# Chapter 2

# RULEMAKING

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# Norm Creation in the European Union

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**Table of contents**

I. Executive Summary ........ 2
II. Norm Creation In the EC and Its Sectors – Context and Overview ........ 6
A. Introductory Note ........ 6
B. An Introduction to the EU Institutions and Lawmaking Processes ........ 15
1. The Commission ........ 15
2. The Council ........ 16
3. The Parliament ........ 18
4. The Court of Justice ........ 19
5. The Interplay Among the Institutions ........ 20
6. EU Lawmaking Instruments ........ 21
7. The EU Legislative Process ........ 24
8. EU Delegated Lawmaking ........ 25
C. Sector Summaries ........ 31
1. The Competition Law Sector ........ 31
2. The Environmental Sector ........ 31
3. The Financial Services Sector ........ 34
4. The Food Safety Sector ........ 37
5. The Telecommunications Sector ........ 38
6. The Workplace Sector ........ 39
III. The Process By Which EU Legislative Proposals Are Developed ........ 42
A. Framing Legislation ........ 42
B. Notice of Development ........ 45
C. Impact Assessment ........ 49
1. Limits of Coverage ........ 50
2. The Impact Analysis process ........ 51
D. Stakeholder consultation (and report) ........ 55
E. Lobbying and Its Regulation ........ 63
F. The Commission's internal processes ........ 65
G. Explanation ........ 67
H. Final Action ........ 68
IV. Creating Implementing Measures ........ 69

A. Delegation Doctrine In the EU ........ 70
B. The Delegated Powers of the Commission ........ 71
C. Comitology ........ 73
1. The Comitology Process ........ 76
2. The Requirement for Standard Rules of Procedure ........ 85
3. The Requirement for a Register ........ 86
4. Access To Information ........ 86
5. Public Participation (Consultation) ........ 88
6. Requirement for Rationale of Decision ........ 90
D. An alternative to comitology? -- European Agencies as Actors ........ 90
E. The “New Approach” to Standards ........ 93
1. Impact Assessment ........ 96
2. Access To Information ........ 97
3. Public Participation ........ 97
4. Explanation Of Decision Rationale ........ 98
F. Delegation Out to International Bodies ........ 98
V. Guidance and Other Forms of “Soft Law”—Giving Reliable Advice ........ 98
VI. EU Institutions and Lawmaking Processes by Sector—the Details ........ 103
A. The Competition Law Sector ........ 103
B. The Environmental Sector ........ 107
C. The Financial Services Sector ........ 112
D. The Food Safety Sector ........ 123
E. The Telecommunications Sector ........ 132
F. The Workplace Sector ........ 137
VII. Conclusion ........ 144

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## I. Executive Summary

This report summarizes the administrative law involved in making generally applicable laws and rules at the European Commission (the "EC") of 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 many of the subjects dealt with are in considerable flux at the moment. With the defeat of the proposed constitutional treaty and the recent substantial enlargement of the EU, change is only to be expected. As will be apparent within, comitology practice, in particular. is in the course of significant change. Also, the adoption of major new regulatory legislation in the environmental area, the REACH regulation dealing chemical issues, establishes a major new European regulatory agency. Every effort has been made to make this report current through April 1, 2007; but it is in the nature of a venture like this, supported by many lawyers and academicians each with other distractions that readers must pay careful attention to recent developments and trends.

[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."

Perhaps most important, the reader should bear in mind 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 lawyers with substantial EU practices have made of six particular sectors of the EC, as noted above, with the helpful advice of high-level Commission staff. These six sectors are varied, but far from the universe of the EU'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 Commission itself. Yet 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 in a study of administrative law, but there are reasons specific to the rather different European context for doing so. Specifically, as a general matter the European Commission, the EU institution most closely resembling the US Executive Branch, has 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 mirror the administrative rulemaking process in the US in important respects. On the other hand, the EU has thus far developed its processes for administrative rulemaking pursuant to legislative delegations much less fully than has the US. Although the Commission has been producing an increasing volume of implementing measures (in American terms, rulemaking), amid much debate over the

[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.

propriety of its processes, 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, providing broadly for public participation, and generally affording judicial review by citizens, NGO's, and the regulated community. Thus, the European Commission's role in proposing legislation to date has been more important, transparent, and open to structured public participation than its role in delegated rulemaking. This is just the opposite from the situation prevailing in the US.

.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. While many of those institutions bear a surface resemblance to American analogues, the European Union has 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 like 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 fifty 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 EU institutions and practices in the rulemaking area cannot be well understood without 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 in particular 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 the Council and on comitology committees.

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 Americans are accustomed to between 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, as well as on the expectations and incentives of the institutional actors.

The European Commission, the EU's executive branch, has its own institutional interests, incentives, and agenda. The Commission is an appointed bureaucracy with 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. As such, it is frequently in opposition to parochial interests of the Member States 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.

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 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.

Yet in general, within the Commission itself, these administrative process reforms have been implemented as the product of political incentive, not legal compulsion. The Commission has 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. The Council and Parliament have yet 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). This is perhaps a natural outcome during the initial period of laying down a regulatory foundation for the new Europe. 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 need for legitimacy and accountability in administrative action at the EU level demands 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 these 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 EU, 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: A lobbyist's victory in the sauce war,"[3] and opened with an account of lobbyists' reaction to a European Commission decision that a vegetable sauce with more than twenty percent lumps was itself a "vegetable"; 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 ever deeper into companies' lives," the Tribune wrote, "so the interest of businesses in defending their causes on the legislative battlefield of Brussels has intensified."[4] The

[3] Graham Bowley, Apr. 5, 2005, at 1, 4.

[4] Id.

article was about companies and the thousands of their lobbyists who now throng the EU capital, but it might as well have been about citizens or NGOs—Friends of the Earth as well as Unilever are there and fighting.[5]

The second story was an op-ed piece, "EU's growth triggers identity crisis,"[6] 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 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 Tribune wrote, "approval of the constitution has been turned into a referendum on issues that have little or nothing to do with the constitution, such as Turkish membership of the EU, the Stability Pact, the Bolkestein directive on liberalizing rules for the service industry, and local partisan rows."[7]

Stunning defeats of the draft in French and Dutch referenda soon consigned the draft constitution to oblivion, at least temporarily.[8] As a result, the EU continues to function under its present treaty regimes. Yet that still has remarkable implications for Europe's national governments. As one author has written, "up to 90 per cent 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."[9] Statistics like these and the growing importance of the "single market" they reflect give the question how EU laws are formed particular interest; to what extent are EU institutions under democratic control, to what extent under the control of 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,

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[5] 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 St. J. (E. Ed.), Nov. 1, 2005, at A1.

[6] William Pfaff, Apr. 5, 2005, at 7.

[7] Id.

[8] 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.

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

rarely invoked and requiring demanding procedures for ratification as well as adoption. At the second level, one finds laws and statutes directly enacted by a parliament, Congress, or similar representative legislative body, no more than a few hundred yearly. In 1996, for example, the European Parliament and Council adopted 484 "legislative" acts. At a tertiary level, beneath that of legislation, one finds the subsidiary legislation or regulations executive authorities—departments, agencies, ministries—adopt under legislative authorization; here the flow rate is still higher—typically, at this level of detail, thousands annually. Again in 1996, following the very different processes employed for "implementing measures" and under rather light supervision, the European Commission adopted 5147 "regulations." Enabling legislation may also authorize subordinate political units (states in the US, Member States in the EU), even private organizations (European standards organizations), to adopt norms under conditions of supervision and, perhaps, required procedure. These norms interact. Finally, at one might think the fourth level, 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. The "soft law" of 1996 is uncounted, but a visit to the Commission's websites will suggest its volume.[10]

The hierarchical level 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.[11]

- For the American Congress, whether and under what conditions to permit nuclear generation of electric energy are judgments fundamentally

[10] The numbers in text are drawn from Georg Haibach, Separation and Delegation of Legislative Powers: A Comparative Analysis, *in* Delegated Legislation and the Role of Committees in the EC, supra note 9, at 53. To similar effect, for different years and making comparisons to similar European national experience, see Gunther Schafer, Linking Member State and European Administrations – the Role of Committees and Comitology*, in* Delegated Legislation and the Role of Committees in the EC, supra note 9, at 3, 6, 9; Josef Falke, Comitology: From Small Councils to Complex Networks, *in* Delegated Legislation and the Role of Committees in the EC*,* supra note 9, at 331, 336.

[11] For example, that African-American school children are psychologically and developmentally disadvantaged by segregated education. *Brown v. Bd. of Educ.*, 347 U.S. 483, 494 (1954).

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.

- 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.[12] Congress has established a Nuclear Regulatory Commission (NRC) 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.[13] 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.[14]

- "Soft law" emerging from the NRC—say, advice that responsible staff elements have developed to define acceptable means of complying with NRC regulations—may be just as political as regulations; but in technical

[12] On the interrelation of expert and political rationales of legitimacy, see Matthew D. Adler, Justification, Legitimacy, and Administrative Governance, *in* Issues in Legal Scholarship – The Reformation of Administrative Law (Philip P. Frickey & John F. Manning eds., 2005), available at http://www.bepress.com/ils/iss6/art3/.

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

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

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 NRC 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.

- 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 and agents, make constitutions; the legislature makes statutes; the political leadership of an executive agency (or the judiciary) makes 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.[15]

- 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.

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

- 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?[16] Whichever choice one makes between these contending views, to Americans it is clear that the President is popularly elected, and thus a politically accountable figure—essentially the only such figure in the executive.[17] Consequently they understand his exercise of authority to be hierarchical, not democratic; Americans do not imagine the executive as a collective.

The tension between superior expertise and politics as the coin of bureaucratic legitimacy, as well as the hierarchy of normative instruments, will be familiar enough to any citizen of a parliamentary democracy, but many of the forgoing propositions will nonetheless seem strange. 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. In a coalition government, a minister will feel political responsibility to her own party as well as to the government of which she is a part. 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 EU 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.[18]

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

[17] 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).

[18] 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. For text of the draft, See http://europa.eu.int/eur-lex/lex/en/treaties/dat/12004V/htm/12004V.html.

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 increasingly the product of what might seem a bicameral legislature (Council and Parliament) acting in coordination with an executive authority (the European Commission); "rules" produced by the executive authority; and guidance emerging from its bureaus. Yet strikingly, the EU executive—the European Commission —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 the European Commission ; the Commission is the source of most pan-European "rules" or implementing measures having the force of law; and soft-law guidance, as well, generally requires its approval. 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 European 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 European 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 European 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.[19]

(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—, "independent" EU agencies such as the European Food Safety Authority or the newly formed European Chemicals Agency,[20] international organizations like the Codex Alimentarius Commission of the FAO and WHO[21] dealing with food safety issues and quasi-private standards organizations such as CEN, the European Committee for Standardization.[22]

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 and local levels 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 review 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

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19 See infra p. 67.

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

21 http://www.codexalimentarius.net/120% web/index_en.jsp.

22 http://www.cenorm.be/cenorm/index.htm; See infra p. 80.

participation and transparency have great importance to this study. 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 the possibilities both for internal manipulation and control, and for distorting or at least obfuscating the public's will. To take two simple examples, looking in opposite directions:

- Twenty 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.

- Twenty 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 compare the norm-generating procedures of the EU and the United States at the second, third, and fourth levels of the hierarchy of norms suggested above. It is limited to the EU itself (with minor attention to pan-European standards organizations), and pays 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 January 1, 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.[23] 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. While each Directorate General has its assigned areas of competence, Commission actions are collectively taken.

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.[24] In practice, of course, the Commission is put under various degrees of legislative pressure by the other institutions, the Member States, interested parties, and civil society.[25]

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.[26] The Commission has, at a minimum, a consultative role during

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[23] To date, every Member State has had at least one commissioner. Treaty Establishing the European Community, art. 213, Nov. 10, 1997, 1997 O.J. (C 340) 3 (hereinafter "TEC"). Beginning with the next Commission, this will no longer be true. See Protocol on the Enlargement of the European Eunion, art. 4, Dec. 24, 2002, 2002 O.J. (C325) 1, available at http://europa.eu/eur-lex/en/treaties/dat/C_2002325EN.016301.htm.

[24] 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.

[25] As this millennium began, it was reported that, of all the 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, at 6, COM (2001) 130 final (July 3, 2001), available at http://europa.eu/eur-lex/en/com/cnc/2001/com2001_0130en01.pdf.

[26] Article 250 TEC.

various stages of the EU legislative processes briefly described in the following pages, 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. For example, should the European Parliament propose amendments to a Council-approved measure that is subject to the co-decision procedures of Article 251 TEC described below, the Commission is responsible to give the Council its view of the proposals; and its 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 Parliament is required to overcome Commission disapproval.[27] Finally, it is at least arguable that the Commission can withdraw a legislative proposal from consideration at any point before its final enactment.[28]

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 great importance to this paper.

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. <u>The Council</u>

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 is 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

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

[28] 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, in theory, it can also withdraw a proposal after this point in time, but 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." See Koen Lenaerts and Piet Van Nuffel, Constitutional Law of the European Union 580–81 (Robert Bray ed., 2d ed. 2005) (hereinafter "Lenaerts and Van Nuffel"). According to the Council, the Commission has no such power. To date, this debate has remained theoretical. Finally, there are also two kinds of withdrawals: a "technical" withdrawal, which can be likened to a "cleaning-up" process by the Commission once a year, consisting of withdrawing proposals that have become obsolete or those for which the discussion is blocked; and a "political" withdrawal, when the Commission disagrees with the amendments introduced by the legislator. See http://ec.europa.eu/governance/better_regulation/simplification_en.htm#_screening. This latter type of withdrawal is rare.

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 (fourteen Member States, or eighteen in the case of a non-Commission proposal), (2) a minimum of 72.3% of the possible votes (255 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.[29] 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 who holds the Presidency of the Council of 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 the European Council "shall provide the Union with the necessary impetus for its development and shall define the general political guidelines thereof."[30] 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

29 See Lenaerts and Van Nuffel, supra note 28, at 821.

30 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/ce321/ce32120061229en00010331.pdf.

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 785 members of the European Parliament (as of 2004) were directly elected by EU citizens from the Member States. The European Parliament is the only EU institution 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.[31] It now shares the power to legislate on matters covered by the co-decision procedure, the most often used legislative procedure,[32] with the Council, giving it effective veto power over that legislation. Where, much less frequently now, the consultative procedure is used, it is able to memorialize the Council, which must act unanimously, but has no formal voting right.

The EU government is not parliamentary in the sense that the members of the Commission are also members of Parliament, chosen from a dominant party or a majority coalition, participating in its acts, and individually responsible to it. While Parliament's members do associate themselves with like-minded others in a variety of groupings, there is no European party structure, as such, and each Parliamentarian campaigns in his or her own country within the framework of its own political institutions.[33] However, the Parliament does have the power to approve or reject the nomination of the slate of Commissioners as a whole, and to discharge the Commission as a whole (through a motion of censure under Article 201 TEC).

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[31] 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 of the TEC, both the Council and Parliament must agree to adopt legislation. For text of the article, see http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/ce321/ce32120061229en00010331.pdf.

[32] See infra pp. 23–24 for discussion of the co-decision procedure.

[33] 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, Members of the European Parliament ("MEPs") sit in the European Parliament according to political grouping, although national parties do tend to remain together within the larger European Parliament groupings. See Paul Craig and Gràinne De Búrca, EU Law: Text, Cases, and Materials 69 (2d ed. 1998).

### 4. The Court of Justice

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[34] provides an important element of check and balance, not unlike the operation of separation of powers ideas in the US. While EU institutions have broad rights of standing, however, with the exception of Commission enforcement actions against Member States concerning their implementation of EU legislation, they bring judicial review actions sparingly. On those rare occasions, those institutions are usually seeking to vindicate their own institutional interests in jurisdiction and authority. Thus, review generated by an EU institution is ill-suited to perform the functions, familiar to American lawyers, of holding EU institutions accountable, challenging the validity (under the EU or European Commission Treaties) of substantive provisions of EU legislation, or testing the legal or policy conformity of EU administrative actions with implementing legislation.

The standing of private parties to seek judicial review is generally limited to the review of "decisions," the products of adjudication, addressed to them.[35] Private parties do not ordinarily have standing directly to challenge binding European Commission legislative acts, whether regulations or directives, even to raise claims that these acts violate the Treaty, fundamental rights, or general principles of EU law.[36] Judicial review issues such as standing are dealt with in greater detail in the "Judicial Review" chapter of this study; 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[37] 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.[38]

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[34] See Art. 230 of the TEC, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/ce321/ce32120061229en00010331.pdf.

[35] Id. 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. See Paul Craig and Gràinne De Búrca, EU Law: text, Cases, and Materials 412 (3d ed. 2003) (hereinafter "Craig and De Búrca")

[36] Private parties harmed by failure of Member States properly to implement EU directives can also sue Member States for damages under the Francovich case. See Case C-6/90 Francovich v. Italy, 1991 E.C.R. I-5357. This amounts, in effect, to an indirect form of judicial review of Member State implementation of EU law which can sometimes raise the issue of validity surrounding institutional implementation of EU law. Francovich 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.

[37] 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.

[38] In *Bi-Metallic Inv. Co. v. State Bd. of Equalization*, 239 U.S. 441, 446 (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 . . . ." Article 230 of the TEC says "of direct and individual concern." A person is not individually concerned if

(continued…)

The situation has not been much changed by the Commission's recently adopted Better Regulation initiatives, discussed below,[39] 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 on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the "Aarhus Convention") in the environmental area, they are not legally binding, insofar as they apply to EU institutions.[40] 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 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. European Commission 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 represented by persons only indirectly accountable to their national constituencies. Member State influence may sometimes 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

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he is affected only as a member of a general class. See Case C-25/62 Plaumann v. Commission, 1963 E.C.R. 95 at 107. To be individually concerned, a person must be affected "by reason of certain attributes which are peculiar to them or by 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." Id. 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 infra n 378 and, especially, in the Environmental Sector report.

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" see Article III-365 of the draft, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/c_310/c_31020041216en00550185.pdf, the draft defined "regulatory act" to exclude legislative acts. See Article I-33 of the draft, *available at* http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/c_310/c_31020041216en00110040.pdf .

[39] See infra note 61.

[40] 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. See infra n. 378 Because it is so focused on environmental matters, the Aarhus Convention is discussed in considerable detail in the sectoral report on environmental matters attached to this report; it will not be much discussed here.

control) of regulatory policy to EU institutions.[41] Member State influence may be seen, as well, in EU legislation that imposes relatively general standards through directives or regulations, or instead enacts specific, 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, and it is possible for electors to send to the EU Parliament representatives from parties other than those they choose to control their 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 and Germanic Member State governments, reflecting the sentiments of their populations to push for more stringent environmental legislation within the Council. Yet the recent addition of Central and Eastern European countries to the EU may 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,[42] textual expressions of EU law can be ordered in a four-part hierarchy—EU and European Commission 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*.[43]

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[41] Cf. Prof. Dr. Ludwig Krämer, EC Environmental Law, Sixth Edition, Sweet & Maxwell (London, 2007) 57-59 (hereinafter "Krämer").

[42] See supra p.10–11.

[43] 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 EU may not go back. When used in the context of enlargement and accession of new Member States to the EU, the expression refers to the "whole corpus of Community law which new Member States have to take over," including:

- "The provisions of the Treaties;
- The decisions taken by the EU Institutions pursuant to the Treaties;
- The case law of the Court of Justice."

(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 of the TEC 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 Treaty does not provide whether to proceed by way of a regulation, directive or decision, but does occasionally prescribe a particular way of legislating.[44]

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 TEC, 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,[45]

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Lenaerts and Van Nuffel, supra note 28, at 51, 359.

[44] E.g., directive (Article 47 of the TEC); recommendation (Article 149.4 (education) and Article 151.5 (culture) of the TEC).

[45] A "regulation" is a Community legislative act described in the TEC as being "binding in its entirety and directly applicable in all Member States." Art. 249 of the TEC, available at http://eur-lex.europa.eu/ LexUriServ/site/en/oj/2006/ce321/ce32120061229en00010331.pdf. "[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." See Craig and De Búrca, supra note 35, at 190.

(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.[46] 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.[47]

(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, as a limitation of its discretion until changed), and are probably best classified as a form

46 See Craig and De Búrca, supra note 35, at 115; Lenhaerts and VanNuffel, supra note 28, at 780–81.

47 Krämer, supra note 41, at 60.

of "communication" or "opinion." 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 to 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,"[48] 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.[49] 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.[50]

## 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 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 basis) in the treaty. Each separate authorizing treaty section 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

[48] See ABA Project -- Outline of EU Environmental Rule-making, Environmental Sectoral Report (hereinafter Environmental Sector Report), at 23, available at http://www.abanet.org/adminlaw/eu/SectRptRule-environmental.pdf. Since 1993 they have been required to be adopted by a joint decision of the European Parliament and the Council, so that they are now arguably legally binding. Kramer, supra note 41, at 61.

[49] Krämer, supra note 41, at 62.

[50] Id.

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 of the TEC. This complex procedure takes place *after* a Commission proposal for legislation has been delivered to 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.[51]

Other issues, governed by Article 175 (or possibly Article 94) of the TEC, call for unanimous voting in the Council and must be subjected to the consultation procedure. Under this procedure, 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 of the TEC. 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 of the TEC.

### 8. EU Delegated Lawmaking

Implementing power, as the term is used in the EU, encompasses the power both to regulate (secondary to, and subject to, legislative measures adopted by Council and Parliament) and to apply rules to specific cases by individual decisions.[52]

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[51] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006 O.J. (L 396) 1.

[52] Koen Lenaerts and Piet Van Nuffel, CONSTITUTIONAL LAW OF THE EUROPEAN UNION ¶ 14-052 (Robert Bray ed., 2d ed. 2005) (hereinafter "Lenaerts and Van Nuffel").

Implementing by regulation, when done by either the Council or the Commission, can be accomplished by use of either directives or regulations. This can generate confusion. Since the Council has the power to implement by regulation, and in some situations the Commission has the power to amend legislation, one cannot always determine whether an action is legislative or *delegated* lawmaking solely on the basis of the actor. Generally, Council directives and regulations are legislative, and Commission directives and regulations are implementing, but this may not always be the case. Thus, one must carefully distinguish for each "directive" or "regulation" whether it was adopted by the Council or the Commission, and whether it is legislation (at the secondary level) or delegated lawmaking (at the tertiary level, what Americans would regard as implementing administrative regulation).

