has now developed into an additional and separate tool. It is one of the few approaches available to the EU in areas in which it does not have the authority to legislate,[372] specifically including "the combating of social exclusion" and "the modernization of social protection systems."[373] Being a soft law instrument, "enforcement" of the EES is by political means.

The "coordination" approach is one that could be generalized into other areas of Commission activity as well. It is particularly well suited to context in which the Community lacks explicit legislative competence or has competence only to define

[372] Another method is the adoption of Community Action Programs. These programs are implemented by the Commission assisted by comitology committees.

[373] *Cf.* Article 137(1), under j and k, ECT.

minimum rules, but Member States nonetheless conclude it would be useful to seek unified or coordinated outcomes.[374]

VII. Conclusion

The American Congress, a representative, openly political, legislative entity, lacks the contextual incentives to treat its own work of legislative drafting with anything approaching the rigor and public exposure the Commission, a non-representative executive branch entity, 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 lawmaking and 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, both lawmaking and 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 the growth of their formal structures.

Particularly noteworthy in this regard is the manner in which the Commission structures its "stakeholder consultations." The importance of policy and the need for forming a political consensus for taking action, and for taking action at the EU level, 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, although it must be recognized that self-drafted replies may also be submitted and if submitted, will be considered by the Commission, 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. On the other hand, it is considerably less hospitable to new ideas and input than is the wide-open "anything goes" format of formal notice -and -comment in American rulemaking. 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 but allows individual voices and new ideas to be heard, in a way the developing EU techniques of specifying in advance the focus of the consultation desired by the bureaucrats may discourage in the interests of efficiency (and in some cases perhaps, administrative

[374] *Cf.* Charles Sabel [PS to supply].

guiding of the discussion past areas the bureaucracy has an institutional incentive to avoid).

The highly interactive character of norm-generation in the EU, perhaps especially in its techniques for developing soft law, is not only an understandable reaction to the political sensitivities of its position in relation to its Member States. It may also reflect an important adaptation to the general circumstances of contemporary government, as hierarchy comes to be replaced by more fluid and interactive consultative networking. Here, one recurs to the quite fluid interactions among European institutions and the authorities of Member States; most of what happens legislatively can be explained in the EU by the struggle between the Member States through the Council and the comitology committees and the Commission and the Parliament for control of policy-making. Further, recall that this discussion has – of necessity – been restricted to what occurs at the level of Europe, but that much implementation, even of European law, is left to the institutions *and* procedures of Member States, under forms of central supervision deliberately fashioned by the Member States themselves, acting in the Council, to be as often persuasive as disciplinarian.

One must bear in mind, as well, that in the legislative context if not the executive, fluid interactivity may be somewhat easier for parliamentary systems than our own; the greater integration between parliament and government, the apparent unity of political responsibility for legislation *and* regulation, has tended to leave questions of control over regulatory development (like control over legislative development) to the political scientists rather than lawyers and courts. The Minister must answer, quite directly, to Parliament; and Parliament must answer for the Minister. "This ongoing connection," Peter Lindseth wrote, "helps to reconcile the reality of delegation (and the agency autonomy that inevitably comes with it) with the legal-cultural ideals of representative democracy grounded in the constitutional legislature that most liberal states have inherited from the eighteenth and nineteenth centuries."[375] Even in the national context, as Lindseth continued, "[t]he diffusion and fragmentation of normative power away from constitutional legislatures over the course of the twentieth century reached a point that, to some observers at least, it has become questionable to claim empirically (if not normatively) that the legislature serves as the constitutional principal in the modern system of regulatory norm-production."[376] "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."[377] In the United States too, despite presidential preferences for a tight command structure, there may lie the

[375] 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.

[376] Ibid.

[377] *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).

same risks of loss of effective political control of administration in a representative democracy, reinforcing the need for tight judicial accountability and control.

If there are American lessons for Europe, they may lie in the realm between legislative development and soft law. The functional need for "comitology" is clear enough, as is the political imperative for its current structure and practices in the sensibilities of, and driving, underlying and ever-present desire for control over EU-level policy and lawmaking by, the EU's Member States. While the European Parliament's resistance to, and desire to have control over comitology is clear, the future shape of both this and other forms of "implementing measure" procedure is not. The Commission so consistently follows and encourages the formalities of 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 adopted through comitology can or should long continue. Here, one might think, the more open notice-and-comment processes that Commission papers promote among European agencies and standards organizations could find a proper place.