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, Professor Edward 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,[53] this is not simply the product of legislative incapacity to resolve all details, so that the creation of subsidiary standard-setters is a practical necessity; it also reflects politicians' 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 Congress creates, executive or independent, will actually set the standards; and consequently the agency's leadership (or the President), not 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 medical devices – and identify with some precision the "essential requirements" of that subject that others are required to honor in implementing legislation, standards or regulations. In these situations, they much more closely resemble EPA regulations bearing on state implementation plans under the Clean Air Act 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?

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[53] See, e.g., David Schoenbrod, Power Without Responsibility 102–05 (1993).

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 legislation that appears to regulate but is subtly drawn so that it does not, or legislation that is hard to implement and enforce, or legislation that *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.[54] 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 legislative acts on a numerical basis, in about the same proportion as regulations dominate statutes in the United States.[55]

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, as a practical matter the Commission has the bulk of the implementation authority. It carries out this authority in two principle 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 of the EC Treaty, 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

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[54] In correspondence, Francesca Bignami writes:

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

E-mail from Francesca Bignami (Dec. 21, 2004) (on file with author Strauss).

[55] See supra note 9.

> 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.[56]

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, legislative measures) and to apply rules to specific cases by individual decisions.[57] 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 aim of harmonizing 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."[58]

Comitology procedures require the Commission to collaborate with legislatively designated committees in exercising its delegated authority. The "comitology" process 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 ("July 2006 Council Decision").[59] 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.[60]

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[56] See supra note 23, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12002E202:EN:HTML.

[57] Lenaerts and Nuffel, supra note 28, at 612., Recall the possibly confusing nature of the "directives" and "regulations" language. See discussion supra p. 20.

[58] Id.

[59] See Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission**,** 1999 O.J. (L 184) 23; Council Decision of 17 July 2006 amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, available at http://209.85.165.104/search?q=cache:MGPgeBm01JoJ:www.stat.fi/eu2006/councildecision_7-2006.pdf+%222006/512/EC%22&hl=en&gl=us&ct=clnk&cd=1&client=firefox-a. 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. Lenaerts and Nuffel, supra note 28, at 614–15. They govern the exercise of delegated power by the Commission when invoked by legislation calling for such delegated action.

[60] See infra p. 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.[61] The Council has used this process in some twenty-five 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.[62] 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 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 has been used only in the employment and social sector and is more extensively discussed in that sectoral report.[63] This "soft law" approach is aimed at identifying goals for mutual pursuit by Member States rather than setting common obligations for Member State implementation.[64] 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.

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[61] In light of the "voluntary" nature of the standards, both as adopted at the EU and 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, infra p. 88, indicates the peculiar nature of their legally binding effect 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.

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

[63] See infra p. 42, 126.

[64] 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.

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,[65] lays 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 and regulations; and they must postpone the enactment of these proposals for twelve months if the Commission declares its intention to legislate on the matter at the EU level. One readily understands this as a measure to secure the common market against local technical standards and regulations that may have a discriminatory or trade-inhibiting 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; but of course the issue is not limited to the food context and New Approach undertakings, discussed at greater length below, are particularly likely to stem from it. DG Enterprise has established a Technical Regulation Information System (TRIS) website,[66] permitting anyone to enroll for e-mailed notification of drafts published in areas of interest, thereby assuring broad public opportunity to comment on proposed technical standards and regulations during the "stand-still" period provided for.[67]

[65] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, 1998 O.J. (L 204) 37. Experience under this Directive is extensively reported in a report from the Commission on the operation of the directive from 1999 to 2001. See Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee: the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final, available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2003/com2003_0200en01.pdf. A communication from the Commission to the European Parliament and the accompanying Commission staff working document, expressed 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." A Communication from the Commission to the European Parliament and the Council on the role of European standardisation in the framework of European policies and legislation, SEC (2004) 1251 at 2, 4, available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2004/com2004_0674en01.pdf. 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 50-67 (2005). And a very recent report strongly suggests that the future lies with increasing reliance on private/public law-generation. See Communication from the Commission to the Council and the European Parliament: Better Regulation for Growth and Jobs in the European Union, COM (2005) 97 final, available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0097en01.pdf.

[66] See http://europa.eu.int/comm/enterprise/tris/. The Commission's 2003 report discussing this website, See infra note 321, at 31, remarks that "it is essential for businesses to know about [notified drafts], on the one hand in order to adapt their products in advance … and on the other so that they can alert their governments and the Commission to any unjustified barriers." See also id. at 36, attributing "the reactions of the Commission and the Member States [as in] a large part due to the intervention of businesses"). No reference is made to the value of notice to others.

[67] The notices one author has thus far received in several months' enrolment have all concerned national standards and regulations, 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.

## 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 to behavior of private parties covered by the main EU legislative instruments in this area. Even so, much of the work of the 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.

The 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), 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,[68] 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.

### 2. The Environmental Sector

The environmental sector, under the Commission's DG Environment ("DG ENV") in Brussels, 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 eco-labeling and on the harmful

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

environmental impacts of chemicals and use of certain products like automobiles, as well as on the life cycle of use, reuse, recycling and disposal of various other products (e.g., electrical and electronic equipment, batteries, packaging, and products containing genetically modified organisms). Manufacturing plant regulation frequently requires implementation by plant specific permits, normally at the Member State level. Product regulation frequently requires implementation through the 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 European Chemicals Agency, beginning to be constructed in 2007 following the passage of the REACH regulation,[69] is to be a somewhat larger agency located in Helsinki, Finland; it will have a regulatory role in the implementation of REACH.

The EU's treaty authority to legislate in the environment, health and safety areas derives chiefly from two main EC Treaty provisions—Article 95 of the TEC (Internal Market) and Article 175 of the TEC (Environment)—although others may be invoked under the "integration" provisions of Article 6 TEC.[70] Article 95(1) and Articles 175(1) and (3) specify use of the "qualified majority voting" co-decision procedure for legislation on environmental issues. Where the consultation procedure must be used for environmental legislation, for example under Article 175(2) and Article 94 of the TEC, 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.

DG Environment acts chiefly through directives; it uses regulations much less often. This may reflect Member State wishes to retain freedom of action on issues touching the environment and natural resources; product-related environmental issues typically involve a more highly centralized EU response. DG Environment also often uses a range of other techniques, such as "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, DG ENV has developed community environmental action plans, , to "set out for a period of four-five years, the objectives, principles and priorities of Community action."[71] While technically "communications,"

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[69] Regulation (EC) No 1907/2006 of the European parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC and 2000/21/EC (O.J. L396/1, 30.12.2006) (hereinafter referred to as REACH).

[70] See supra note 23.

[71] Krämer, supra note 41, at 60-61.

these arguably are now legally binding on the Commission.[72] Under the current (Sixth) Environmental Action Plan, the Commission has also used sectoral action programs.

The Commission uses normal processes of legislation to develop environmental legislation for proposal to the Council and Parliament. In the environmental sector, these processes have recently been marked by extensive use of consultation procedures, impact assessment, and other new forms of "better lawmaking." The environmental sector has been a bellwether in the early development of these techniques in the EU.

DG ENV uses the comitology process extensively -- to elaborate environmental legislation, to set standards under it, or to update it over time ("adaptation to scientific and technical progress"). In the context of eco-labeling, for example, the regulation[73] contemplates the development of particular eco-labeling criteria through a regulatory committee, which in turn engages in broad-based consultation with representatives from industry and ENGOs, although such consultation is not required under the rules governing comitology. The Energy-Using Products Directive will utilize a similar approach for developing eco-design standards for specific product groups.[74]

More sparingly, DG-ENV has also used the "New Approach" to technical harmonization and the "Global Approach" to conformity assessment in the environmental sector.[75] 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. 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

[72] Id.

[73] Regulation No 1980/2000, 2000 O.J. (L 237) 1 (EC).

[74] European Parliament and Council Directive 2005/32/EC Establishing a Framework for the Setting of Ecodesign Requirements for Energy-using products and amending Council Directive 92/42/EEC and Directives 96/57/EC and 2000/55/EC of the European Parliament and Council, 2005 (O.J. 191) 29.

[75] See EC, Guide to the Implementation of Directives Based on the New Approach and the Global Approach, 2000, accessible through the Europa server at http://europa.eu.int.

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 Lawmaking and Regulation Initiatives.

The leading character of DG ENV practice is owing in many respects to the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the "Aarhus Convention"), which has required the Commission to introduce into the environmental sector more specific and detailed procedural provisions with regard to participation, right of access, and limited forms of judicial review rights than it has made available generally -- and to do so as to itself and other EU institutions as well as to Member States. The Aarhus Convention figures prominently in the sectoral report.

### 3. <u>The Financial Services Sector</u>

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 the DG of the 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.

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, in particular as a result of the recommendations of a committee of independent persons chaired by Baron Alexandre Lamfalussy (dubbed the committee of wise men), appointed 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 in 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[76] and meetings with interested parties. The publication of its initial

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

report in November 2000 itself called for a wide debate on its preliminary conclusions, and the committee released its final report in February 2001.[77]

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 suggesting the establishment of a European SEC with power to apply a single European rulebook, the committee focused on four levels within the regulatory process:

- Level 1: 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.
- Level 2: 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.
- Level 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.
- Level 4: There should be strengthened enforcement of EU rules to ensure greater consistency and timeliness in the implementation of directives.[78]

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. The committee recommended that before it draws up a legislative proposal, 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 apply to tertiary as well as secondary

[77] See infra note 78.

[78] Final Report of the Committee of Wise Men on the Regulation of European Securities Markets , (February 2001) at 4, 94, available at http://ec.europa.eu/internal_market/securities/docs/lamfalussy/wisemen/final-report-wise-men_en.pdf.

legislative acts. Finally, the committee recommended accelerating the timetable for adopting the FSAP.

The committee's recommendations received widespread support. Within a few weeks of the final report's release, the European Council resolved that the four level approach should be implemented, including the recommendations on transparency and consultation.[79] Three months later, the European Commission established the European Securities Committee (the "ESC")[80] and the advisory Committee of European Securities Regulators ("CESR").[81]

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 EC Treaty to give the European Parliament an equal role with the Council in controlling the Commission in carrying out its executive role.[82] This 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,[83] 2004 saw the creation of a parallel architecture of advisory and regulatory committees for the banking, insurance, and occupational pensions sectors.[84]

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[79] Resolution of the European Council of 23 March 2001 on More Effective Securities Market Regulation in the European Union, 2001 O.J. (C 138) 1, available at http://eur-lex.europa.eu/Result.do?arg0=more+effective+securities+market&arg1=2001&arg2=&titre=titre&chlang=en&RechType=RECH_mot&Submit=Search. 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 supra p. 16.

[80] Commission Decision of 6 June 2001 establishing the European Securities Committee 2001/528, 2001 O.J. (L 191) 45 (EC).

[81] Commission Decision of 6 June 2001 establishing the Committee of European Securities Regulators 2001/527, 2001 O.J. (L 191,) 43 (EC).

[82] See Press Release, Commission, Implementation of financial services legislation in the context of the Lamfalussy Report (Feb. 5, 2002), available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/02/44&format=HTML&aged=1&language=EN&guiLanguage=en, and Press Release, Commission, Financial markets: Commission welcomes Parliament's agreement on Lamfalussy proposals for reform, (Feb. 5, 2002), available at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/02/195&format=HTML&aged=1&language=EN&guiLanguage=en.

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

[84] See Commission Decision of 5 November 2003 establishing the Committee of European Banking Supervisors 2004/5/, 2004 O.J. (L 3) 28 (EC); Commission Decision of 5 November 2003 establishing the Committee of European Insurance and Occupational Pensions Supervisors 2004/6, 2004 O.J. (L 3) 30 (EC); Commission Decision of 5 November 2003 amending Decision 2001/527/EC establishing the Committee of European Securities Regulators 2004/7, 2004 O.J. (L 3) 32 (EC); Commission Decision of 5 November 2003 amending Decision 2001/528/EC establishing the European Securities Committee 2004/8, 2004 O.J. (L 3) 33 (EC); Commission Decision of 5 November 2003 establishing the European Insurance and Occupational Pensions Committee 2004/9, 2004 O.J. (L 3) 34 (EC); Commission Decision of 5 November 2003 establishing the European Banking Committee 2004/10, 2004 O.J. (L 3) 36 (EC); Directive 2005/1/EC of the European Parliament and of the Council of 9 March 2005

(continued…)

#### 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 hygiene, 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").[85]

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 Authority. 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 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,[86] 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

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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 2005/1, 2005 O.J. (L 79) 9.

[85] Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, 2002 O.J. (L 31) 1, 6, available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf.

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

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 concerning authorization of products (in the form of Directives or Regulations), 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. <u>The Telecommunications Sector</u>

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 twenty-five incumbent operators still maintain a very strong market position.

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[87] set the stage for a broad debate on the liberalization and harmonization of telecommunications in the EU, which 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

[87] Towards a dynamic European economy, Green Paper on the development of the common market for telecommunications services and equipment, COM (1987)_290 final (June 30, 1987).

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: the DG of Information Society and Media, the DG of Competition, and the DG of Internal Market. Most Council and Parliament Directives in the telecommunications sector are adopted under Article 95 of the EC Treaty (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."[88]

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 the 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.

### 6. <u>The Workplace Sector</u>

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").[89] The express role given to unions and employers in

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[88] Commission Decision 2002/622/EC of 26 July 2002 establishing a Radio Spectrum Policy Group, art. 5, 2002 O.J. (L 198) 49, 50.

[89] 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 include 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 also deals with legislation on free movement of workers, including pensions, coordination of social security schemes, equality between men and women, and anti-discrimination.

the legislative process give this EU sector a special character. These "Social Partners," as they are known in European usage, are given special rights as initiators, consultants, and implementers of the law regulating them.[90] Reflecting the relative balance of power in this sector between the Member States and the Community, the EU's usual practice is to use "directives" establishing "minimum requirements" for "gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States."[91] There are some exceptions, however.[92] The EU 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 of the EC Treaty 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) of the EC Treaty requires that the Social Partners be consulted on this point ("the possible direction of Community action").[93] Consultation may extend to 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 committees—none of which are comitology. Rather, all are consultative committees comprised of three or six members per Member State, and representing the national government, the trade unions and the employers' associations.

The DG EMPL appears to have complied with the Commission's 2002 Communication on Consultation in its actions since publication of that communication,[94]

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[90] Because of these official roles, Articles 138 and 139 of the TEC, supra note 23, 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 to reach agreement, as has happened on issues such as working time and portability of supplementary pension rights.

[91] Article 137 of the TEC. See supra note 23.

[92] For instance, in the area of social security, See 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, 2006 O.J. (L 114) 1. Regulation 1408/71 on the coordination of social security systems is the key EU law on social security.

[93] See supra note 23.

[94] Partners are broadly defined as those organizations representing employers and employees taking part in the Consultations, at whatever stage; the fact that other stakeholders take part in the consultation cannot impair the status of Social Partners

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.[95] For DG EMPL alone, there are some 170 groups and subgroups of experts and advisers.

Implementation is generally left to the Member States, rather than comitology at the EU level. Member States, in turn, may entrust implementation of normal legislation to the Social Partners, under Article 137(3) of the EC Treaty. The Member States nonetheless remain responsible for the result.

A "social dialogue" process under Article 139(2) of the EC Treaty, unique to the labor area, allows the Social Partners 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 point of mandatory consultation with them by the Commission, notify the Commission, under Article 138(4) of the EC Treaty, that they choose to use the procedure in Article 139(2) of the EC Treaty 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.[96] This agreement can then result in one of two legal instruments. When it is within the scope of Article 137 of the EC Treaty, and on the joint request of the Social Partners, it can be adopted into law as a Council and Parliament Directive[97] 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 in such a politically sensitive area. 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

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[95] Press Release, European Commission, Transparency and Better Regulation : Commission puts online a public register of expert groups (Aug. 11, 2005), available at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/1382&format=HTML&aged=1&language=EN&guiLanguage=en.

[96] 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). In addition, there is a "sectoral Social Dialogue" that works through structured committees. The various Social Partners taking part in the deliberations of those sectoral committees and referred to in the recent Commission publication "Recent developments in the European Sectoral Social Dialogue" (September 2006) all can lay claim to their representativeness. Currently, over 50 organizations are consulted. For further details on the representativeness of sectoral and non-sectoral Social Partners, see the sector summary on workplace regulation *infra* and note417 .

[97] While Article 139, ¶2 of the TEC speaks only of a "Council Decision," such decisions have so far been in the form of directives. See supra note 23.

competence only to define the minimum rules, an EES procedure for generating this guidance, and known 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 Legislative Proposals Are Developed

### 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[98] 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."[99] 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;[100] 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 sets 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,[101] the European Court may in some situations give directives an indirect legal effect in private litigation even 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."[102]

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98 See supra discussion on p. 26.

99 Art. 249 of the TEC. See supra note 23.

100 See International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78), available at http://www.imo.org/Conventions/contents.asp?doc_id=678&topic_id=258.

101 Arts. 226 and 228 of the TEC. See supra note 23.

102 Craig & De Búrca, supra note 45, at 227; See also id., "The Legal Effects of Directives," at 202; Sacha Prechal, Directives in EC Law (2d ed. 2005). For example, a directive will often set a time by which compliance is required; after the expiration of that time, private parties may be able to avail themselves of national non-compliance with the directive defensively in litigation with the non-complying nation or its agencies.

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 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 the 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[103] 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.[104]

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 political friends are brought into this process, or that for some particular initiative—health care

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

[104] 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.

reform or the creation of an energy policy—the White House will establish a more general consultative framework to shape its recommendations, none of this is commanded by law. There are no equivalents in statutory development for the internet notices and consultations that mark American rulemaking, now broadly exposed and engageable on the internet. Neither are there American *legislative* equivalents of the public analytic regimes American *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 EU and EC Treaties, in contrast, cause the European Union to operate within a regularized procedural framework for the development of legislative proposals. Under the treaties, 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.[105] This regime would have been continued by the draft European Constitution. The reason for giving the Commission this monopoly is to prevent the submission of legislative proposals inspired by nationalistic interests. That could undermine the Community. The Parliament and the Council have authority to amend and adopt or reject what the Commission proposes (although the Council cannot directly amend a Commission proposal contrary to the views of the Commission);[106] the precise extent of this authority generally depends on the type of legislation involved and the subject matter of the legislation. But the Commission's monopoly of the right to initiate legislation gives it broad discretion regarding the form, objective, content, and the timing of any proposal, and the authority to decide what preparatory work should be done before 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[107] give the Council and Parliament—and certainly the European Council of Heads of State—considerable influence over what will emerge

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[105] One of the exceptions to this rule arises in the workplace sector, where "**Social Partners**" (i.e., unions or employers) can themselves initiate a "social dialogue" process under Article 173 of the TEC, See supra note 23, which itself can result in the adoption of legislation. Other exceptions occur in the justice, liberty, and security areas.

[106] Article 250 of the TEC. See supra note 23.

[107] 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, supra note 35, 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) supra note 18. See generally the thoughtful analysis in Paul Craig, European Governance: Executive and Administrative Powers under the New Constitutional Settlement 3 Int'l J. of Const. L. 407 (2005).

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 regard for its credibility as an institution has led it 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.[108] The development of a legislative proposal is normally assigned to or undertaken by the Directorate General responsible for the subject matter.

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 Amsterdam Treaty, without explicitly creating private rights of enforcement, added a certain legal obligation to the Commission's political incentives.[109] 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;[110] 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:

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[108] 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.

[109] See Protocol 7 of the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts - Declarations adopted by the Conference - Declaration relating to the Protocol on the application of the principles of subsidiarity and proportionality , 1997 O.J. (C 340) 140; Interinstitutional Declaration on Democracy, Transparency, and Subsidiarity No. 10/93, Bull. of the E.C. 118.

[110] The principles allocating responsibility as between the EU and its Member States suggest, 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.

> — except in cases of particular urgency or confidentiality, consult widely before proposing legislation and, wherever appropriate, publish consultation documents;
>
> — justify the relevance of its proposals with regard to the principle of subsidiarity; whenever necessary, the explanatory memorandum accompanying a proposal will give details in this respect. The financing of Community action in whole or in part from the Community budget shall require an explanation;
>
> — take duly into account the need for any burden, whether financial or administrative, falling upon the Community, national governments, local authorities, economic operators and citizens, to be minimized and proportionate to the objective to be achieved . . . .[111]

The consequence is to create pre-proposal obligations of consultation and analysis in conjunction with legislative proposals, which 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[112] and in connection with the just adopted regulation of the chemical industry.[113] The responsible Directorate General for the subject matter will begin informal consultations with Member State experts and others as drafts are prepared.[114] 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.[115]

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[111] See Protocol 30 of the Treaty of Amsterdam, supra note 109. The excerpts quoted from the Protocol can be found at http://europa.eu.int/eur-lex/en/treaties/selected/livre345.html.

[112] See infra p. 65. .

[113] See infra p. 55 and note 156.

[114] 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.

[115] Nonetheless, one encounters suggestions that pre-proposal consultations 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 29-30 (2005) (hereinafter Get Connected), available at http://www.brc.gov.uk/ downloads/pdf/getconnected.pdf, 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

(continued…)

The Commission's work plan is published in numerous formats at its worksite,[116] including an Annual Policy Strategy (APS) and Work Program (WP).[117] Once the APS and WP are in place, each DG establishes an Annual Management Plan (AMP) translating the priority initiatives and the strategic objectives of the Commission into concrete operations. The AMP enables management to plan, follow up, and report on all the activities and resources of each DG.

Perhaps the most useful of these preliminary documents, because they contain contact information within the responsible DG, are the "roadmaps"[118] Commission guidance requires its directorates to develop and publish concerning the proposals adopted as elements of the Commission's APS and WP. 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).[119]

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> 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).

[116] See http://ec.europa.eu/atwork/programmes/index_en.htm.

[117] 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.,; Communication from the Commission on Impact Assessment Guidelines, SEC (2005) 791 (June 15, 2005), available at http://ec.europa.eu/governance/impact/docs/SEC2005_791_IA%20guidelines_annexes.pdf. The Annual Policy Strategy, a general policy document that sets out the priorities of the Commission for the following year, is generally adopted in February of the preceding year and takes the form of a non-binding communication from the Commission to the European Parliament and the Council. Although a Commission document, it takes account of feedback received from the Parliament and the Council, and can therefore be considered to be the result of an inter-institutional dialogue. The annual Commission Work 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.

[118] See SEC (2004) 1175.

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

> **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

(continued…)

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.

**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).

They must 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.[120] 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, thereby facilitating the preparation of their input as part of the mandatory consultation process."[121]

### C. Impact Assessment[122]

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.[123] For the Commission, unlike for the American Congress, this is a seriously considered obligation, underscored by formal commitments it made in 2002 and reinforced in 2005[124]—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,[125] including most impact assessments that have been completed.[126] 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

[120] The Roadmap must also indicate whether an Inter-Service Steering Group will be established. See supra note 117 at 7. When a DG does not plan to convene such a group, it must provide reasons.

[121] SEC (2005) 790, supra note 117, at 3.

[122] 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, e.g., Lawrence Kogan, Exporting Precaution: How Europe's Risk-free Regulatory Agenda Threatens American Free Enterprise (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,, supra note 117, at 3.

[123] 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. See Environmental Sectort Report, supra note 48, at 4.

[124] Communication from the Commission on Impact Assessment, COM (2002) 276 final (May 6, 2002), available at http://ec.europa.eu/governance/impact/docs/key_docs/com_2002_0276_en.pdf. 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.

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

[126] Id. Very few of the statements here are restricted from public access.

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."[127] These actions include "[a]ll regulatory proposals, White Papers, expenditure programs and negotiating guidelines for international agreements (with an economic, social or environmental impact)."[128] 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."[129]

### 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, [and] proposals following international obligations."[130] 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."[131] 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

[127] Communication from the Commission on Impact Assessment, supra note 124, at 5. Thus, the Commission retains unilateral control over which proposals are subject to an impact assessment ("IA"). This creates opportunities for strategic maneuvering; an independent, quantitative definition of "major initiatives," similar to that used in the U.S. under Executive Order 12866, would reduce this problem significantly. See Robert W. Hahn and Robert E. Litan, Counting Regulatory Benefits and Costs: Lessons for the US and Europe, 8 J. Int'l Econ. L., 473, 486–95, 501–07 (2005).

[128] Communication from the Commission on Impact Assessment Guidelines, supra note 117, at 6.

[129] Id.

[130] Id.

[131] Id. 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. at n. 7

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,[132] 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.[133] 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 of the EC Treaty), but also via the right to pass a motion of censure on the activities of the Commission (Article 201 of the EC Treaty).[134] One could imagine impact analysis undertakings contributing to, rather than detracting from, these controls.

### 2. The Impact Analysis process

The mechanics of this guidance is, like general adherence, a work in progress. Prior to the communications of 2002, practice was highly variable from directorate general to directorate general.[135] 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?

(5) How do the options compare?

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[132] Lenaerts and Van Nuffel, supra note 28, at 618; See also supra note 23.

[133] For a case successfully brought by a Member State, See Case C-393/01 France v. Commission, 2003 E.C.R. I-5405 at ¶¶40–60. For a case where the Court found the implementing power not to have been exceeded, See Case C-284/94 Italy v. Commission, 1997 E.C.R. I-3519 at ¶¶20–46; Lenaerts and Van Nuffel, supra note 28, at 618.)

[134] Lenaerts and Van Nuffel, supra note 28, at 394–96, 618.

[135] 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. See iinfra Section C, The Financial Services Sector, p. 93. A similar result seems to have obtained in the Food Safety sector. See infra Section D, The Food Safety Sector, p. 107.

(6) How could future monitoring and evaluation be organized?[136]

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,[137] elaborating on 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."[138] These minimum standards were themselves specified in Commission communications.[139] The consultations are conducted through the Commission's "your voice" website[140] As the guidance itself put, "[i]n order to be credible, impact assessment cannot be carried out behind 'closed doors.'"[141]

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," with no particular emphasis on quantification or cost-benefit balancing.[142] "[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."[143]

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[136] Communication from the Commission on Impact Assessment Guidelines, supra note 117, at pp. 2–3 (Table of Contents).

[137] http://ec.europa.eu/governance/impact/docs/ia_technical_guidelines_en.doc.

[138] http://ec.europa.eu/governance/impact/expert_en.htm.

[139] Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission, COM (2002) 704 final (Nov. 12, 2002), available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF; See *also* On the collection and use of expertise by the commission: principles and guidelines, COM (2002) 713 final (Nov. 12, 2002), available at http://ec.europa.eu/governance/docs/comm_expertise_en.pdf.

[140] Since not everyone has access to the internet they can, and probably should, also use the more traditional alternatives.

[141] Impact Assessment in the Commission, supra note 137, at 9. (emphasis added).

[142] 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, available at http://www.ucl.ac.uk/laws/clge/docs/Scott%20and%20Holder.pdf (the article has also been published as chapter 8 of Law and New Approaches to Governance in the EU and the US (Gráinne de Búrca and Joanne Scott, eds., 2006). Addressing the procedures requiring provision for public participation at the local level, they find democratizing tendencies supportive of new governance ideas—"a more inclusive, less technicist environmental assessment procedure, with public involvement in decision making expressed in the manner of an entitlement to participate, and to access to the courts to enforce its provisions." Id. at 16.

[143] Communication from the Commission on Impact Assessment, supra note 124, at 16.

American authors have criticized this aspect sharply, urging the EU to "specify[] that the primary objective of regulation is to maximize net benefits."[144] Commission adherents would reply that the Communities's 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 also lower "net benefits."

One hundred pages of supplementary guidelines and illustrative annexes published in the summer of 2005[145] offered a basis for "*rigorous and comprehensive analysis … easily accessible to the non-specialist*."[146] 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.[147] 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."[148] The Commission presents this approach as a "simple multi-criteria analysis," and carefully distinguishes it from the alternative approaches of "cost-benefit analysis, which compares positive and negative impacts expressed in the same units, normally in monetary terms, and cost-effectiveness analysis, which compares the costs of achieving a given objective."[149] In fact, the approach suggested by the Commission seems compatible with what is commonly considered cost-benefit analysis in the U.S.,

[144] Hahn and Litan, supra note 114, at 500; See generally Kogan, supra note 122.

[145] Communication from the Commission on Impact Assessment Guidelines, supra note 117.

[146] SEC (2005) 790, supra note 117, at 2–3.

[147] 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.

[148] Communication from the Commission on Impact Assessment Guidelines, supra note 117, at 39 (emphasis omitted).

[149] Id. n. 45.

where the term "formal" or "quantified" cost-benefit analysis is reserved for the fully quantified type of assessment.[150]

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 and edification of the external institutions to whom legislative proposals are eventually sent, the Council and the Parliament. Implementing decisions and measures—decisions subject to comitology, for example—do not appear in the Work Program, and are normally exempt from the procedure.

The contrast with American practice could hardly be more striking. In the United States, impact analysis is principally understood as a technique by which the President may discipline and influence executive action; although impact analysis is also promised in connection with legislative measures, it has yet to be seriously undertaken in that context. For the EU, impact assessment is much more a device for 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 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;[151] 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. One can learn when an Environmental Impact Statement (EIS) has been submitted for review by careful observation of OIRA's website. This posting occurs, however, only after the agency hopes to have completed its analysis—OIRA does not make the documents public or

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

[151] See 40 C.F.R. §§ 1501.7 (for the requirement) and 1508.22 (for substance to be included).

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.[152] 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),[153] one of the more controversial legislative actions proposed in recent years, which was finally adopted in December 2006 and will enter into force on the first of June 2007. The proposal, captured in six enormous files on the Commission's website,[154] runs about 1200 pages (mostly, to be sure, technical annexes the Commission characterized as not new[155]). 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 thirty-three pages.[156] 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;[157] the Final Regulatory Impact Analysis published on the agency website ran to 249 pages.[158] Under the Commission's 2005 guidance, an Impact Assessment Report should be no longer than thirty pages (excluding annexes), following a set format.[159]

### 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

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152 See Communication from the Commission on Impact Assessment Guidelines, supra note 117.

153 SEC (2003) 1171/3 (Oct. 29, 2003) concerning COM(2003) 644 final.

154 http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm.

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

156 An account of initial experience with Impact assessments appears in the Report on European Governance (2003-2004), SEC (2004) 1153 (Oct. 22, 2004), and in the Report from the Commission on Better Lawmaking, Annex 3 at 35, COM (2003) 770 final (Dec. 12, 2003). At least initial experiences with impact assessments suggested that they could be highly politicized. Bignami recalls that when she was reviewing the bargaining history of the Data Protection Directive, there was a tiff about the regulatory impact statement: the Commission produced one; the 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.

157 70 Fed. Reg. 18184–91 (Apr. 8, 2005). The statement of basis and purpose accompanying the rule ran 49 pages. Id. at 18136–84.

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

159 Communication from the Commission on Impact Assessment Guidelines, supra note 117 at 14.

carried this commitment through in a series of Communications[160] and websites committed in various ways to the process.[161] 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.[162] 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 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*.[163]

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[160] A consultation document: Towards a reinforced culture of consultation and dialogue-Proposal for general principles and minimum standards for consultation of interested parties by the Commission COM (2002) 277 final (June 5, 2002) led, after inputs collected at http://ec.europa.eu/comm/secretariat_general/sgc/consultation/histo_en.htm, to two final documents: Towards a reinforced culture of consultation and dialogue-General principles and minimum standards for consultation of interested parties by the Commission, COM (2002) 704 final (Nov. 12, 2002) and On the collection and use of expertise by the Commission: Principles and Guidelines, COM (2002) 713 final (Nov. 12, 2002).

[161] 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.

[162] 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.

[163] Towards a reinforced culture of consultation and dialogue-General principles and minimum standards for consultation of interested parties by the Commission, supra note 160, at 10 (emphasis added). The

(continued…)

Recall that these are principles developed and, as the contents of the Yourvoice website[164] suggest, most often honored in connection with the development of legislative drafts, not rulemaking.[165]

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[166]—the "principles and standards for consultation only apply to major policy initiatives."[167] "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 other standards, the Commission itself acknowledges that it needs to do better in providing

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guidance documents of June 2005, supra note 117, 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 is hard to obtain.

A September 2005 report of the UK's Better Regulation Task Force, Get Connected:, supra note 115, both expressed "surprise[] that the Commission does not publish information about how well individual Directorates General comply with the agreed standards for consultation," believing that information to be a part of the citizen's "right to know," and indicated agreement with the soft law approach. Id. at 3. The report states that "[t]he 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." Id. at 25. The report then, however, indicates that "[w]e 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." Id. at 8. .

[164] See supra note 161.

[165] Indeed, the Commission wholly exempts rulemaking—the comitology process and other forms of exercising 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 with nearly the same force to delegated lawmaking. It is precisely such an exercise of delegated powers that most needs to be checked and made accountable.

[166] Communication from the Commission on Impact Assessment Guidelines, supra note 117..

[167] Get Connected, supra note 115, at 22. Commission adherents may answer that the Get Connected report does not clarify that the Impact Analysis Guidelines, which are precisely applicable to all items on the Commission Legislative and Work Program (CLWP) (except for Green Papers and proposals for consultation with the Social Partners), provide for application of the minimum consultation standards.

> reasoned feedback to respondents and in demonstrating how it has taken account of their views.[168]

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

> The problem with a legally binding requirement to consult is that it creates an opportunity and perhaps even an incentive for those dissatisfied with a particular policy outcome to challenge proposals in court on the grounds of inadequate consultation. This would prolong the legislative process and introduce considerable uncertainty over when and how any legislation enters into force . . . The United States puts a legal duty on government agencies to consult to a minimum standard on significant proposals. There is no equivalent legal duty anywhere in the EU and we do not think it proportionate to introduce one.[169]

Europeans are also quick to point out that the legally minimum binding requirement for rulemaking notice in the U.S., while allowing "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.[170] Nor would one wish to suggest that members of

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[168] Id. at 24.

[169] Id. at 25.

[170] 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 (Aug. 28, 2004), 2004 O.J. (L 275) 17, available at http://ec.europa.eu/food/committees/advisory/index_en.htm, establishing an advisory group on the food chain and animal and plant health, particularly for this purpose. One might analogize a committee with this function to the groups formed under the American Negotiated Rulemaking Act (NRA), 5 U.S.C. §§ 561 et. seq. The formation process for special committees in the EU, if the documents at the above website 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 thirty-six organizations selected for this committee appear to have these characteristics, including NGOs as well as industrial representatives, unions, federations, organizations, etc. See 2005 O.J. (C 97) 2, available at, http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/c_097/c_09720050421en00020002.pdf, (and corrigenda available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/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,, no process external to Commission politics is provided for testing the Commission's success in

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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.[171] Yet the use of stakeholder consultations as a routine means of exploring public views across the whole of the European spectrum, and the manner in which they are treated both by respondents and by the Commission itself, offer a striking contrast to the American framework for legislative development.

Perhaps because these consultations are undertaken at an early stage in the development of proposals for legislation, before a proposal has assumed concrete form, they have a different character than what might be thought the American analog, the "notice" American agencies publish in connection with notice-and-comment rulemaking. In usual American practice, the draft is created first and the public consulted afterwards, and this has a number of consequences. First, it contributes to a certain rigidity and defensiveness on the agency side; the process of creating the draft is itself political—compromises need to be made within the drafting body and stances taken, that may then be difficult to depart from whatever input is received. 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,[172] one can find rulemakings with hundreds of thousands of participants, many of whom submit electronic forms with unverifiable identities.[173] 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

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achieving a representative body. This is no different from many other situations 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 civil society organizations organized at European level from which those consultative bodies tend to be drawn. See 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."

[171] See Lobbying and Its Regulations, infra p. 61.

[172] See supra pp. 14–16.

[173] The difficulties, and a resourceful empirical study, are thoughtfully developed in David Schlosberg, Stephen Zavetoski & 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 at http://erulemaking.ucsur.pitt.edu/doc/papers/SDEST_Western_05.pdf. See also the website of the erulemaking research group at the University of Pittsburgh, http://erulemaking.ucsur.pitt.edu/.

study.[174] 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 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."[175] 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,[176] require reporting of results and feedback; reports of closed consultations are made in a statistical way on the Yourvoice site.[177]

The REACH process, already encountered,[178] 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

[174] This is particularly the case for consultations undertaken through its approach to "interactive policymaking," See http://ec.europa.eu/yourvoice/ipm/index_en.htm, as for example a consultation closing in April 2007 on capturing and storing carbon dioxide underground, See http://ec.europa.eu/environment/climat/ccs/consult_en.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.

[175] Schlosberg, supra note 173, at 23–24. 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.

[176] See supra note 160.

[177] See, e.g., "Response statistics for 'The transparency of regulations and standards in the area of services,'" available at http://ec.europa.eu/yourvoice/results/services/index_en.htm; "Response; "Review of the New Approach," available at http://ec.europa.eu/yourvoice/results/4/index_en.htm.

[178] See supra note 51.

representatives from applicant countries . . . ."[179] There followed stakeholder conferences on the White Paper in April 2001[180] and May 2002,[181] and a November 2003 workshop[182] 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;[183] it attracted an unusual level of response—again, one thoroughly documented on its website: 968 participants in an Interactive Policymaking tool that was, in part, a structured questionnaire,[184] and a total of 6400 comments of varying length and detail.[185] 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[186]) 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.[187]

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.[188] Here, very clearly, is an effort at political, not intellectual or technical, influence. Yet the very structure of the declaration's site,[189] 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

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[179] Commission White Paper: Strategy for a future Chemicals Policy, at 6, COM (2001) 88 final (Feb. 27, 2001).

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

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

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

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

[184] See the analysis at http://ec.europa.eu/yourvoice/results/253/index_en.htm. Of the 968, only eighty-eight indicated that they had sent comments in addition to those presented through the interactive tool; about sixty percent of the filings were made on behalf of individuals; 587 filings came from Germany; no other country contributed more than eighty-one (by the UK). The comments attached to these filings are organized at http://ec.europa.eu/comm/environment/chemicals/pdf/ipm_stakeholder_reactions.pdf.

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

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

[187] Filling sixty-five computer screens in this case.

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

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

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 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.[190]

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.[191] 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

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

[191] Report on European Governance (2003-2004), Sec. 2.2 at 6, SEC (2004) 1153 (Sept. 22, 2004); See also Report from the Commission on Better Lawmaking, 2003, Annex 2 at 32–34, COM 2003 770 final (Dec. 12, 2003).

White Paper makes interpretation unnecessary. The Commission was explicit:

> Better consultation and involvement, a more open use of expert advice and a fresh approach to medium-term planning will allow it to consider much more critically the demands from the Institutions and from interest groups for new political initiatives. It [the Commission] will be better placed to act in the general European interest.

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

> Both the proposals in the White Paper and the prospect of further enlargement lead in one direction: a reinvigoration of the Community method. This means ensuring that the Commission proposes and executes policy; the Council and the European Parliament takes decisions; and national and regional actors are involved in the EU policy process.[192]

### E. Lobbying and Its Regulation

The Commission has adopted a relatively detailed code of conduct for itself[193]—albeit one that has not prevented the whiff of public scandal[194]—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,[195] 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.[196] 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:

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192 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, at 73–74, available at http://www.law.harvard.edu/students/orgs/hela/papers/BignamiCreatingRights1.pdf.

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

194 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, Intl. Herald Tribune, Apr. 19, 2005, at pp. 1, 3.

195 http://ec.europa.eu/civil_society/code/index_en.htm.

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

> 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.[197]

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.[198]

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.[199]

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.[200] Its website carries an extensive list of accredited lobbyists,[201] making evident that lobbying the Parliament is a major activity.[202] In late April, 2005, it

[197] Answer given by Mr Santer on behalf of the Commission, 1999 O.J. (C 348) 70, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/1999/c_348/c_34819991203en00700070.pdf.

[198] http://ec.europa.eu/civil_society/interest_groups/approche/annexe2_en.htm#c.

[199] Id. The reference is to a distinctly American scandal. See Philip Shenon, Inquiry on Lobbyist Casts a Shadow in Congress, .N.Y. Times, Apr. 11, 2005. Rules of the American Congress regulate with elusive precision the meals and other benefactions members are permitted to receive. But See supra note.194.

[200] Rules of Procedure of the European Parliament 9(2) and Annex IX, available at http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+RULES-EP+20040720+TOC+DOC+XML+V0//EN&language=EN.

[201] http://www.europarl.europa.eu/parliament/expert/lobbyAlphaOrderByOrg.do?language=EN.

[202] See Jerome Glass, Why throw a spammer in the lobbying machine, EuropeanVoice.com, Vol. 11, No. 15, Apr. 21, 2005, available at 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:

(continued…)

appeared that political pressure was growing to create more formal structures, including an independent watchdog organization, in the wake of embarrassing disclosures of vacations taken with friends who were also persons highly interested in the EU's affairs.[203] That appearances of conflict of interest might arise from genuine friendships in political circles is hardly unknown.[204]

### 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[205]) not open to public view. Once the impact assessment and consultation processes are concluded, the responsible Directorate General sends a draft text, along with an explanatory memorandum (in a standardized format governed by internal Commission rules) to all interested Directorates General and to the Legal Services, with a request for approval ("inter-service consultation").[206] There is then an attempt to reach a compromise text that satisfies all the DG's involved (who have their own agendas and are responding to lobbying), and the revised text then goes to the College of the Commissioners, where attempts are made at *cabinet* level to reach a political compromise on outstanding matters if necessary.[207] Where this is successful, the Commissioners approve through a written procedure; where this is unsuccessful or

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> 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. See 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.

[203] Id.; Bennhold, supra note 194.

[204] E.g., Justice Antonin Scalia's opinion refusing to recuse himself in a case involving Vice President Cheney, from whom he had accepted the gift of air transportation when they were both invited duck hunting in a distant venue. For a similar, if understated, view, See Get Connected, supra note 115, at 43.

[205] 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.

[206] Id. at 76.

[207] Id.

"where the text is of political significance," the Commissioners discuss the matter orally and can adopt a text as the Commission proposal by majority vote.[208]

Note here a characteristic that 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,[209] the structure of the EU may be such as to make its actors—and perhaps especially the Commission—sensitive to the expectations of its more demanding members. The incentives for Europe's bureaucrats are quite different to those American agency staffs might experience—not only that consensus should be achieved on the particular matter they are proposing, but also that Member States and their populations on an ongoing basis perceive EU processes as attentive to their concerns:

> Notwithstanding that procedural rights emerged in different historical periods and that they were informed by different cultural traditions and supranational interests, they display one striking common characteristic: they afford citizens a greater set of entitlements against European government than in their place of origin. What 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

[208] Art. 219 TEC.

[209] Bignami, supra note 192.

> input from the European Parliament. In no way can the Commission be said to enjoy an electoral mandate when it undertakes its mission.[210]

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.[211]

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.[212] These require it, in the first instance, to maintain a level of in-house expertise enabling it to act as an 'intelligent customer' when organizing and acting on external expertise. The use of internal resources is preferred. If outside help is to be sought, the scope and objective of the experts' involvement, and the questions they will address, are to be set out clearly. Both mainstream and divergent views are to be considered, and departments are to maintain a record of the process including the terms of reference and the main contributions of different experts or groups of experts. The experts themselves, and also the Commission, are made responsible for monitoring any possible conflict-of-interest issues that could jeopardize the quality of the advice. And transparency is also a central consideration: experts must highlight the evidence (*e.g.* sources, references) upon which they base their advice, as well as any persisting uncertainty and divergent views; within the framework of freedom of information legislation, the principal documents associated with the use of expertise—in particular the advice itself—are to be made available to the public as quickly as possible;[213] 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

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[210] Id. at 88–89.

[211] See also Francesca Bignami, The Challenge of Cooperative Regulatory Relations After Enlargement, Duke Law School Research Paper No. 55, Sept. 2004, at 33–34, available at http://ssrn.com/abstract=527552.

[212] Communication from the Commission On the Collection and Use of Expertise by the Commission: Principles and Guidelines, COM (2002) 713 (Dec. 11, 2002).

[213] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

subject principally to political enforcement—by the Council or Parliament rather than the courts. Article 253 of the The EC Treaty 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."[214] This treaty requirement is normally thought to be satisfied by the recitation of "whereas" clauses at the beginning of EC legislation.[215] 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, as American courts would require. The proposed European Constitution carried this Treaty provision forward in Articles I-38(2) and II-101, ¶ 2(c) which included in the "Right to Good Administration" "the obligation of the administration to give reasons for its decisions."[216]

In addition, the Commission accompanies its legislative proposals with explanatory memoranda setting out the results of consultations, which are available in all languages. As characterized in the recent UK Better Regulation Task Force report,[217] 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.[218] They are not the kind of explanation American courts have long demanded as an adequate reasoned explanation of a rulemaking decision.[219]

### H. Final Action

Once the Commission has agreed on a proposal for a regulation or a directive, it is published in the Official Journal of the European Communities, Part C (recently, the Commission has been putting the text on the internet and only referring to it in a note in the Official Journal). An explanatory memorandum, which is not an integral part of the proposal, is made available to the public in the form of an official COM-document.[220] The Commission's proposal is then transmitted to the Council, which passes it on to the European Parliament, the Economic and Social Committee and the Committee of the

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[214] See supra note 23.

[215] Krämer, supra note 41 at 55.

[216] See supra note 18. Note, however, that draft Article II-101, ¶ 2(c) is in the context of provisions relating to an "individual measure" that would "adversely" affect an individual.

[217] Get Connected, supra note 115, at 39.

[218] Id. The Get Connected Report refers to the Commission's 2004 Better Lawmaking Report. The Commission's 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://ec.europa.eu/governance/impact/docs/key_docs/com_2006_0289_en.pdf.

[219] See, *e.g.*, *Indep. U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847 (D.C. Cir. 1987), cert. denied, 484 U.S. 819 (1987).

[220] Id.

Regions (the latter two of which normally must render opinions). The formal legislative process, with which this report does not deal, then commences.

## IV. Creating Implementing Measures

We turn now to what we have described as the tertiary level of legislation, "rulemaking" in the American context. Legislative measures frequently establish general, rather than detailed, requirements. Their doing so is encouraged by a contemporary preference that requirements imposed on the private economy be formulated as standards to be met, rather than as detailed, prescriptive rules to be obeyed—the logic being that private actors will be best able to find the most efficient means of compliance. The legislative use of "standards," of course, naturally invites 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. Those who must satisfy the standards and those who are to measure adherence to them will both be eager for authoritative advice about measures that will be accepted as meeting them. The more general the legislative measures are, the more such detail will be subsequently sought and, likely, supplied. The level of detail in legislation is, as noted above,[221] 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.

EU 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—adopted 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, in considering the means by which law is shaped in Europe, one must always take into account that national implementation is a major element; the procedures and expectations operating at the Member State level inevitably shape the European experience. Even when the use of the "directive" format permits Member States freedom of approach, the EU may find it necessary to adjust the dimensions of that freedom from time to time as experience develops. It will be for the EU to reach judgments over time as to what approaches do or do not honor the directives' essential requirements., creating one important context for tertiary legislative measures. Similarly, EU "regulations" creating law directly applicable to private individuals may 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. These will be discussed below as comitology, "new approach" standards, and other forms of reference to external

[221] See supra pp. 24–25.

international or pan-European bodies. We first consider, however, the more general question of "delegation."

### A. Delegation Doctrine In the EU

In the EU as in the United States, "legislative power," as such, cannot be delegated, but nonetheless executive branch actors *may* validly be invested with the authority to create texts having the force of law. This paradoxical statement creates difficulties of theory in both places. In American theory, one finds some movement towards an understanding that rulemaking is an exercise of executive, not legislative authority, and that the questions about it are whether executive authority has been adequately constrained.[222] In Europe, resolution is achieved by characterizing the conferral of tertiary lawmaking powers 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 provides standards sufficient to permit assessment whether the regulator has acted with legality, the EC treaties and EU case law insist that Commission implementation powers be demonstrably subsidiary to, and measurable against, legislatively created norms.

The draft European Union Constitution, after clarifying the nomenclature,[223] would have stated these constraints in some detail. Article I-33 would have 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," 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").[224] Article I-35 would then explicitly have stated 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."[225] It would also have imposed boundaries for 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."[226] The draft Constitution went on to require in Article I-36 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:

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[222] Whitman v. American Trucking Assns, 531 U.S. 547 (2001).

[223] See supra note 18.

[224] Id. (emphasis added).

[225] Id.

[226] Id.

(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.[227]

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*."[228] Finally, Article I-37 provided for a second type of "delegated" European regulation, European "implementing regulations."[229] Like Article I-35, it would have required that "European laws lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers."[230]

## B. The Delegated Powers of the Commission

The constitutional treaty having failed of adoption, these matters remain governed by the pre-existing treaties. Article 202 of the

The EC Treaty 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."[231] 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." 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 of the EC Treaty and through the so-called standards process.[232] The Council has provided for

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227 Id.

228 Id. (emphasis added).

229 Id. (emphasis added). 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 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).

230 Id.

231 See supra note 23. (emphasis added), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12002E202:EN:HTML.

232 Implementation by Member States, chiefly of directives, is beyond the scope of this Report.

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,[233] 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 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.[234]

Thus, as Bignami also reports,[235] the pattern of consultation in the EU is quite the reverse of that in the United States. The very recent revisions in comitology practice, discussed in the following pages, while enhancing the role of Parliament, do not appear to have addressed the UK Task Force concerns. Even the draft Constitution, which essentially would have made Parliament a political equal to the Council in supervising

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233 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/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. This list includes 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/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/internal_market/securities/esc/index_en.htm. See *also* Yannis V. Avgerinos, Essential and Non-essential Measures: Delegation of Powers in EU Securities Regulation, 8 Eur. L. J. 269, 270 (2002), available at http://www.blackwellsynergy.com/servlet/useragent?func=synergy&synergyAction=showTOC&journalCode=eulj&volume=8&issue=2&year=2002&part=null; See infra the discussion of the European Aviation Safety Agency p. 79.

234 Get Connected, supra note 115, at 19.

235 Bignami, supra note 192, at 86:

> 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.

Commission proposals for implementing measures, specified no greater degree of public participation in the adoption of those measures than currently exists.[236]

### C. Comitology

For the Commission itself, implementing measures are most frequently the product of a process known as "comitology," 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.[237] As required by Article 202 of the EC Treaty, this process is given some structure by the so-called comitology decisions.[238] These decisions are designed to allow Member State and, increasingly, Parliamentary control over the process, but do not yet involve substantive public notice or participation. Essentially, they commit Commission proposals for implementing measures to the active oversight of committees of experts made up of Member State representatives, normally national bureaucrats from the relevant ministry, with the results to be reported to Council and Parliament, before they can become effective.[239] These committees, which are chaired by non-voting Commission bureaucrats, participate in a complicated and relatively secretive legislative process involving first themselves and the Commission, and then the Council and the Parliament. In effect, the Member States have forced the Commission to exercise its "delegated" implementing powers only under careful supervision by "representatives" of Member State governments acting through their relevant Ministries. That, in general, comitology committees must approve drafts of implementing legislation before it can move forward suggests that they exercise real legislative powers, on which the Commission is dependent.[240] We discuss, first, the practice of comitology itself and then the increasingly complex supervision relations with the Council and Parliament.

[236] 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, 3 Intl. j. Const. L., 407, 430 (2005) and Paul Craig, The Hierarchy of Norms, *in* European Union Law for the Twenty-First Century: Rethinking the New Legal Order 75–94, (T. Tridimas & P. Nebbia, eds., 2004). .

[237] http://ec.europa.eu/civil_society/apgen_en.htm.

[238] See Council Decisions 87/373/EEC, available at http://www.dst.dk/pukora/epub/upload/2285/6_5_en.pdf, and 1999/468/EC, available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_184/l_18419990717en00230026.pdf, as further modified by Council Regulations 806(2003) (qualified majority) and 807(2003) (unanimity), and by Council Decision 2006/512/EC, available at http://www.stat.fi/eu2006/councildecision_7-2006.pdf. The text seeks only to describe the current state of practice, to the extent that can be known. For a historical account of its development, See, e.g., Georg Haibach, The History of Comitology, in Delegated Legislation and the Role of Committees in the EC, supra note 9, at. 185–215.

[239] See Lenaerts and Van Nuffel, supra note 28, ¶¶1 4-054, 14-061, at 614–16, 619. See Appendix to this Report for a list of committees, organized by the supervising DG.

[240] One commentator argues that the Commission succeeds in dominating the process notwithstanding the existence of the committees. Daniel Gueguen, Caroline Rosberg, Comitology And Other EU Committees and Expert Groups: The Hidden Power of the EU: Finally A Clear Explanation, Europe Information Service (European Public Affairs Series)(February 2004) (compare p. 61 with p. 65)("The Hidden Power").

American readers should be aware that comitology committees are unique institutions, which should not be confused with other "committees" (frequently with similar names) consulted by the Commission during the drafting phase of legislation headed for the Council and Parliament.[241] Comitology is a subject of both fascination and mystery in Europe. Highly fluid and variable, over subject matter and over time, it combines elements of politics and expertise in ways that all the principal actors of the EU itself – Commission, Council, Parliament, Member States – appear to find reassuring, but that are largely opaque to the outside world. Comitology committees have a real influence on the shape of implementing legislation and as a result play a key role in the decision-making process. "Many of the executive legal acts adopted by the Commission are 'routine' measures, but decisions of enormous political importance are also made in these Committees, for example the embargo against British beef in connection with the BSE crisis in 1996".[242]

In a lengthy workshop on an earlier draft of this report, held in Brussels in February 2007, knowledgeable participants from various Commission DG's found "comitology" the aspect of the draft they were most eager to address, to the extent that one could hardly provoke contributions on other subjects. These paragraphs have been significantly revised in light of those comments. A principal impression they conveyed was that the increasing engagement of Parliament, the fact that regulatory implementing measures under legislation adopted by the co-decision method could no longer become final until it had been consulted, was arming more reliance on the possibility of developing implementing measures using comitology -- that secondary legislation was deciding less and leaving more to resolution by tertiary legislation. For Parliament, if not for outside participants, the draft implementing measure emerging from the comitology committee may be experienced much as a draft regulation in American practice. And yet the reported reality, also, is that the volume of comitology drafts reported to Parliament may be so high as to defeat effective oversight.[243] Our commentators were emphatic that this report ought not portray comitology as a mysterious sinkhole, that the experience from the inside was one of regularity and wisdom that contributed a great dealt to the success of the EU enterprise. Nonetheless, access to its workings remains

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[241] Advisory committees, scientific committees and expert groups assist the Commission before it proposes legislation to the Council and the Parliament, by providing the Commission with non-binding opinions or advice on future legislative proposals, and as a result are influential even before the Commission considers drafting a proposal (e.g. they may issue studies laying the basis for a future Commission proposal). These are not, however, the same committees involved in the Comitology process, notwithstanding much confusion and apparent overlap in names.

[242]. The Hidden Power, 53.

[243] "Comitology: we have bitten off more than we can chew, say MEPs," EU Food Law, May 11, 2007, p. 32 ("Although considered a breakthrough for the European Parliament at the time it was agreed, in practice the [June 2006] agreement means MEPs are inundated by emails from the Commission … 'Who ever reads those comitology emails from the Commission,' asked [one MEP,] with the majority of MEPs admitting they did not." The story reported unanimous adoption, without debate, of draft reports on Water Policy, End of Life vehicles, Waste electrical and electronic equipment, hazmats in electrical and electronic equipment , and waste batteries and accumulators.)

difficult even for the European public (who are in a position to rely on their political representatives), much less for American commentators.

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.[244] Some Directorates (Employment, for example) employ comitology hardly at all, whereas others (Agriculture, Enterprise, SANCO) report hundreds, even thousands, of annual events. The Commission Secretariat maintains a Register of Comitology covering comitology documents from January first, 2003.[245] Here one can occasionally find notice of agendas in advance of meetings,[246] 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.[247] 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.[248] Comitology procedures have changed considerably over the years, particularly as Parliament's place has strengthened, and for this reason early studies[249] are of uncertain continued relevance.

The types of Article 202 "implementing" measures, the enactment of which may be delegated to the Commission," has been characterized by one source as follows:

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[244] See Appendix to this Report, which lists the number of committees each DG supervises.

[245] http://ec.europa.eu/transparency/regcomitology/registre.cfm?CL=en.

[246] 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.

[247] It may be possible to request them, See the report on transparency in Get Connected, supra note 115, 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. The Report from the Commission on the working of committees during 2004, 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. Id. at 4. (emphasis added)

[248] 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 not be 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, available at http://www.unicri.it/wwd/trafficking/legal_framework/docs/2003_209_ec.pdf.

[249] E.g., the collection of essays in Christian Joerges & Ellen Vos, EU Committees: Social Regulation, Law and Politics (1999).

- "Legislation of an abstract and/or general type, such as the adoption of directives intended to harmonize technical or economic developments, the preparation or the revision of appendices in order to make the original more effective, etc."

- "Executive activities on a concrete and individual level, such as imposing marketing restrictions on certain products in certain areas and on all measures in connection with the administration/management of a common market organization"

- "Advisory work, such as the evaluation of any aspects of the common foodstuffs laws, which might affect public health or the assistance, provided by experts from the Commission, with all questions relating to technical harmonization and standards."[250]

### 1. The Comitology Process

In implementing Article 202's requirement that "procedures" used in the exercise of its delegated implementing powers "be consonant with principles and rules to be laid down in advance by the Council….", the Council has adopted a series of generic decisions, the Comitology Decisions, spelling out the types of procedures to be used, when they are to be used, the powers of the committees using each type, and the procedures that must be used with regard to legislation passing through each type of procedure and committee. Comitology was originally provided for in 1987[251]; a second Comitology Decision was adopted in 1999,[252] and this decision was amended in important ways by a Council Decision of 17 July 2006.[253] It is this amended Decision that we refer to as, simply, the Comitology Decision.

The basic framework for comitology begins with legislative specification of one of five different comitology regimes, each using a committee constituted as described above (Member State representatives qualified in the particular field, chaired by a non-voting representative of the Commission), but following a distinct procedural regime. The Commission presents a proposed draft of its intended action (for our purposes, an

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[250] The Hidden Power, p. 50.

[251] Council Decision 87/373/EEC (1987) O.J. L197/33.

[252] Council Decision 1999/468/EC (1999) O.J. L814/23. Once the Comitology Decision was revised in 1999, the Commission began case-by-case revision of existing legislation to "align" it to the Comitology Decision. In 2003, the Council and Parliament enacted four regulations that aligned more than 300 pieces of underlying legislation to the Comitology Decision -- one regulation for the pieces of legislation for which each of the main types of legislative procedure were applicable. Regulation EC. No. 1882/2003, for example, O. J. (L 284) 1, 31 October 2003, governs the co-decision procedure.

[253] Council Decision of 17 July 2006 amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission (2006/512/EC).

implementing measure) to the committee which, after deliberation, delivers an opinion on the proposal.

- *Advisory Committee*

If a committee is denominated "advisory," its actions are simply advisory in character. Nonetheless, the Comitology Decision requires that an advisory opinion be recorded in the committee's minutes, and gives each Member State the opportunity to have its position recorded there as well.[254] Further, it requires that the Commission "shall take the utmost account of the opinion," and that it "shall inform the committee of the manner in which the opinion has been taken into account."[255] Advisory committee decisions are normally taken by consensus, but Article 3(2) of the Comitology Decision allows decisions to be made "if necessary by taking a vote," without spelling out what type of voting is to apply.

In short, according to one source, an advisory committee opinion can potentially influence the outcome considerably.[256] Generally, this procedure is used when the matters under discussion are not very sensitive politically. While the Commission is expected as a political matter to respond to negative advice in a final instrument taking action, as a legal matter its resolution may take effect without further formalities.

- *Management Committee*

The management procedure is applied by management committees to the adoption of "management measures such as those relating to the application of the common agricultural and common fisheries policies, or to the implementation of programmes with substantial budgetary implications."[257] Because a management committee is normally involved in management of markets and community programs, it will usually be dealing with a proposed decision, not a proposed directive or regulation. In the agricultural field, however, the use of management committees is not limited to administrative adjudication, and can extend to implementing rules to be adopted through the management procedure.[258]

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[254] The Comitology Decision, Article 3(3).

[255] Id., Article. 3(4).

[256] The Hidden Power, p. 29.

[257] Comitology Decision, Article 2(a).

[258] See, e.g., Article 40 of Council Regulation (EC) No 3 18/2006 of 20 February 2006 on the common organization of the markets in the sugar sector (OJ L 58, 28.2.2006 (listing such rules); For examples of such rules set by regulation, *see* Commission Regulation (EC) No 95 112006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 31 812006 as regards trade with third countries in the sugar sector (OJ L 178, 1.7.2006, p. 24); Commission Regulation (EC) No 95212006 of 29 June 2006 laying down detailed rules for the application of Council Regulation (EC) No 31812006 as regards the management of the Community market in sugar and the quota system (OJ L 178,-1.7.2006, P. 391).

The opinion of a management committee is not formally binding on the Commission, although as may be evident it can have considerable political force. The committee may issue a positive opinion, or no opinion (which will have the effect of having issued a positive opinion, in the sense that the Commission is free to go ahead, if it chooses to do so). It may also issue a negative opinion. In any case, once a management committee issues an opinion, the Commission "shall" adopt a measure (which can apparently include a measure that has been changed to accommodate the committee's opinion), which "shall" take effect immediately. In the case, however, that the measure adopted by the Commission is "not in accordance with the opinion of the committee," the measure adopted by the Commission must be communicated to the Council "forthwith." The Commission "may," but need not, defer application of its measure for a period of time laid down in the legislation being implemented, but not to exceed three months, during which time the Council may by a qualified majority "take a different decision." If the Council does not amend the Commission measure within the allowed time, it enters into force.[259]

- *Regulatory Committee*

If a committee is denominated "regulatory," control may rest in the Council alone or, as is more likely given the 2006 amendments,[260] in the Council *and* Parliament. As the most demanding of the ordinary forms of comitology, "regulatory" comitology is the principal concern of this discussion. EU legislation normally requires that the Commission collaborate with a relevant regulatory committee when the Commission implements the legislation in question through a Commission regulation, directive or decision.[261]

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[259] In practice, management committees do not often deliver negative opinions. Cf., The Hidden Power, p. 61. This may, perhaps, result from the Commission negotiating with the Committee to avoid such opinions.

[260] Council Decision on 17 July 2006 amending Council Decision 1999/468/EC, supra note 59; See *also* Thomas Christiansen & Beatrice Vaccari, The 2006 Reform of Comitology: Problem Solver or Dispute Postponed?, 3 EIPASCOPE 9 (2006), available at http://www.eipa.eu/files/repository/eipascope/Scop06_3_2.pdf. 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." See Christiansen & Vaccari, at 9–12.

[261] Although there are no clear and certain rules, a number of guidelines (and exceptions to them) are used in choosing the form of the action. The first is the content and purpose of the act. A Comitology act amending a basic act will usually be of the same type/format (on the basis of the so-called "form parallelism" principle). A Comitology act implementing legislation, but standing alone and independent of the basic act, may be either a regulation or a directive, since the standard Comitology provisions in a basic act usually do not specify the format/type of the implementing measures. In this case, factors like whether the implementing measures should apply directly to those regulated, or should be addressed primarily to Member States for further implementation may be dispositive. A directive could, for example, be implemented by a Regulation. E.g.*,* Commission Regulation of 6 April 2001 laying down the active substances of plant protection products to be assessed in the second stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC and revising the list of Member States designated as rapporteurs for those substances. Decisions are normally reserved for administrative adjudication. That said, Decisions may be used to adopt provisions which are neither adjudication nor generally applicable rules. See, e.g., Commission Decision 20001729/EC of 10 November 2000 on a standard contract covering the terms of use of the Community Eco-label (OJ L 293, 22.11.2000, p. 20); Commission Decision of 7 September 2001 on guidance for the implementation of Regulation (EC) No 76112001 of the European Parliament and of the Council

(continued…)

As of 2006, regulatory committees exist in two forms. The amended Comitology Decision now specifies that the pre-2006 "regulatory procedure" (found in Article 5) is to be used for "[M]easures of general scope designed to *apply essential* provisions of basic instruments, including measures concerning the protection of the health or safety of humans, animals or plants." A new "regulatory procedure with scrutiny" (found in new Article 5a) must be used where the basic legislation was adopted by co-decision and "provides for the adoption of measures of general scope designed to *amend non-essential* elements…by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements." (Emphasis added)

(1) Routine treatment of a draft measure that is *not* "quasi legislative"

Under the pre-2006 procedures, with regard to a draft measure that is not considered "quasi legislative," the Commission's proposal will come into force routinely *either* 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.) The Commission proposal will also take effect, even if not approved in committee, if the Council does not take definitive action on it within three months. Should a qualified majority of the Council *oppose* the Commission's draft within that time, the Commission must submit a revised proposal (or seek legislative action) to effect an implementing measure of this type.

If, as is now usual, the underlying legislative act was adopted by co-decision, drafts are also transmitted to Parliament. Parliament then has one month in which it may adopt a resolution informing the Commission of its view that the draft exceeds the Commission's delegated powers, is not compatible with the aim or the content of the basic instrument, or does not respect the principles of subsidiary or proportionality. Should this happen, the Commission is obliged to reexamine its draft and to report, with an explanation, the action it intends to take. Whenever the Commission substantially modifies its action from its earlier draft, the result is resubmission to this parliamentary review.

(2) *Regulatory procedure with scrutiny, for "quasi legislative" drafts.*

If the draft measure in question is considered "quasi legislative," the July 2006 amendments to the comitology decision have outlined a new "regulatory procedure with scrutiny." "Quasi legislative" measures are those "measures [implementing co-decided basic acts] of general scope designed to amend non-essential elements [of the basic acts] *inter alia* by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements."[262] The "non-essential" language, note, is *not* to distinguish these "quasi legislative" implementing measures from another type

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allowing voluntary participation by organizations in a Community eco-management and audit scheme (EMAS) (OJ L 247, 17.9.2001, p. 24).

[262] Council Decision on 17 July 2006 amending Council Decision 1999/468/EC, supra note 59, at 1.

of "quasi legislative" measure that deletes or adds "essential" elements; rather, it expresses the formal jurisdictional limitation on implementing measures, that tertiary legislation is competent to deal *only* with "non-essential elements." Changing essential elements would require secondary legislation – i.e., co-decision by the Council and Parliament on the basis of a Commission draft. As suggested above, however, the very fact of this more intensive form of comitology may in practice be permitting more to be accomplished by its means.[263]

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. Thus, even if the relevant committee agrees with the Commission's proposal, new Article 5a under the July 2006 amendments requires that both the Parliament and the Council be given copies of the draft measure, and empowers each to disapprove the measure (the Council by a qualified majority, and the Parliament by an absolute majority). Should either legislative authority disapprove the draft, the Commission must either amend its proposal or seek legislation. Not only does "regulatory procedure with scrutiny" give Parliament the right to disapprove; 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 subsidiarity or proportionality."

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. When a qualified majority of the Council has agreed with the comitology committee's opposition to the Commission's draft within this two-month window, that ends matters; the Commission must now amend it or seek legislation, and its disapproved draft is never submitted to the Parliament.

- *Safeguard committee*

The final comitology regime, "safeguard," is a rarely invoked amalgam. The provision covering the safeguard procedure in the Comitology Decision does not even contain the normal provisions for the organization of a committee that it does for the other committee types. Safeguard committees have been used mainly to protect the interests of the EU or of Member States in taking defensive measures in international trade cases. For example, a safeguard committee was used in the US-EU steel crisis, after the US introduced import restrictions on certain steel products that could have harmed the EU market.[264]. The committee's function was to consult with the Commission, and to approve a proposed Commission regulation to establish provisional safeguard measures against the US prior to its implementation.

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[263] See p. 74 above.

[264] The Hidden Power, p. 53.

- *Common provisions*

The Comitology Decision sets out certain provisions applicable to the regulatory, management, and advisory committees:

- Each comitology committee is to be composed of representatives of Member States, and is chaired by a non-voting representative of the Commission. (Articles. 3, 4, and 5, ¶ ¶ (1) respectively).
- The legislative process for implementing measures can only be initiated by the representative of the Commission submitting to the committee a draft of the measures to be taken, along with a time limit for taking action. (Articles. 3, 4, and 5, ¶ ¶ (2) respectively).
- The committees then deliver their opinion on that draft within the time-limit. (Id.).
- Each committee is to adopt its own rules of procedure, which must be based on "standard rules of procedure which shall be published in the Official Journal." (Article 7(1))
- "The principles and conditions on public access to documents applicable to the Commission shall apply to the committees." (Article 7(2)).
- The Commission must inform the Parliament "on a regular basis" of the "committee proceedings," with certain specifics spelled out in this regard, and of any transmission of measures to the Council pursuant to the various procedures. (Article 7(3)).
- The "*references* of all documents" sent to the European Parliament under the provisions of Art. 7, ¶ 3, "shall be made public in a register" set up by the Commission. (Article 7(5))(emphasis added).
- A list of all of the committees used in comitology must be published in the Official Journal, specifying in the case of each committee the legislation under which it was set up and functions. (Article 7(4)).

- *Some reflections on practice*

As appears from the Commission's most recent reports on the working of committees,[265] the elaborate comitology provisions regarding Council and Parliament

[265] See, e.g., Report from the Commission on the working of committees in 2002, COM (2003) 530 final (Aug. 9, 2003), Report from the Commission on the working of committees in 2003, COM (2004) 860 final (Jan. 7, 2005), and Report from the Commission on the working of committees in 2004, COM (2005) 554 final (Nov. 10, 2005).

review were rarely invoked in the period before the recent revisions, and most committee contributions were, at least on the surface, minor. In regard to the implementation of the RoHS Directive in the environmental sector[266], however, Parliament has now enacted a resolution characterizing a draft as beyond Commission authority, 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 seventeen referrals to the Council in 2004,[267] *no* referrals to the Council in 2003, and seven, in 2002. Of course one may say, as the Commission does,[268] 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.[269]

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[266] RoHS stands for the "restriction on hazardous substances." For the directive, see Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment, 2003 O.J. (L 37) 19, available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_037/l_03720030213en00190023.pdf.

[267] "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 (with a high concentration 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," supra Section 5, p.20.

[268] See Report from the Commission on the working of committees in 2004, supra note 265, at 6; the final paragraph of "The Interplay Among the Institutions," supra Section 5, p. 20.

[269] See, e.g., http://ec.europa.eu/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:[270]

| DG | 2001-04 committees[271] | 2001-04 regulatory procedures[272] | 2001-04 meetings[273] | 2002-03 opinions[274] | 2002-03 instruments[275] |
|---|---|---|---|---|---|
| ENTR | 33 | 18 | 200 | 1126 | 1012 |
| EMPL | 8 | 3 | 52 | 32 | 5 |
| AGRI | 30 | 4 | 1383[276] | 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[277]** | **256** | **100** | | | **7313[278]** |

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 7000 comitology acts would generally fail to attract Parliamentary correction, and involve the Council only twenty-four times, may reflect Commission caution;[279] 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 and the length of SANCO agendas suggests that discussion of any given item is most often perfunctory.[280]

270 A similar analysis of earlier experience appears in Josef Falke, Comitology: From Small Councils to Complex Networks, *in* Delegated Legislation and the Role of Committees in the EC, supra note 9, at 331, 343.

271 Where the number varied between the reports, the highest number is given. Variance was minor.

272 Where the number varied between the reports, the highest number is given. Variance was minor. Number of regulatory committees does not include the number reported as operating under more than one procedure, and is consequently low.

273 The meetings are for all purposes; statistics broken down by type of meeting were not available.

274 The opinions are of all types, whether favorable or not, in all types of procedures.

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

276 These were predominantly management meetings.

277 The Total may include DGs without *any* regulatory procedures

278 The number includes only the listed DGs; other DGs not using regulatory procedure contributed a not insignificant additional number of instruments.

279 Cf. Barry R. Weingast & Mark J. Moran, Bureaucratic Discretion or Congressional Control? Regulatory Policymaking by the Federal Trade Commission, *in* Gellhorn and Byse's Administrative Law: Cases and Comments 131 (Peter L. Strauss et al., eds, 8th ed. 1987)..

280 See supra p. 70.

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 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[281]—are certainly consistent with the Commission's claims. But the process is not one currently open to contemporary observation, general public participation or influence.[282] And one general account of comitology practice in ENV, under prior regimes and thereby possibly 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.[283]

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."[284] 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,[285] 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 (concerning pharmaceuticals).[286] No link for consultations appears on its web site. By consulting the "news" link that is there,[287] one can find invitations to comment on draft guidance documents, coordinated with the European Medicines Agency site,[288] but no information about comitology activities. The ENTR consultations link[289] is no more informative. The comitology process, mild as it may be, is hidden from view.

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281 Gunther Shafer, Linking Member State and European Administrations – the Role of Committees and Comitology, *in* Delegated Legislation and the Role of Committees in the EC, supra note 9, at 3, 20. See also the case study on comitology in connection with GMOs in Annette Toeller & Herwig Hoffman, Democracy and the Reform of Comitology, *in* Delegated Legislation and the Role of Committees in the EC, supra note 9, at 25, 37. These were, of course, both highly controversial matters and so unlikely to be representative of general practice.

282 See Shafer, supra note 281, at 22.

283 Demmke, supra note 9, at 285–87.

284 http://ec.europa.eu/civil_society/apgen_en.htm.

285 See supra note 245.

286 http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/dir200120ec.htm.

287 http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm.

288 http://www.emea.eu.int/; See also infra note 311.

289 http://ec.europa.eu/enterprise/newsroom/cf/newsbytheme.cfm?displayType=consulation.

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 result in either 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. Comitology meetings, themselves may or may not be preceded by public notice, but in any event they will be held in small venues, to which only the members and a limited number of "experts" seconded by members will be invited.

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.[290] 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.[291]

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."[292]

### 2. The Requirement for Standard Rules of Procedure

Article 7(1) of the Comitology Decision requires the adoption by each committee of rules of procedure "on the basis of standard rules of procedure" to be published in the

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[290] Some Free Associations on Administrative Judicial Review, draft paper presented at the University of San Diego January 20, 2005, at 3 (hereinafter Some Free Associations). A similar analysis appears in print in Martin Shapiro, "Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?, 68 Law & Contemp. Probs. 341 (2005).

[291] Some Free Associations, supra note 290, 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.

[292] Id. at 5.

Official Journal by the Commission.[293] The Commission published such rules on 31 January 2001, and intends to adopt an updated version to bring them into compliance with its new rules on access to documents.[294] Nonetheless, the Commission reports that as of 2003 only 94 out of a total of 263 committees had adopted rules of procedure based on the standard rules.

### 3. The Requirement for a Register

Article 7(5) of the Comitology Decision requires the publication by the Commission of the "references" of all documents sent to the European Parliament. The conditions and restrictions on access to comitology documents on the Register is dealt with in Commission Decision 2001/937.[295] The Commission makes available references to all documents sent to the Parliament, not just the ones falling into the category of those legally required to be sent. Recently the Commission has also taken steps to make those Register references available to the public simultaneously with transmission of the documents to the Parliament. Documents referred to have traditionally had to be individually requested under Regulation 1049/2001. The Commission is also moving to make the documents themselves available in a public repository, as long as they *prima facie* are not subject to an exclusion. Due, however, to one of the key exceptions to Regulation 1049/2001 noted above, its Article 4(3) which provides an exception from disclosure where documents may "seriously undermine the institution's decision-making process," all draft implementing measures and supporting documents in the comitology process are to be put in the public repository only *after* the committee has delivered its formal opinion on the draft measure or subject. In short, they will be available to the public only after the key decisions have been made. As also noted above, this exception is carried over to Regulation 1367/2001 by the terms of Article 6(1).

### 4. Access To Information

The Comitology Decision, as noted above, provides that the "principles and conditions" on public access to documents apply to the comitology process. It also provides for various forms of public access to documents, names of committees, an annual report on the working of the committees, and access for the Parliament to committee documents. Further, one of the purposes of the 1999 Comitology Decision was to improve information to the public concerning committee procedures. Specifically, the Comitology Decision provides that (1) the principles and conditions on public access to documents applicable to the Commission are applicable to the comitology decisions, (2) the Commission was to publish in the *Official Journal of the European Communities* a list of all committees which assist the Commission in the

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293 O.J. (C 38) 6 February 2001.

294 See Report on Committee Work During 2003 at 2.

295 2001/937/EC. ECSC, Euratom: Commission Decision of 5 December 2001 Amending Its Rules of Procedure; O. J. L 345, 29/12/2001, p. 94.

exercise of implementing powers (Article 7),[296] (3) an annual report on the working of committees is to be published, and (4) the references to all documents related to committees which have been transmitted to the European Parliament must be made public in a register set up by the Commission.

In unilateral Statement No. 5 with regard to the enactment of the Comitology Decision the Commission announced its intention "to make documents communicated to the European Parliament available to the public, except those deemed to be confidential."[297] The Commission confirmed this commitment in the discussions on the 2002 Agreement with the European Parliament referred to above, and committed itself to put the public, as far as possible, on an equal footing with the Parliament in regard to comitology documents transmitted to the Parliament.

Finally, Regulation 1367/2006, the Regulation implementing the Aarhus Convention which deals with the environmental area, defines "Community institution or body" broadly so as to apparently cover comitology committees:

> [A]ny public institution, body, office or agency established by, or on the basis of, the Treaty except when acting in a judicial or legislative capacity. However, the provisions of Title II [dealing with access to environmental information] shall apply to Community institutions or bodies acting in a legislative capacity.[298]

Thus, this Regulation appears to apply to access to environmental information during the comitology process, subject to all the exceptions and limitations noted above with regard to the Commission's actions preparing legislation.

Nonetheless, the comitology process remains, to a large degree, a "black box." None of the documents providing rights to access to documents discussed above in the context of the Commission's procedure for preparing proposals for legislation appear to apply to comitology by their terms, although Article 7, Section 2 of the Comitology Decision may make them applicable generally, subject to their exceptions. But in any case the Commission takes the position that the exceptions of Article 4(3) of Regulation 1049/2001 relating to undermining the decision-making process, set out above, allow the Commission to shield from the public view all comitology documents until too late -- after the comitology committees have acted.

[296] Such list must, with respect to each committee, set forth the basic instrument(s) under which the committee is established.

[297] This Statement does not appear to have been published in the Official Journal.

[298] Regulation 1367/2001 at Article 2(1)(c). This would seem to cover even members of comitology committees that are representatives of Member States.

### 5. Public Participation (Consultation)

The Commission's extensive guidance with regard to its own decision process when preparing proposed legislation, and its consultation practices in doing so, are by their terms uniformly made not applicable during the comitology process. Nor, again, does this change with the adoption of Regulation 1367/2006 implementing the Aarhus Convention with respect to environmental matters, except with regard to "plans and programmes" relating to the environment, as defined, and subject to all of the discussion above with regard to the Commission's procedures for preparation of legislation. Even so, however, the process is somewhat more open than it may appear, at least to a good lobbyist. It is just that there are no rights outside of the area of "plans and programmes," much less rights backed up by standing rules that allow broad judicial review, and thus no effective public accountability.

The June 2002 Communication on Impact Assessment appears to exclude the comitology process without coming out and saying so directly. It includes only proposals submitted for inclusion in the Annual Policy Strategy or the Work Program, and then only for "[r]egulatory proposals, such as directives and regulations…."[299] It goes on to say, however, that the following are excluded:

> [P]roposals like Green Papers where the policy formulation is still in process, periodic Commission decisions and reports, proposals following international obligations and executive decisions for example, *implementing decisions, statutory decisions and technical updates, including adaptations to technical progress*. Commission measures *deriving from its powers of controlling the correct implementation* of Community Law are equally exempted. (Emphasis added).

The Commission, of course, is said to be exercising "implementation" powers in the comitology process, since EU delegation doctrine precludes delegation of "legislative" powers, no matter that what the comitology process produces is delegated legislation of general applicability in many cases. It must also be noted that the bulk of the comitology measures in the environmental field are termed adaptations to either scientific or technical progress, or both.

Both of the 2002 Consultation Communications appear to exclude comitology implicitly from their provisions through use of similar language. The June 2002 Communication, for example, provides that:

> For the purpose of this document 'consultations' means those processes through which the Commission wishes to trigger input from outside interested parties to its policy-shaping prior to a decision by the College of Commissioners. Consequently, the following fields are excluded from the scope of the general principles and minimum standards:

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[299] Id., p. 5.

> -- Specific consultation frameworks foreseen in the Treaties (*e.g.,* the roles of the institutionalized advisory bodies; the social dialogue according to articles 137 to 139 TEC) or provided for in other Community legislation
>
> -- Consultation requirements under international agreements
>
> -- *The participation of Member States' representatives through the so-called comitology procedure[footnote: According to Council Decision 1999/468/EC].*[300]

As a further indication, page 9 of the Communication notes that:

> The proposal is that the Commission will be guided in the conduct of its open and/or focused consultations on major policy initiatives [footnote] by [this document.]
>
> [The footnote provides "Major policy initiatives are, in particular, those that will require an extended impact assessment."]

As noted earlier, the 2002 Communication on Impact Assessment Guidance, which is apparently still in effect (but with updated June 2005 Guidelines), appears to rule out the application of impact assessment to the comitology process.

The June 2005 Impact Assessment Guidelines have similar provisions. In the discussion of which proposals require an impact assessment, the Commission notes that:

> The following are also normally exempted: periodic Commission decisions and reports, proposals following international obligations and Commission measures deriving from its powers of controlling the correct implementation of EC law and executive decisions. Footnote 7.[301]
>
> Footnote 7 says:
>
> The latter category includes *implementing decisions*, *statutory decisions*, technical updates, including *adaptations to technical progress*, competition decisions or acts which scope is limited to the internal sphere of the Commission. COM (2002)276.[302]

While none of the above provisions say clearly and expressly that all aspects of comitology measures, including the Commission's activities (as opposed to just those,

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[300] Id. at 10.

[301] June 2005 Impact Assessment Guidelines at 6.

[302] Id.

perhaps, of the Member state representatives on the committees), are excluded from all of their provisions, the Commission's past practices and apparent inclinations would seem to make this by far the most likely outcome.[303] Rights may be created under Regulation 1367/2006 as to "plans and programmes" relating to the environment, but not beyond the scope of that Regulation.

### 6. Requirement for Rationale of Decision

There are no obligations for rationale of decision applicable specifically to the comitology process (except in Article 8 of the 1999 Comitology Decision and Article 5 of the October 200 Interinstitutional Agreement on Comitology, dealing with the Parliamentary review process), although Article 253 TEC's requirements (as to which compliance is normally thought to be shown simply by use of "whereas" clauses) is apparently applicable to adoption of directives and regulations by whatever means.

## D. An alternative to comitology? -- European Agencies as Actors

Comitology is a process that develops implementing measures through the Commission itself. One might also imagine—and to a limited extent find—European legislation creating agencies that, like American independent regulatory commissions, would be empowered to enact implementing measures in a delimited field of action. 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."[304] 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.[305] 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

[303] It should be noted that the Commission's Report on the Working of Committees for 2003 makes no comment on the applicability of any of the Better Government initiatives of the Commission, nor of Aarhus implementation, although it does, in a section titled "Wider Developments," deal with the proposed changes to the process of delegated legislation in the proposed European Constitution. Id., Section 1.5 at 3.

[304] Communication from the Commission: the operating framework for the European Regulatory Agencies, at 2, COM (2002) 718 final (Dec. 11, 2002).

[305] Cf. supra pp. 10–12. .

economic assessments."[306] 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."[307]

As of May, 2007, the EU's central website for European agencies[308] identified twenty-two "Community agencies," defined there as "a body governed by European public law; it is distinct from the Community Institutions (Council, Parliament, Commission, etc.) and has its own legal personality. It is set up by an act of secondary legislation in order to accomplish a very specific technical, scientific or managerial task, in the framework of the European Union's 'first pillar.'" This appears to be a rapidly expanding list; three of the 22 listed (including the European Chemicals Agency, which will play major roles under the new REACH legislation) are identified as "under preparation; when the first draft of this report was prepared two years previous, the apparent number was nine. While time has not permitted a survey of the current 22, it was apparent of those initially found—the Office for Harmonization in the Internal Market,[309] the Community Plant Variety Office,[310] the European Medicines Agency,[311]

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[306] Communication from the Commission: the operating framework for the European Regulatory Agencies, supra note 304, at 5, 8; http://ec.europa.eu/governance/governance_eu/decentral_en.htm.

[307] Joanne Scott & David M. Trubek, Mind the Gap: Law and New Approaches to Governance in the European Union, 8 Eur. L. J. 1, 16 (2002), available at http://www.blackwell-synergy.com/servlet/useragent?func =synergy&synergyAction=showTOC&journalCode=eulj&volume=8&issue=1&year=2002&part=null. "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, 8 Eur. L. J. 133 (2002), arguing that the virtue of committees, as opposed to agencies, is that they offer superior hope (if sufficiently transparent) of mediating between expertise and democracy in a knowledge society, at 145; Giandomenico Majone, Delegation of Regulatory Powers in a Mixed Polity, 8 Eur. L. J. 319 (2002), one of the stronger proponents of the agency model; and Xénophon A. Yataganas, Delegation of Regulatory Authority in the European Union (Jean Monnet Working Paper Mar. 1, 2001), available at http://www.jeanmonnetprogram.org/papers/01/010301.html, arguing the political necessity of some delegations to independent agencies.

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

[309] http://oami.europa.eu/en/default.htm. The agency is concerned with Community trademarks and design registration, Its 2004 annual re port, available at http://oami.europa.eu/en/office/diff/default.htm, is devoid of mention of "rulemaking" or "implementing measure," and one finds no evident links from its website to such matters.

[310] http://www.cpvo.europa.eu/default.php?res=1&w=1130&h=707&lang=en&page=accueil.php. Essentially a Community patent office for plant varieties, in 2004 the CPVO adopted administrative guidelines for determining plant varieties, available at http://www.cpvo.eu.int/documents/lex/guidelines/VDguidelinesEN.pdf, pursuant to authority granted in Commission Regulation (EC) 1239/95, Art. 30. The site gives no indication of the procedures followed, or 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.

[311] 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 for implementation of medicines for humans and http://www.emea.eu.int/htms/general/direct/legislation/legislationvet.htm for implementation of veterinary medicines. It appears that this information is often also published on the DG ENTR

(continued…)

the European Food Safety Authority,[312] the European Maritime Safety Agency,[313] the European Aviation Safety Agency,[314] the European Network and Information Security Agency,[315] and the European Railway Agency[316]—that they have regulatory functions. They generally have been 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 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"[317] that engages in a process strongly resembling American notice-and-comment rulemaking[318] to generate standards on a variety of subjects (including, in contradistinction to Commission practice, an apparent disposition to draft its proposals *prior* to initiating public consultation).[319] Like the Commission, it maintains a published rulemaking

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Pharmaceuticals Unit website, available at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm; the rules of its committees explicitly undertake public consultation on "concept papers, draft guidelines and general regulatory developments with . . . all interested parties (industry, health care professionals, patients/consumers or other)." Committee on Medicinal Products for Human Use: Rules of Procedure, EMEA/CHMP/111481/2004, at 11, available at www.emea.europa.eu/pdfs/human/regaffair/11148104en.pdf.

[312] http://www.efsa.europa.eu/en.html. 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.

[313] http://www.emsa.eu.int/. EMSA, like EASA, is an adjunct to DG Energy and Transport, but unlike that agency, See infra note 314,, no "rulemaking" unit or activity is readily discernable on its website.

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

[315] http://www.enisa.europa.eu/, established in March, 2004.

[316] http://www.era.eu.int/. ERA is the EU's newest agency, under formation as an adjunct to DG Energy and Transport, like 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).

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

[318] 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, all in advance of final agency adoption of a rule.

[319] See Regulation (EC) 1592/2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, 2002 art. 13, O.J. (L 240) 1, 8, 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;

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

program[320] 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 whom 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.

Other agencies have no regulatory powers. The European Environment Agency, for example, is limited to developing information and data on the state of the European environment.

### E. The "New Approach" to Standards

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. In this process, the Council passes product-specific legislation establishing "essential requirements" for certain areas of regulation, with regard to products to be placed on the market in Europe.. As already noted,[321] 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 into 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.[322] 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.

It is important to note, with regard to the standards process, that there is no generic legislation empowering the Commission to act, as there is in the comitology process. The New Approach was announced in a Council Resolution of 7 May 1985,

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

321 See supra note 65.

322 Id.

and has been the subject of several Council Resolutions since then, but the Commission's authority to act, other than under Article 202 of the EC Treaty, is found in each separate piece of product-related legislation setting essential requirements.

Further, the Commission itself apparently enacts no secondary legislation as such (*e.g.,* anything entitled a regulation or directive) -- it (1) invites one of the European standards organizations to develop standards by issuing a "mandate" to that organization, (2) approves the standards then developed and publishes them in the Official Journal, unless, presumably, it "considers" that they do not "entirely meet the essential requirements," in which case it (3) decides whether or not the standards must be withdrawn after obtaining the opinion of the Directive 83/189/EC Committee.

Finally, the Commission takes the position that the European Standards published in the Official Journal are not legally binding. Rather, these 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[323]—essentially the same as an American business would experience if it followed a "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."[324] A manufacturer may choose a different path, but then will have the burden of establishing that its products conform to the essential requirements.

Once they are transposed into national law, the issue would then become whether they were legally binding as a matter of Member State law, not EU law. Even then, they are not legally binding on the regulated community, since compliance with them is not mandatory -- they remain, rather, a "safe harbor," one method that the regulated community can use, if it chooses, to demonstrate compliance with the relevant essential requirements. It might be said, however, that they become legally binding on other Member States, who must accept demonstrations of compliance with essential requirements that rely on the "harmonized" national standards based on them.

For purposes of this analysis, the question becomes whether any of the Commission's actions in standardization constitute "rulemaking" as this project is using the term, and what is the status of the Commission actions in standardization, however,

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[323] Technical standards "cannot replace a legal text, or change what the legislator has decided." Id. at 3. "Only the text of the directive is authentic in law." Id. at 4. Note that the standards, once produced, are not public documents as such; it appears people must purchase them as transposed by national authorities. The directives themselves are collected at http://www.newapproach.org/Directives/DirectiveList.asp.

[324] Id. at 29.

characterized, under the various regulations and Commission Communications discussed earlier that deal with impact assessment, access to documents, public participation, and statements of reasons for actions. We examine only the actions of the Commission, since the European Standards organizations are private organizations and the actions of the Member States are beyond the scope of this paper.

As for the first question, none of the Commission's actions appear to constitute adoption of the standard forms of legislation like a directive or a regulation. The issuance of the mandate, for example, seems essentially managerial.

The approval and publication of European Standards in the Official Journal, however, bears some resemblance to adoption of a determination of general applicability and future effect. Further, these standards would be legally binding on the Member States if there were any requirement that the latter must transpose them into national standards.[325] Note, however, that there is apparently no such requirement on the face of, *e.g.*, the Packaging Waste Directive applicable in the environmental area, and discussed in that sectoral report. Further, as noted above, even when transposed under national law, the national standards are not legally binding requirements on the regulated community, because compliance with them is voluntary even if compliance with the essential requirements is not. It is at least the case, however, that once transposed into national standards, these standards bind other Member States, in the sense that those Member States must "presumptively" accept products that have made compliance demonstrations under them. On balance, their publication as European Standards might be characterized as a "disguised" directive for that reason, or at least as a decision embodying a form of administrative notice with legal consequences, reflecting the Commission's determination of their compliance with essential requirements.

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 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

[325] Where they are protested, of course, such a duty would arise only if the Commission did not decide that they should be withdrawn after receiving the opinion of the Directive 83/189/EC Committee.

period.[326] It is by this means that, it is hoped, the wheat of genuine protection can be winnowed from the chaff of favoritism to industry.

One can get the misimpression, from the Commission's published guide and the TRIS website, that standardization work is uniquely done by *national* standard-setting organizations acting in coordination with *national* authorities. 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)[327] "following consultation with the Member States,"[328] to develop Union-wide harmonized standards;[329] elsewhere, it lists a significant number of mandates issued.[330] The CEN website gives, sector by sector, elaborate reports on the progress of mandated standards through its processes.[331] In doing so it makes evident that it, too, proceeds very largely by committee action.[332] 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.[333] Recently the 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.

### 1. Impact Assessment

The Commission's June 2005 Impact Assessment Guidelines apparently do not apply to Commission actions during the Standards process for the reasons discussed above with respect to comitology -- such Commission actions would likely be said to be excluded as "periodic Commission decisions and reports…and Commission measures

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[326] See Guide to the Implementation of Directives based on the New Approach and the Global Approach ch. 4 (2000) (hereinafter Guide to the Implementation of Directives), http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf..

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

[328] See Guide to the Implementation of Directives, supra note 326, Table 4.1 at 28.

[329] Id. at 28, 40–43.

[330] Id. at 12. Tables in Schepel, supra note 65, 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.

[331] 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.

[332] Schepel, supra note 65, at 101 describes CEN and its processes.

[333] See supra note 65, at 9; See *also* the Commission documents and Schepel, supra note 65, passim.

deriving from its powers of controlling the correct implementation of EC law and executive decisions."[334]

### 2. Access To Information

Turning to the question of access to information, and particularly documents, during the standards process, the Commission does in fact provide some access to the process. The question remains, however, of the applicability of Article 255 TEC and Regulations 1049/2001 and 1367/2006 to these Commission actions in implementation of the standardization process. Both Article 255 TEC and Regulation 1049/2001 apply to documents held by the Commission.[335] Article 2(3) of Regulation 1049/2001 says that:

> This Regulation shall apply to all documents held by an institution, that is to say, documents drawn up or received by it or in its possession, in all areas of activity in the European Union.

Article 12(2) of that regulation further requires, "subject to Articles 4 [Exceptions] and 9 [Sensitive Documents]," "direct access, in electronic form or through a register," to:

> In particular, legislative documents, that is to say, documents drawn up or received in the course of procedures for the adoption of acts which are binding in *or for* the Member States. (Emphasis added)

It would thus seem that the real issue is whether documents involved in the standards process, which are drawn up or received by or in the possession of the Commission, are covered, unless they are properly withheld under the exceptions of Article 4 of the sort discussed earlier in other contexts. Given the position taken by the Commission on the application of the exceptions in Article 4, ¶ 3 of the Regulation in the comitology process, it is not clear that the Commission would conclude that the public has rights to documents during the standards process under the Regulation, whatever its voluntarily applied policy in this regard.

### 3. Public Participation

As to public participation in the standards process, there are a number of ways that effective lobbyists can gain access to it. In general, however (with the exception of some possibilities in the environmental area, suggested by the Aarhus convention and

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[334] June 2005 IA Guidelines, p. 6 Note 7 says specifically that "implementing decisions, statutory decisions, [and] technical updates" are included in the excluded categories.

[335] Regulation 1049/2001 applies to documents held by "institutions," which is defined under Article 1(a) to mean the European Parliament, Council and Commission. Thus, whatever the outcome under Regulation 1367/2006, where the applicability of access to information is broadened to "Community institutions and bodies," it would appear that European standards bodies do not fall within the ambit of either Article 255 TEC or Regulation 1049/2001.

discussed in that sectoral report) there are no *rights* to participation in rulemaking activities. The 2002 Comunications on Consultation are not legally binding, and are in any case limited in their application to "major policy initiatives"[336] -- that is, those that "will require an extended impact assessment."[337] It is unlikely that they will apply by their terms to Commission actions in the Standards process.

#### 4. Explanation Of Decision Rationale

Article 253 of the EC Treaty would appear to apply to Commission decisions to issue a mandate and to approve the resulting standards as European Standards and publish them in the Official Journal, as well as its decision whether or not to withdraw standards after obtaining the opinion of the Directive 83/189/EC Committee. Article 253 covers *decisions* of the Commission, and would therefore seem to require statement of the reasons on which each such decision was taken, unless the language referring to "proposals or opinions…required to be obtained by this Treaty" is read as limiting its application to decisions taken by the Commission during the normal legislative process.

### F. Delegation Out to International Bodies

The Commission and expert bodies also act together in the formulation of norms where other international bodies are ultimately responsible for the generation of standards. A notable example is the Codex Alimentarius Commission that the FAO and WHO have jointly created to develop standards, guidelines, and related texts concerning food purity[338]. Here, the Commission may use a committee format to develop joint positions with Member States on matters to be considered on forthcoming agendas. And for these committees (not comitology committees), agendas and discussion papers may be noticed and made available in advance of meetings.[339]

## 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

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[336] E.g., 5 June 2002 Guidelines at 9.

[337] E.g., id., n. 11.

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

[339] 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 on April 25-29, just like the Codex Committee on Food Additives and Contaminants, in preparation for the Codex Alimentarius Commission meeting in Rome on 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. See supra note 269.

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.[340] 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."[341]

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,[342] although one confidently supposes that strong political incentives as well as these formal obligations underlie it.

Here, too, these steps are preliminary and tend to be quite structured and pointed—the Commission exposes the questions on which it wishes public commentary, and does not present its policy choices until after this consultative process has been completed. Its questionnaires tend to elicit, and its reports to highlight in their statistical character, the distributional issues (across Europe and across stakeholder constituencies) that its formal commitments arise from. But the firm and explicit commitment to consultations like these is considerably stronger than one would find attached to most American agency processes for generating soft law.[343]

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[340] 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 Admin. L. Rev. 803 (2001).

[341] 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.

[342] See the "overview on the Commission's framework of consultation and dialogue with civil society and other interested parties" at http://ec.europa.eu/civil_society/apgen_en.htm, collecting and linking sources. As noted previously, See supra discussion on p. 76 and note 284, 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.

[343] 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, the FDA annually publishes a list of guidance under development in the Federal Register, with an invitation to the public to participate. It maintains an electronic docket, 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.

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, for example, 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.*, like some major industries in 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.[344] 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, and so on. First for pilot river basins, and then for all Europe's river basins generally, the Directive seeks to generate information and management plans that will achieve good water status for all European waters by 2015. It establishes a complex implementing structure of working groups and local river basin authorities acting under the supervision of a strategic coordinating group and "the European water directors," a group comprised of national ministers responsible for water issues and the water director of the EU's DG Environment. The multi-national character of this collective is the natural product of the national responsibilities entailed. The collective has undertaken to develop soft law guidance for the staged implementation of the directive under a "Common Implementing

[344] Directive 2000/60/EC establishing a framework for Community action in the field of water policy, 2000 O.J. (L 327) 1 (hereinafter Water Framework Directive), available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/l_327/l_32720001222en00010072.pdf. See also http://ec.europa.eu/comm/environment/water/water-framework/index_en.html.

Strategy."[345] 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.[346] 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;[347] the library includes, in particular, a several hundred page document[348] 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.[349] As is common, however, and although both Article 14 and this guidance strongly emphasize the need for consultation in advance of action, the library contains only completed documents—not opportunities for public consultations.[350] Portions of the WFD's CIRCA site *do* contain

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[345] See http://ec.europa.eu/environment/water/water-framework/objectives/implementation_en.htm. The strategy is discussed at some length in Scott & Holder, supra note 142, at 12, remarking on the flexibility and reflexivity of the results.

[346] www.circa.europa.eu.

[347] http://forum.europa.eu.int/Public/irc/env/wfd/home (last visited Apr. 2005). It may be advisable first to register as a user of CIRCA, a registration process that is not controlled.

[348] http://forum.europa.eu.int/Public/irc/env/wfd/library?l=/framework_directive/guidance_documents/participation_guidance&vm=detailed&sb=Title (last visited Apr. 2005).

[349] Art. 14 of the Water Framework Directive, supra note 344, at 16, reflecting commitments in the preamble 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.

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.

[350] Annex III to the Guidance on Public Participation in the WFD, Common Implementation Strategy for the Water Framework Directive (2000/60/EC), available at http://www.wrrl-info.de/docs/Guidance_doc_8_Public_participa_klein.pdf, reported the working process of the group responsible for developing it.

(continued…)

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 . . . ."[351] 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.
>
> In conclusion, we had to refuse your application for full access to the WFD CIRCA system.[352]

No recourse was stated or evident.

"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.

[351] Email of April 9, 2005 (on file with author).

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

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.[353] 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. DG COMP is, organized into both cross-cutting Directorates—A (Policy and Strategy Support); F (Cartels); G (State Aid, Cohesion and Competitiveness); and I (State Aid Policy and Strategic Coordination)—and industry-specific ones—B (Energy, Basic Industry, Chemicals and Pharmaceuticals); C (Information, Communication and Media); D (Services); E (Industry, Consumer Goods and Manufacturing); and H (State Aid – Network Industries, Liberalized Sectors and Services). With the exception of Directorate H, the industry-specific Directorates are responsible for both merger control and agency investigations in the respective industries.

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

Articles[354] 81 and 82 of the EC Treaty set out the competition law principles for the Community, and Article 83 of the EC Treaty grants the Council and Parliament authority to legislate with regard to them. Article 202 of the EC Treaty 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 of the EC Treaty 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 Article 86 of the EC Treaty 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, adopted on the basis of Article 83 TEC, and the Merger Regulation, adopted on the basis of Articles 83 and 308 TEC. 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 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 have 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

[354] For all references to the TEC, See supra note 23.

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*[355] and the Economic and Social Committee (EESC), which intervened in the legislative process for adoption of the Merger Regulation and Regulation 1/2003.[356]

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 of the EC Treaty 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.[357] 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

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[355] As established in the Rules of Procedure of the European Parliament, supra note 200, art. 42, the Committee on Economic and Monetary Affairs of the Parliament is in charge of following all the procedures relating to antitrust, mergers, state aid, and is responsible for preparing the Parliament's opinion on proposals from the Commission.

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

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

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 Exemption Regulations (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 of the EC Treaty specifically, although public comments and articles can play a role. Public participation in the development of Commission Block Exemption Regulations is of key importance to the Commission, since 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.[358]

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.[359] Because the Commission must work through the Advisory Committee, whose members are representatives of the NCA's, input in 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.[360] 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 explanations or publication requirements, but notices are published in the O.J. series C and made available in other ways. Notices are not normally subject to judicial review, but where they have a

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[358] See ABA Project --,Competition Sector Report at 30–31, available at http://www.abanet.org/adminlaw/eu/SectRptRule-Competition-SchildABA2.pdf.

[359] Id. at 31; Commission Regulation (EC) No. 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, 2004 O.J. (L 123) 11, available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_123/l_12320040427en00110017.pdf.

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

*de facto* normative content or create new rights and obligations, they may be reviewed.[361]

## B. The Environmental Sector

EU administrative law in the environmental sector deals primarily with regulation of the environmental impacts of (1) industrial and commercial manufacturing plants (including the environmental impacts of industrial accidents), (2) the products those plants make, (3) major public and private infrastructure projects, and with various aspects of nature protection.[362] EU environmental sector regulation of plants encompasses regulation of air and water pollution; waste (*e.g.*, waste, hazardous waste, waste shipment, waste oil, and PCB's), including waste releases to the environment from industrial accidents and other sources; and regulation of impacts on special environments such as wetlands, groundwater, and natural areas. EU environmental sector product regulation focuses on eco-labeling and life cycle regulation of the harmful environmental impacts of chemicals and products containing chemicals, packaging, batteries, electrical and electronic equipment, products containing genetically modified organisms, and automobiles. EU 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.

While EU level environmental legislation is now extensive, and has generally led the development of environmental regulation in Europe[363], its implementation and enforcement is typically left up to the Member States. This has proved to be the Achilles heel of the regulatory system.[364] Plant regulation typically requires implementation by plant specific permits issued at the Member State level. Product regulation, on the other hand, has frequently required implementation by listing of products or product types through EU-level comitology, much as in the field of food safety. With the passage of the new REACH regulation affecting chemicals and products containing chemicals (almost all products), and the creation of a new European Chemicals Agency, much more of this form of product regulation will now be done at the European Commission level than in the past.[365]

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.

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[361] See Case C-303/90, France v. Commission, 1991 E.C.R I-5315.

[362] See Krämer, supra note 39, for a comprehensive overview and critique of EU environmental law by a former Commission official, and acute observer, who participated extensively in its development.

[363] Id. at 448-52.

[364] Id. at 418-41, 459-62, 471-73.

[365] See supra*,* note 69.

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 European Chemicals Agency, beginning to be formed in 2007 after passage of the REACH regulation, will be a larger agency, located in Helsinki, Finland. It will play an important role in implementing the regulatory provisions of REACH.

The EU'S treaty authority to legislate in the environment, health and safety areas arises principally under Articles 95 TEC (Internal Market) and Article 175 TEC (environment).[366] Legislation adopted under this authority pre-empts that of the Member States;[367] the Treaty and secondary legislation nonetheless permit the Member States leeway to impose requirements going beyond EU legislation (*e.g.*, under Article 176 TEC, and through a so-called "safeguard" clause pursuant to which Member States, under certain conditions, may temporarily restrict activities permitted by EU legislation).[368]

The sources of authority for EU environmental law govern the legislative procedure used. The bulk of environmental legislation is grounded in three EC Treaty provisions – Article 175(1) TEC governing environmental measures as such, Article 175(3) TEC governing environmental action programs, and Article 95(1) TEC governing internal market measures. Each of these specifies the use of the co-decision procedure, the legislative procedure of Article 251 TEC, requiring qualified majority voting in the Council and Parliamentary concurrence. By force of the "integration" requirements of Article 6 TEC, environmental or environmentally related measures may also be adopted under other EC Treaty provisions dealing, for example, with agriculture (Article 37 TEC) and transport (Article 80 TEC), each with its special requirements.

The consultation procedure of Article 175(2) TEC, which requires unanimous consent in the Council and only consultation with Parliament, is used for environmental matters that:

a. are primarily of a fiscal nature,

b. affect town and country planning

c. affect quantitative management of water resources or affect, directly or indirectly, the availability of those resources,

d. affect land use, with the exception of waste management, or

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[366] Treaty Establishing the European Community [TEC]

[367] Krämer at 56-59.

[368] See, e.g., TEC, Arts 30, 95(4)-(10) and 174(2).

e. significantly affect a Member State's choice between different energy sources and the general structure of its energy supply.

Under Articles 95(2) and 94 TEC, 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 also subjected to the consultation procedure.

In the environmental area, the European Commission has usually acted through directives rather than regulations. More use has been made of regulations recently, however – e.g., in the recently adopted chemicals legislation entitled "REACH," which deals with products, requires a Community wide regulatory system and creates the new Community-level European Chemicals Agency to assist in its implementation.

The Commission also makes broad use of "communications" in the environmental area to express its views on a problem. These often take the form of strategies, green or white papers, reports or simply communications; not legally binding, they may be accompanied by draft of a proposed directive, regulation, or resolution. There is no legal difference among these various forms.[369] The Commission also uses non-binding guidance notes to explain how Member States or the regulated community can best interpret or apply certain pieces of EU environmental legislation – for example spelling out by industry category in "BREF"s the "best available techniques" for manufacturing plant or other environmental controls.

For many years the Commission has used Community Environmental Action Programs setting out for a period of four-five years the objectives, principles and priorities of Community action. Sectoral action programs can be used, as has been done in the current Sixth Environmental Action Plan. Since 1993, Article 175(3) TEC has required that these programs be adopted by a joint decision of the European Parliament and the Council. In consequence, it can be argued that they are binding on the Commission.[370]

The Commission uses normal processes of legislation to develop environmental legislation for proposal to the Council and Parliament. In the environmental sector, these processes have of late been marked by extensive use of consultation procedures, impact assessment, and other new forms of "better lawmaking." The environmental sector has been a bellwether in the early development of these techniques in the EU.

DG-ENV uses comitology processes extensively, as for example in the implementation of the Waste Framework Directive and the WEEE and RoHs Directives.[371] It will do so, as well, under the REACH Regulation. Comitology

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[369] Krämer at 60.

[370] Krämer at 61 so argues.

[371] Waste Framework Directive 2006/12, 2006 O.J. (L 114) 9; Waste Electrical and Electronic Equipment Directive 2002/56, 2002 O.J. (L 37) 24 (hereinafter referred to as the WEEE Directive), available at

(continued…)

processes are 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 with regard to Parliamentary power over, and rights to participate in, the comitology process; these have resulted in a 2006 agreement on expanded rights for the Parliament.

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 fall in the area of packaging and packaging waste[372] and, to a limited extent, in respect of product marking under the Waste Electronics Directive. The use of the New Approach in the packaging waste area has been marked by controversy, and it is not uniformly used even for packaging issues. The Eco-label Regulation, on the other hand, does not invoke the New Approach, but relies upon comitology to develop eco-label criteria.[373]

EU environmental legislation has anticipated many elements now common throughout EU administrative law. As early as 1985, it imposed "impact assessment" requirements (chiefly dealing with *environmental* impact) case-by-case on Member State action with regard to certain types of specific public and private projects.[374] The same Directive had provisions requiring public access to information, public participation, and by 1997, mandatory written reasons for decision.[375] Access to information principles and requirements developed, more generally, in the environmental area as early as 1990, in an environmental directive applicable to the Member States with regard to access to information on the environment.[376] By 1996, the Integrated Pollution Prevention and Control (IPPC) Directive contained both requirements of public access to information about permits and rights of public

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http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_037/l_03720030213en00240038.pdf; Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment, 2003 O.J. (L 37) 19, available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_037/l_03720030213en00190023.pdf (hereinafter referred to as the RoHS Directive). 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.

[372] European Parliament and Council Directive 94/62/EC on Packaging and Packaging Waste, 1994 O.J. (L 365) 10, as subsequently amended in 2004 O.J. (L47) 26.

[373] Regulation 1980/2000 on a Revised Community Eco-label Award Scheme, 2000 O.J. (L 237) 1.

[374] 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).

[375] Id., Articles 6(2) and (3), 8, 9.

[376] 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).

participation in Member State permitting actions; it did, however, not provide rights against EU institutions themselves.[377]

The environmental sector is still on the "cutting edge" of progress on better governance and administrative law rights in the EU. Implementation of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the "Aarhus Convention")[378] has required the Commission to introduce more specific and detailed procedural provisions about participation, rights of access to information, and judicial review into the environmental sector then it has made available generally -- and to do so for itself and other EU institutions as well as to Member States. The Commission adopted a "package" of three legislative proposals -- two directives and one regulation -- to complete implementation of Aarhus. The directives, adopted in 2003, dealt with access to information and public participation at the Member State level. [379] The regulation, adopted in 2006, dealt with access to information, public participation, and judicial review at the EU level.[380]

This development has not been without its difficulties. Even in respect of its specific focus on environmental issues, the Commission's implementation of the Aarhus Convention has been carefully narrow -- possibly so narrow as to constitute a violation of the Convention.[381] For example, even the expanded Aarhus Convention rights of access to information are subject to "exceptions" that can be applied by the Commission to preclude access to key documents during preparation of legislation, and particularly during the comitology and standards processes, until too late to be of real use.[382]

And the Commission has not yet chosen to expand the Aarhus rights beyond the environmental area. For example, the regulation implementing the Aarhus Convention provides narrow rights to public participation in the formulation of "plans and programmes" "relating to the environment," but not as to matters of policy formulation, nor to preparation of legislation or rulemaking or to the delegated legislation processes, whether relating to the environment or more generally. Similarly, the Aarhus

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

[378] Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, 25 June 1998, 2161 U.N.T.S. 447, available at http://www.unece.org/env/pp/welcome.html.

[379] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (2003 O.J. (L 41) 26); Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programs relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC (2003 O.J. (L 156) 17).

[380] European Parliament and Council Regulation 1367/2006, 2006 O.J. (L 264) 13 (hereinafter Regulation 1367/2006).

[381] See Krämer at 149-62, 441.

[382] Id. at 153-54, 157.

Convention's provisions on access to information applicable to the environmental area (and the EU implementation of them in the environmental area in EU Regulation (EC) No. 1367/2006, noted above) are considerably broader in scope, more detailed and far-reaching, than those of the existing, generally applicable EU Regulation (EC) No. 1049/2001.[383] For these reasons, the Convention is extensively dealt with in the environmental sectoral report, but not in these pages (or the corresponding pages of other principal chapters).

To summarize the current state of affairs with regard to preparation of legislation and delegated legislation at the EU level in the environmental sector, impact assessment of environmental sector rulemaking through the Commission's preparation of legislative proposals takes place through the Commission's general "better legislation" procedures laid out in several communications. These impact assessment procedures do not create "rights" to their application, however, and are not applicable to the delegated legislation processes of comitology and standards setting.

## 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").

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 to medium sized companies ("SME's") and start up companies.

Financial sector legislation has undergone a dramatic change over the last ten years as the EU has attempted to develop a single integrated financial market in order to foster economic growth. The legislation of the late 1980s and the early 1990s, 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

[383] 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)) at 2 (Explanatory Memorandum).

introduction of the Euro as the single currency of eleven Member States on the first of 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.[384] The Commission proposed to adopt forty-two 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, as well as 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 "Basel 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 September 11, 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, by using a 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

[384] See ABA Project on the EU Administrative Rulemaking Process: Financial Services Field Report (Dec. 22, 2005), available at http://www.abanet.org/adminlaw/eu/SectRptRule-FinancialSvcs_12-22-05_draft.pdf.

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 demonstrating the economic benefits of financial integration, such as the Economic and Financial subcommittee’s report on financial stability and a research paper by London Economics, an independent consultancy.

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 set up a committee of independent persons on July seventeen, 2000, dubbed the committee of wise men and 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,[385] 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.[386] 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:

- Level 1: 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.

- Level 2: 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.

- Level 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.

- Level 4: 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. 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

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

[386] See supra note 78.

users, including through the use of open hearings and the Internet. It also recommended that a summary of the consultation process 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.[387] The European Commission moved quickly to establish the European Securities Committee (the "ESC")[388] and the advisory Committee of European Securities Regulators ("CESR").[389]

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

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[387] Resolution of the European Council on More Effective Securities Market Regulation in the European Union, Stockholm (Mar. 23 2001), available a*t* http://www.cesr-eu.org/data/document/ResolutionStockholm.pdf.

[388] Commission Decision 2001/528 of 6 June 2001 establishing the European Securities Committee, 2001 O.J. (L 191) 45 (EC).

[389] Commission Decision 2001/527 of 6 June 2001 establishing the Committee of European Securities Regulators, 2001 O.J. (L 191) 43.

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, adopted its own charter,[390] and, after a period of consultation, also adopted a public statement of consultation practices.[391]

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 of the EC Treaty, 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 of the EC Treaty.[392] 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 of the EC Treaty to give the European Parliament an equal role with the Council in controlling the Commission as it carries out its executive role.[393] 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;

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[390] The Charter of the Committee of European Securities Regulators, which took effect on September 11, 2001, is available on the CESR website at http://www.cesr-eu.org/index.php?page=foundingtexts&mac=0&id=.

[391] CESR, Public Statement of Consultation Practices, December 2001 (CESR/01-007c), available at http://www.cesr-eu.org/popup.php?ref=01-007c.

[392] The Stockholm resolution envisaged that the Parliament would be kept informed of the ESC's proceedings, 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 Resolution of the European Council on More Effective Securities Market Regulation in the European Union, supra note 387, ¶ 5.

[393] See Commission press release by 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, Feb. 5, 2002 (SPEECH/02/44), available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/02/44&format=HTML&aged=1&language=EN&guiLanguage=en; Commission press release, Financial markets: Commission welcomes Parliament's agreement on Lamfalussy proposals for reform, Feb. 5, 2002 (IP/02/195), available at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/02/195&format=HTML&aged=1&language=EN&guiLanguage=en.

- 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;[394]

- 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.[395]

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. After further prolonged discussion,[396] this led to the creation in 2004 of a parallel architecture of advisory and regulatory committees for the banking, insurance, and occupational pensions sectors.[397] Eventually, the debate between the Council and the Parliament was resolved by the introduction of the new regulatory procedure with scrutiny, under which the Parliament effectively has the right to "call back" Level 2 regulations where it considers that the proposed implementing measures exceed the Commission's powers or fail to respect the principles of subsidiarity or proportionality.[398]

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

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[394] CESR announced the formation of its market participants consultative panel on July, 10 2002. See press release CESR/02-111, available at www.kredittilsynet.no/archive/stab_word/01/01/10072073.doc.

[395] See Commission welcomes Parliament's agreement on Lamfalussy proposals for reform, supra note 393.

[396] See, e.g., European Commission, Note to the Ecofin Council: Financial regulation, supervision and stability (Dec. 2002), available at http://ec.europa.eu/comm/internal_market/finances/docs/cross-sector/consultation/ecofin-note_en.pdf.

[397] See Commission Decision 2004/5 of 5 November 2003 establishing the Committee of European Banking Supervisors, 2004 O.J. (L 003) 28 (EC); Commission Decision 2004/6 of 5 November 2003 establishing the Committee of European Insurance and Occupational Pensions Supervisors, 2004 O.J. (L 003) 30 (EC); Commission Decision 2004/7 of 5 November 2003 amending Decision 2001/527/EC establishing the Committee of European Securities Regulators, 2004 O.J. (L 003) 32 (EC); Commission Decision 2004/8 of 5 November 2003 amending Decision 2001/528/EC establishing the European Securities Committee, 2004,O.J. (L 003) 33 (EC); Commission Decision 2004/9 of 5 November 2003 establishing the European Insurance and Occupational Pensions Committee, 2004 O.J. (L 003) 34 (EC); Commission Decision 2004/10 of 5 November 2003 establishing the European Banking Committee, 2004 O.J. (L 003) 36 (EC); 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, 2005 O.J.(L 079) 9.

[398] Council Decision of of 17 July 2006 amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, see supra note 59.

of the consultation practice 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 feedback statements on the internet, 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, Yourvoice,[399] as a single access point to a wide variety of consultations not limited to 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.[400] 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.[401] 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 improvements to the consultative process to achieve the "inclusion and participation of users and other stakeholders in financial services".[402]

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.[403]

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399 http://ec.europa.eu/yourvoice/index_en.htm. See also supra note 161.

400 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, (Jul. 25, 2003) and Financial services: new group will give consumers and SMEs a stronger voice in EU policy making, IP/04/450, (Apr. 2, 2004), both available at http://ec.europa.eu/comm/internal_market/finservices-retail/finuse_en.htm.

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

402 Financial Services, Consumers and Small Businesses, A User Perspective on the Reports on Banking, Asset Management, Securities and Insurance of the Post FSAP Stocktaking Groups, FIN-USE Forum, October 2004, at 16–17, available at http://ec.europa.eu/internal_market/fin-use_forum/docs/opinion1_en.pdf.

403 See, e.g., Commission Work Program for 2005, COM (2005) 15 final (Jan. 26, 2005).

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.[404] 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.[405]

The Commission's 2005 White Paper on financial services policy from 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.[406] Indeed, the White Paper itself includes an impact assessment presenting the parameters that influenced the choices set out in it.[407] 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 Assessment[408] and its publication of revised guidelines for impact assessments in 2005.[409]

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.[410] They vary significantly as to the extent to which

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[404] 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 (Mar. 26, 2003).

[405] See supra p. 98.

[406] See White Paper: Financial Services Policy 2005-2010, COM (2005) 629 final (Dec. 1, 2005).

[407] See Annex II to the Commission White Paper, supra note 406, at Annex to the White Paper Financial Services Policy (2005-2010) - Impact assessment COM (2005) 629 final, SEC (2005) 1574 (Dec. 1, 2005).

[408] See Communication from the Commission on Impact Assessment, COM (2002) 276 final (June 5, 2002); Commission Staff Working Paper, Impact Assessment: Next Steps, In support of competitiveness and sustainable development, SEC (2004)1377 (Oct. 21, 2004).

[409] See Communication from the Commission on Impact Assessment Guidelines, supra note 117.

[410] See Markets in Financial Instruments Directive ("MiFID"), available at http://www.markets-in-financial-instruments-directive.com/MiFID.htm. Compare Article 4.1(2) MiFID, which states that the Commission

(continued…)

they prescribe parameters within which the Commission must act.[411] 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.[412]

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.[413] 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[414] 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.

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.

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"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.

[411] Compare the relatively high degree of flexibility given with respect to the implementation of the conduct of business principles in Article 19 MiFID, 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. See MiFID, supra note 410.

[412] See, e.g., Commission Regulation (EC) No 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, 2004 O.J. (L 149) 1.

[413] 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.

[414] CESR aims to allow a three month consultation period on significant issues. See CESR Statement of Consultation Practices, supra note 391, ¶3(b)(v).

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.[415] This is followed by an iterative series of meetings of the Commission with the ESC, in the light of which (and with 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 it. 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,[416] CEBS has consulted on a number of issues associated with the implementation of the proposed capital requirements directive,[417] and CESR has consulted on the cross-border notification procedure for UCITS funds under the UCITS directive[418] and on the implementation of the market abuse directive.[419]

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.[420] The Commission did consult publicly on these measures (although it only allowed a short one-month comment period).

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[415] 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 2005-2010, supra note 406, at 5.

[416] 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 at http://www.ceiops.org/media/files/consultations/consultationpapers/cp_0505.pdf.

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

[418] See CESR's guidelines for supervisors regarding the notification procedure according to Section VIII of the UCITS Directive, CESR/05-484 (October 2005), available at http://www.cesr-eu.org/index.php?page=consultation_details&id=70.

[419] See 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 at http://www.cesr-eu.org/index.php?page=consultation_details&id=51.

[420] Commission Recommendation 2004/913 of 14 December 2004 fostering an appropriate regime for the remuneration of directors of listed companies, 2004 O.J. (L 385) 55 (EC); Commission Recommendation 2005/162 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 O.J. (L 52) 51 (EC).

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.[421] Similarly, the breadth and range of the FSAP, and the complexity and iterative nature of the process, have given rise to concerns about "consultation fatigue."[422]

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 center 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 Commission's 2005 white paper aims at "dynamic consolidation" rather than a new action plan on the scale of the original FSAP, but still lists seventy-two concrete tasks and activities for the Community institutions over the next five years, some of which will only come to fruition long after that.[423] Even if there is no new FSAP, these tasks and activities will continue to test the quality of the EU's rulemaking processes.

### D. <u>The Food Safety Sector</u>

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 of the EC Treaty. Usually drawing on the authority of Articles 95 of the EC Treaty (internal market), 153 of the EC Treaty (consumer protection), or 152 of the EC Treaty (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 hygiene, food contact material, food color, and food flavoring. The implementation of food safety legislation frequently uses comitology. National draft regulations submitted as required by the Commission under the 1998 Standstill Directive are an important source for DG SANCO's food safety initiatives.[424]

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

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421 See, *e.g.*, Inter-institutional Monitoring Group: Third Report Monitoring the Lamfalussy Process, Nov. 17, 2004, at 14, available at http://ec.europa.eu/comm/internal_market/securities/docs/monitoring/third-report/2004-11-monitoring_en.pdf.

422 See, e.g., supra note 407.

423 Commission White Paper: Financial Services Policy 2005-2010, supra note 406, at Annex 1.

424 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, 1998 O.J. (L 204) 37. As discussed above, See supra p. 28, the Standstill Directive requires Member States to postpone the enactment of national legislation for twelve months if the Commission declares its intention to legislate on the matter at the EU level.

foods and food ingredients, including food packaging; this legislation also established the European Food Safety Authority. Prior legislation, such as the 1997 Novel Foods Regulation, the 1989 Framework Directive on Food Additives, 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 Regulation 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.

Currently, 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 by comitology and in the form of Commission Directives or Regulations. Less often, the Commission issues Decisions to individuals (in the case of the 1997 Regulation and the 2003 Genetically Modified Foods Regulation,[425] using comitology). Some of the older legislation (*e.g.*, the 1989 Food Additives Directive), however, requires authorization through the adoption of Council and Parliament 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).

Traditionally, consultation on new legislation by DG SANCO took place in Brussels only, in various fora[426] which were called on by DG SANCO on a largely ad-hoc and as needed basis. These usually involved only European level participants, with

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[425] Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, 2002 O.J. (L 31)1; Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients, 1997 O.J. (L 43) 1; Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, 2003 O.J. (L 268) 1. Interestingly, in the case of the 2003 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. Regulation (EC) 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods, 2003 O.J. (L 309) 1.

[426] Fact-finding has 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.

no consultation organized via the web or at Member State or regional level.[427] The conclusions and transcripts of the consultations were only sometimes 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 were still 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 two years, however, DG SANCO's practices have changed significantly, and in 2006 DG SANCO launched nine food related internet consultations.[428] 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),[429] and involve substantive participation by the European Food Safety Authority. Based on data gathered between 2001 and 2004, DG SANCO had the fifth largest number of comitology committees among the DG's, the second highest number of meetings, the second highest total output in opinions, and the third highest total output in instruments.[430] Roughly half 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; 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,

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[427] Participants are normally invited 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).

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

[429] 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.

[430] See table supra p. 74.

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,[431] 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 DGs, comitology in DG SANCO entails considerably less consultation, both in terms of the number of events and the number of participants, than measures adopted under co-decision. 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 of the EC Treaty 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. These actions follow procedural paths that are specific to the particular legislation involved, but which have the same basic though somewhat more uniform functional steps in the wake of the passage of the 2002 General Food Law Regulation and the recent generic 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 (*e.g.*, novel foods[432]) or at the

[431] See supra note 86.

[432] See supra pp. 34, 106–08.

Community level by the EFSA (the more common case) 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 are available only in English.

Thereafter, the Commission prepares a draft proposal[433] 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[434] be made public in accordance with the general 2001 Regulation on access to information. 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 *and* individually concerned."[435]

The net result is that there is 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[436] and establish deadlines,[437] a major improvement in the

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433 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. See Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (hereinafter New Food Contact Material Regulation), at 10, 2004 O.J. (L 338) 4.

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

435 See New Food Contact Material Regulation, supra note 433, Art. 14 (emphasis added).

436 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 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, and on public consultation of any draft measure. In all of these areas, the current practice of informal consultation by applicants of

(continued…)

clarity of procedure.[438] 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 may not be available in all EU languages.

The European Court of Justice may force the pace of change as to procedures for authorization. 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 employed must be designed with prudence and precision."[439] 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;
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> 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.
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> 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

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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.

[437] 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.

[438] 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 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, 2004 O.J. (L 226) 22.

[439] Opinion of Advocate General Geelhoed, in Joined cases C-154/04 and C-155/04, at 15, available at http://www.healthchoice.org.uk/documents/CHC_advocate_opinion.pdf.

subject in 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.[440]

In its resulting judgment of July 12, 2005,[441] 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.[442]
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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 with the European Food Safety Authority is carried out transparently and within a

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[440] Id. at 15, 18–20.

[441] Joined Cases C-154/04 and C-155/04**,** The Queen, on the application of: Alliance for Natural Health and Nutri-Link Ltd v Secretary of State for Health (C-154/04) and The Queen, on the application of: National Association of Health Stores and Health Food Manufacturers Ltd v Secretary of State for Health and National Assembly for Wales (C-155/04), 2005 E.C.R. I-6451.

[442] Id. at ¶¶ 72–73.

reasonable time. By providing for the procedure established in Article 5 of Decision 1999/468 to apply, Article 4(5)[443] 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.[444]

## E. The Telecommunications Sector

Three DGs have competence in the area of electronic communication: DG Information Society and Media; DC Competition; DG Internal Market. 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 twenty-five 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, which 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[445] (the "1987 Telecommunications Green Paper") in June 1987. This Green Paper set the stage for a broad debate

[443] The article applies the Comitology Decision, See supra note 59.

[444] See Joined Cases C-154/04 and C-155/04, supra note 441, at ¶¶ 81–83.

[445] Communication by the Commission, Towards a dynamic European economy: Green Paper on the development of the common market for telecommunications services and equipment, (COM (1987) 290 (June 30, 1987), available at http://aei.pitt.edu/1172/01/telecom_services_annex_COM_87_290.pdf.

on the liberalization and harmonization of telecommunications in the EU and resulted in the liberalization of all telecommunications services by January 1, 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. It launched a public consultation of stakeholders in 2006, and a new legislative proposal is expected to be implemented around 2009-2010.

Most Council and Parliament Directives in the telecommunications sector are adopted under Article 95 of the EC Treaty (Internal Market). Early in the process of breaking up national monopolies, the Commission used its powers under Article 86(3) of the EC Treaty to "ensure the application" of Article 83 of the EC Treaty by addressing "appropriate directives or decisions to Member States."[446] 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 in wide 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 ultimately upheld on all grounds. More recently, however, the Commission has not used this legislative tool.

Recently, Article 95 EC Treaty has been used as a legal basis for a "Roaming Regulation",[447] adopted ad-hoc under the co-decision procedure of Art.251 EC.[448] This Regulation fixes community-wide maximum price limits on the charges that mobile network operators may levy for the provision of mobile roaming services. It directly regulates both wholesale and retail tariffs. This use of Article 95 to regulate the pricing of international roaming services is open to challenge.[449] Article 95 concerns the "approximation of laws," requiring the "existence or likely existence of disparate laws" at national level. Yet no Member State laws regulate roaming tariffs at the Member State

[446] See supra note [354 – citing Art. 83 in Competition].

[447] Proposal for a Regulation of the European Parliament and of the Council on roaming on public mobile networks within the Community and amending Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services - COM/2006/0382 final.

[448] On May 23, in its plenary session in Strasburg, the European Parliament approved the Council's consolidated compromise position of 16 April 2007. Prices will gradually be reduced over a period of 3 years (summer 2007 – summer 2009).

[449] The authors of the Telecommunications Sectoral report, it may be noted, are counsel to the GSM Association, which has objected to the use of Article 95 as a legal basis for the roaming regulation.

level, nor is it likely that any such laws will be adopted. While the contribution of the Roaming Regulation to a sense of European identity is obvious, the regulation thus appears to rely a very broad interpretation of the powers conferred by Article 95 to the Community. The Community's competence to regulate retail prices in the telecommunications sector is also likely to be questioned.

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 of the EC Treaty (secondary legislation), one Commission directive to be adopted under Article 86 of the EC Treaty and one proposed Commission Decision on a regulatory framework for radio spectrum (delegated lawmaking). 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, and entered into force on January 2, 2001.[450] The main directives are the Framework Directive, the Access Directive, the Universal Service Directive, and the Authorization Directive.

In addition to these instruments, the Commission has adopted other non-binding measures that play an important role in the functioning of the framework. Commission Recommendations[451] 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[452]. Finally, the Commission also presents its proposed policy in any given area in the form of Communications to the Council and the Parliament, serving as indicator of the lines the Commission wishes to pursue.

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.

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450 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. (L 336) 4.

451 Ex. Commission recommendation on relevant product and service markets, COM(2003) 497

452 Ex. Commission Guidelines on market analysis and the assessment of significant market power (2002/C 165/03)

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 and 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."[453] 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[454] 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).

- 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.

An additional implementation mechanism is the European Regulators Group for electronic communications networks and services ("ERG"), created by Commission Decision 2002/627/EC.[455] The ERG is an informal body which is not subject to the rules

[453] ABA Project on the Administrative Law of the European Union: Telecommunication Regulation Field Report (hereinafter Telecommunication Sector Report), at 17, available at http://www.abanet.org/adminlaw/eu/SectRptRule-Telecommunications_Amory.pdf.

[454] CEPT stands for "Conférence Européenne des Postes et Telecommunication". CEPT was established in 1959 and since 1992, it has been composed of national authorities. CEPT is to consider, in a European context, public policy and regulatory matters relating to posts and telecommunications and to foster the harmonization of regulations. See their website at http://www.cept.org/.

[455] Commission decision 2002/627/EC of 29 July 2002 establishing the European Regulators Group for Electronic Communications Networks and Services, 2002 O.J. (L 200)38, as amended by Commission Decision 2004/641/EC of 14 September 2004, 2004 O.J. (L 293) 30.

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.

In addition to triggering secondary legislation and its role in delegated lawmaking, the Commission also ensured that Member States implement and enforce Directives in an effective and appropriate way. 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 a helpful 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 regular 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 EU 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 notify their market assessment to the Commission indicating which remedies they intend to apply. 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.

In the context of the 2006 Review, the Commission announced that it would simplify the Article 7 procedure to alleviate the administrative burden and accelerate the notification procedure. As such a simplified notification procedure would be introduced in markets which had already been found competitive or for which the proposed measures do not change significantly.

### F. <u>The Workplace Sector</u>

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.[456]

The express role given to unions and employers in the legislative process gives the EU sector of workplace regulation unique characteristics. These "Social Partners," as they are known in European usage, are given special rights as initiators, consultants and implementers of the law regulating them.[457] While this deeply modifies the normal institutional balance in the decision process, their role remains subject to Commission guidance. As more fully detailed in the sectoral report, the Social Partners appear in three guises: a substantial number of representative organizations, more than 50 at the moment, qualified by the Commission on the basis of stated criteria, who may be consulted under Article 138 of the TEC[458]; the three horizontal pan-European organizations (the European Trade Union Confederation,[459] the Union of Industrial and Employers Confederations of Europe,[460] and the European Center of Enterprises[461]), and finally those Social Partners that may claim to be representative of a specific sector ("sectoral Social Partners") and that take part in the "sectoral Social Dialogue" which is structured around the work of specialized committees. These last two categories of Social Partners are by far the most important, as they are representative enough to engage in the negotiation and implementation procedures of Article 139 TEC. For this reason, these two categories are sometimes identified as the *"European"* Social Partners, to distinguish them from the larger, merely consultative group. This is to reflect

[456] Article 141 of the TEC provides a further basis for legislation in this area. See supra note 23.

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

[458] See http://www.ec.europa.eu/employment_social/social_dialogue/ represent_en.htm.

[459] 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.

[460] Established in 1958, the UNICE 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 representing small and medium-sized companies, the UEAPME, participates in the European Social Dialogue as part of the UNICE delegation.

[461] CEEP was created in 1961, and deals with the activities of enterprises with public participation and enterprises of general economic interest."

the fact that the *"European*" Social Partners are considered the most representative and thus the most active on the legislative scene of the EU, especially at the negotiation and implementation stages. However, it should be pointed out that there is no legal distinction between them and the many other Social Partners that are merely consulted at the beginning of the legislative process. In the future, other organization may become representative enough to be granted a bigger role at all stages of workplace rulemaking. For instance, the representativeness of the sectoral Social Partners is established on the basis of regular studies conducted by academic institutions.

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) of the EC Treaty can establish "minimum requirements," but only for "gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States"),[462] rather than regulations. Soft law and important special soft law processes are also important. 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 first decided to launch a dialogue which could bring about progress through broad agreements, paving the way to the adoption of the Agreement on Social Policy on October 1, 1991. This Agreement, the most important decision-making reform in European labor law, was subsequently integrated into the Protocol on Social Policy, and annexed to the Maastricht Treaty. The Protocol was signed by eleven of the then twelve Member States of the European Community. The UK government, the one non-signatory, decided to "opt out" of the Social Chapter, arguing that its provisions constituted unnecessary and damaging intervention into the operation of the labor market and the relationships between employers and employees. In 1997 it reconsidered this position and ratified the social dialogue provisions of the Agreement when they were incorporated into the Amsterdam Treaty. Upon ratification, these provisions became part of the EC Treaty as Articles 138 and 139. As remarked above, Article 138 gives Social Partners an advisory role. Article 139 defines a role for the European Social Partners as initiators in workplace rulemaking; it provides that agreements they negotiate may 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 of the EC Treaty, 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

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[462] Id. 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. (L 254) 64; Lenaerts and Van Nuffel, supra note 28, at 302.

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 (i.e., Council unanimity).[463]

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,[464] and Article 138(2) of the EC Treaty requires that the Social Partners be consulted on this point ("the possible direction of Community action"). If action *is* to be taken, the resulting, required consultation process that then occurs again involves mandatory consultation of the Social Partners (this time, on the content of the initiative), This consultation also is to include two additional pan-European organizations: 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 interests, and the Committee of the Regions (CoR), a Treaty-based consultative committee made up of appointed representatives of local and regional authorities.[465] 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.

These committees should not be confused with those established through the comitology procedure. They are generally comprised of three or six members per Member State, representing the national government, the trade unions and the employers' associations. Exceptionally, the members of the advisory committee on equal opportunities, for the 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.[466] Unlike the Commission's web-based comitology register, there is no central register.

[463] Unanimity voting in the Council does not always go together with mere consultation of the Parliament. Under Article 42 of the TEC, co-decision and unanimity voting in the Council are required. See supra note 23.

[464] In some areas, EU legislation is not an option at all (*e.g.*, social exclusion and social protection. *Cf.* Article 137(1)(j), (k) of the TEC, supra note 23).

[465] Article 137(2) of the TEC. This provision requires consulting the ESC and CoR.

[466] See for instance the web page dedicated to the Advisory Committee on safety and Health at work at: http://ec.europa.eu/employment_social/health_safety/acsh_en.htm

DG EMPL appears to have complied with the Commission's 2002 Communication on Consultation in its actions since publication of that communication,[467] 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.[468] For DG EMPL alone, there are some 170 groups and subgroups of experts and advisers, according to the following typology:

- Advisory Groups (fourteen groups and sub groups)—Example: Advisory Group on the Equality of Opportunity between Women and Men;
- Permanent Expert Groups (ninety-five 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) of the EC Treaty, 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.

DG-EMPL does not much use implementation through 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 six favorable opinions in 2004 based on a total of ten meetings (with no instrument being adopted in 2004).

The "social dialogue" process under Article 139(2) of the EC Treaty, allows the European Social Partners both to develop and to implement legislation and enforceable agreements. At either point of mandatory consultation with Social Partners during consultation processes under Article 138(4) of the EC Treaty, the European Social Partners can notify the Commission that they choose to use the procedure in Article 139(2) of the EC Treaty 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. This agreement can then result in one of two legal instruments. When it is within the scope of Article 137 of the EC Treaty, and on the joint request of the European Social Partners, it can be adopted into law as a

[467] See footnote 94 above

[468] **http://www.statewatch.org/news/2005/feb/com-expert-groups-2004.pdf**

Council and Parliament Directive[469] 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 European Social Partners can also themselves *initiate* an Article 139 of the EC Treaty 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 of the EC Treaty). This process is one of the few settings in which EU law permits legislation to be initiated by any body other than the Commission.

Implementation of a matter adopted under the authority of Article 139 of the EC Treaty agreement can take place in one of two ways. First, if the agreement has been incorporated into a Council and Parliament Directive, the normal responsibility for transposition and implementation lies with the Member States (although the European Social Partners can choose to implement normal legislation themselves under Article 137(3) of the EC Treaty, and because an "agreement" is involved, may be able to do so under Article 139(2) of the EC Treaty as well, the process next to be described[470]), even in cases where the provisions are implemented through collective bargaining by the Social Partners. The Member States associate the European 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."[471] In this case, it is the European 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 of the EC Treaty. Article 139(2) of the EC Treaty states that the Community level agreements "shall be implemented," 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 Social Partners' agreement. The Commission has signaled some concern with the level of monitoring and enforcement with this method of implementation.[472]

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[469] While Article 139(2) of the TEC speaks only of a "Council Decision," such decisions have so far been in the form of directives. ABA Project: The Administrative Law of the European Union workplace Legislation, at 14, available at http://www.abanet.org/adminlaw/eu/SectRptRule-Workplace_Kirch_4-13-05.pdf.

[470] [**Check**]

[471] Article 139(2) of the TEC. See supra note 23.

[472] See Proposal for a Council decision establishing a Tripartite Social Summit for Growth and Employment, COM (2002) 341 final (June 26, 2002).

Given the lack of real power on the part of the Community to force labor law reform and change on the Member States, soft law plays a large role in the EU workplace sector. 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, the Council promulgates European Employment Guidelines each year on the basis of a Commission proposal. 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. On the basis of proposals from the Commission, the Council has also issued specific Recommendations to Member States complementing the Employment Guidelines since 2000. These employment guidelines have been integrated with the EU's macroeconomic and microeconomic policies, and set for a three year period, since 2005.

The EES has initiated a new procedure, the "open method of co-ordination," at Community level. 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 largely left 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; thus, although the strategy relies on the use of quantified targets, it leaves Member States free to choose the means to achieve them. To foster mutual learning and build knowledge, Member States use the EES to exchange their good practices and experience in meeting these objectives; this process of iteration, it is believed, will produce steady progress toward best practices. 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. Finally, relying on the use of quantified measurements, targets, and benchmarks facilitates country surveillance, the proper monitoring and evaluation of progress.

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. 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,[473] specifically including "the combating of social exclusion" and "the modernization of social protection systems."[474] Being a soft law instrument, "enforcement" of the EES is through political mechanisms.

The "coordination" approach is one that could be generalized into other areas of Commission activity as well. It is particularly well suited to a context 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.[475]

## 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

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

[474] Cf. Article 137(1)(j), (k) of the TEC. See supra note 23.

[475] Cf. Charles F. Sabel, Global Democracy?, 37 N.Y.U. J. Int'l L & Pol., 763 (2005).

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 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."[476] 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.[477]
>
> . . . .
>
> 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.[478]

In the United States too, despite presidential preferences for a tight command structure, there may lie the 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 continue for long. 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.

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[476] Peter Lindseth, Agents Without Principals?: Delegation in an Age of Diffuse and Fragmented Governance 3 (University of Connecticut School of Law, Working Paper No. 18, 2004), available at http://lsr.nellco.org/cgi/viewcontent.cgi?article=1017&context=uconn/ucwps.

[477] Id.

[478] 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).

# VIII. Appendix 1: Comitology Committees assisting the European Commission

### Total numbers of committees May 2007

*Policy Sector:*

| | |
|---|---|
| Enterprise and industry (DG ENTR) | 34 |
| Employment. social affairs and equal opportunities (DG EMPL) | 4 |
| Agriculture and rural development (DG AGRl) | 30 |
| Energy and transport (DG TREN) | 36 |
| Environment (DG ENV) | 31 |
| Research (DG RTD) | 5 |
| Information society and media (DG INFSO) | 9 |
| Fisheries and maritime affairs (DG FISH) | 4 |
| Internal market and services (DG MARKT) | 13 |
| Regional policy (DG REGIO) | 2 |
| Taxation and customs union (DG T AXUD) | 10 |
| Education and culture (DG EAC) | 7 |
| Health and consumer protection (DG SANCO) | 16 |
| Justice. freedom and security (DG JLS) | 16 |
| External relations (DG RELEX) | 2 |
| Trade (DG TRADE) | 12 |
| Enlargement (DG ELARG) | 4 |
| Europe Aid (AIDCO) | 14 |
| Humanitarian Aid (DG ECHO) | 1 |
| Eurostat (ESTAT) | 9 |
| Budget (DG BUDG) | 2 |
| European anti-fraud office (OLAF) | 1 |
| Informatics (DG DIGIT) | 1 |

### Enterprise and industry (DG ENTR)

1. Advisory Committee on standardisation in the field of information technology (SOGITS)
2. Machinery Committee
3. Advisory Committee on the approximation of the laws of the Member States relating to medical devices
4. Committee for harmonisation of national regulations relating to cableway installations designed to carry persons
5. Committee for the adaptation to technical progress of legislation on the removal of technical barriers to trade in agricultural and forestry tractors
6. Committee for the adaptation to technical progress of legislation on the removal of technical barriers to trade in detergents (CA TP-DETERGENTS)
7. Committee for the adaptation to technical progress of legislation on the removal of technical barriers to trade in fertilisers (CA TP-FER TILISERS)
8. Committee for the adaptation to technical progress of legislation on the removal of technical barriers to trade in motor vehicles and their trailers
9. Committee for the adaptation to technical progress of legislation to remove technical barriers to trade in aerosol dispensers (CATP/AEROSOLS)
10. Committee for the adaptation to technical progress of legislation to remove technical barriers to trade in electro-medical equipment used in human or veterinary medicine
11. Committee for the adaptation to technical progress of legislation to remove technical barriers to trade in measuring instruments (from 2005)
12. Committee for the adaptation to technical progress of legislation to remove technical barriers to trade in

pressure vessels

13. Committee for the adaptation to technical progress of the directives on the removal of technical barriers to trade in colouring matters which may be added to medicinal products
14. Committee for the adaptation to technical progress of the directives on the removal of technical barriers to trade in cosmetic products (CATP/COSM)
15. Committee for the harmonisation of national legislation relating to recreational craft
16. Committee on directives relating to textile names and labelling
17. Committee on Drug Precursors
18. Committee on the Adaptation to Technical Progress of the Directives for the Elimination of Technical Barriers to Trade in Dangerous Substances and Preparations
19. Committee on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses (EXPLOSIVES)
20. Management Committee for the fourth multi-annual programme for small and medium-sized enterprises in the European Union (SMEs)
21. Management Committee on horizontal questions concerning trade in processed agricultural products not listed in Annex I
22. Standing Committee on approximation of the laws relating to construction products
23. Standing Committee on medicinal products for human use
24. Standing Committee on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)
25. Standing Committee on the approximation of the laws of the Member States concerning pressure equipment
26. Lifts Committee
27. Standing Committee on veterinary medicinal products
28. Telecommunications Conformity Assessment and Market Surveillance Committee (TCAM)
29. Committee for the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery
30. Committee for the approximation of the laws of the Member States relating to noise emission in the environment by equipment for use outdoors
31. Measuring Instrument Committee (Not yet convened)
32. Committee for the Entrepreneurship and Innovation Programme (EIP Management Committee)
33. The programme committee for the execution of the specific programme 'Co-operation' implementing the 7th Framework Programme (2007 - 2013) of the European Community for research, technological development and demonstration activities - Configuration 'Space'
34. The programme committee for the execution of the specific programme 'Co-operation' implementing the 7th Framework Programme (2007 - 2013) of the European Community for research, technological development and demonstration activities - Configuration 'Security'

### Employment, social affairs and equal opportunities (DG EMPL)

1. Committee for the technical adaptation of legislation on the introduction of measures to encourage improvements in the safety and health of workers at work
2. Committee for the technical adaptation of legislation on the minimum safety and health requirements for improved medical treatment on board vessels
3. Advisory Committee on The European Year of Equal Opportunities for all
4. Committee for the implementation of the Community Programme for Employment and Social Solidarity - PROGRESS - 2007-2013

### Agriculture and rural development (DG AGRI)

1. Committee on Agricultural Structures and Rural Development (STAR Committee)
2. Committee on the conservation, characterization, collection and utilization of genetic resources in agriculture

3. Community Committee on the Farm Accountancy Data Network (FADN)
4. European Agricultural Guidance and Guarantee Fund Committee
5. Implementation Committee for aromatised wine-based drinks
6. Implementation Committee for spirit drinks
7. Management Committee for bananas
8. Management Committee for beef and veal
9. Management Committee for cereals
10. Management Committee for direct payments
11. Management Committee for fruit and vegetables
12. Management Committee for hops
13. Management Committee for live plants and floriculture products
14. Management Committee for milk and milk products
15. Management Committee for Natural Fibres
16. Management Committee for olive oils and table olives
17. Management Committee for pigmeat
18. Management Committee for poultrymeat and eggs
19. Management Committee for products processed from fruit and vegetables
20. Management Committee for raw tobacco
21. Management Committee for seeds
22. Management Committee for sheepmeat and goatmeat
23. Management Committee for sugar
24. Management Committee for wines
25. Standing Committee on Traditional Specialities Guaranteed
26. Regulatory Committee on Organic Farming
27. Regulatory Committee on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (OAP)
28. Standing Forestry Committee (SFC)
29. Committee on the Agricultural Funds
30. Rural Development Committee

**Energy and transport (DG TREN)**

1. Advisory Committee for the technical adaptation of the Community procedure to improve the transparency of gas and electricity prices charged to industrial end-users
2. Advisory Committee on application of the legislation on access for Community air carriers to intra-Community air routes
3. Advisory Committee on measures taken in the event of a crisis in the market in the carriage of goods by road and for laying down the conditions under which non-resident carriers may operate national road haulage services within a Member State (cabotage) - on hold
4. Advisory Committee on the conditions under which non-resident carriers may operate national road passenger transport services within a Member State (cabotage) - on hold
5. Advisory Committee on unfair pricing practices in maritime transport
6. Committee for the promotion of high efficiency cogeneration of heat and power based on useful heat demand and primary energy savings in the internal energy market" (Combined heat and power committee)
7. Committee for the interoperability of electronic road toll systems
8. Committee for implementation of the multi-annual framework programme for action in the energy sector (2003 to 2006) (Intelligent energy for Europe)
9. Committee for the implementation of the rules governing the distribution and management of permits allocated to the Community for heavy goods vehicles travelling in Switzerland
10. Committee on the adaptation to technical progress on the possible adoption of a harmonised method of analysis of the risks concerning minimum safety requirements for tunnels in the trans-European road network
11. Committee for harmonisation of national measures on the indication by labelling and standard product information of the consumption of energy and other resources by household appliances
12. Committee for the establishment of conditions for the interoperability of the trans-European high-speed rail system
13. Committee on the implementation of common rules for the transport, distribution, provision and storage of natural gas
14. Committee for the implementation of legislation on conditions of access to the network for cross boarder

exchanges of electricity

15. TEN-E Guideline - Committee for the implementation of the series of guidelines for trans-European energy networks
16. Committee on adaptation of the legislation concerning reciprocal recognition of national boat-masters' certificates for the carriage of goods and passengers by inland waterway
17. Committee on application of the legislation concerning the definition and use of compatible technical specifications for the procurement of air traffic management equipment and systems
18. Committee on application of the legislation on access to the ground handling market at Community airports
19. Committee on application of the implementation of legislation on improving ship and port installation security
20. Committee on application of the legislation on harmonisation of technical requirements and administrative procedures in the field of civil aviation
21. Committee on the application of legislation on harmonisation and common rules on the security of civil aviation
22. Committee on driving licences
23. Committee on Energy Demand Management (Directive 2002/91/EC on the energy performance of buildings)
24. Committee on Safe Seas and prevention of pollution from ships + regulation (COSS)
25. Committee on tachograph (CATP)
26. Committee on the transport of dangerous goods
27. Committee overseeing the conditions governing imports of agricultural products originating in third countries following the accident at the Chernoby I nuclear power station - on hold
28. Community/Switzerland Transport Committee (rail and road)
29. Developing European Railways Committee
30. EASA Committee (air safety) - (European Aviation Security Agency)
31. Marco Polo Committee
32. Single Sky Committee (SSC)
33. Technical Adaptation Committee on Roadworthiness Testing
34. Ten-Financial Assistance Committee
    - Ten-Energy Financial Assistance Committee
    - Ten-Transport Financial Assistance Committee
35. Transport infrastructure charging
36. Committee for the nuclear decommissioning assistance programme

**Environment (DG ENV)**

1. Advisory Committee for implementation of the directive on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations
2. Committee for application of the regulation authorising voluntary participation by undertakings in the industrial sector in a Community eco-management and audit scheme (EMAS)
3. Committee for implementation of the directive on packaging and packaging waste
4. Committee for implementing the directive establishing a Community policy regarding water
5. Committee for the adaptation to scientific and technical progress and implementation of the directive on protection of waters against pollution caused by nitrates from agricultural sources
6. Committee for the adaptation to scientific and technical progress and implementation of the directive on the incineration of hazardous waste
7. Committee for the adaptation to scientific and technical progress and implementation of the directive on urban waste water treatment
8. Committee for the adaptation to scientific and technical progress and implementation of the directives on waste
9. Committee for the adaptation to scientific and technical progress of the directive on conservation of wild birds (ORNIS)
10. Committee for the adaptation to technical and scientific progress of the directive on the quality of water intended for human consumption
11. Committee for the adaptation to technical progress and application of the Community award scheme for an

eco-Iabei (ECO-LABEL)

12. Committee for the adaptation to technical progress and implementation of the directive on the contained use of genetically modified micro-organisms
13. Committee for the adaptation to technical progress and implementation of the directive on the deliberate release into the environment of genetically modified organisms
14. Committee for the adaptation to technical progress and implementation of the regulation on the evaluation and control of the risks of existing substances
15. Committee for the adaptation to technical progress of legislation to remove technical barriers to trade in dangerous substances and preparations
16. Committee for the adaptation to technical progress of the directive on the control of volatile organic compound emissions resulting from the storage of petrol and its distribution from terminals to service stations (VOC)
17. Committee for the adaptation to technical progress of the directive on the quality of bathing water
18. Committee for the application of the directive relating to the availability of consumer information on fuel economy and C02 emissions in respect of the marketing of new passenger cars
19. Committee for the protection of species of wild fauna and flora by regulating trade therein (CITES)
20. Committee on implementing legislation on ambient air quality assessment and management
21. Committee on the conservation of natural habitats and of wild fauna and flora (HABITAT)
22. Committee on the financial instrument for the environment (LIFE)
23. Climate Change Committee
24. Management Committee for application of the directive on the standardisation and rationalisation of reports on the implementation of certain directives relating to the environment
25. Management Committee to monitor production and consumption of substances that deplete the ozone layer (SDO)
26. Standing Committee for implementation of the directive concerning the placing of biocidal products on the market
27. Standing Committee for implementation of the directive on the control of major accidental hazards involving dangerous substances
28. Committee for Directive 2003/65/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes
29. Regulatory Committee on the implementation of the European PRTR
30. Civil Protection Committee
31. Committee for the implementation of the Directive on Sulphur content in Marine Fuels

**Research (DG RTD)**

1. Standing Committee for Agricultural Research (SCAR)
2. The programme committee for the execution of the specific programme 'Co-operation' implementing the 7th Framework Programme (2007 - 2013) of the European Community for research, technological development and demonstration activities
   - Specific
   - Health
   - Food, Agriculture and Fisheries, Biotechnology
   - Nano-sciences, Nano-technologies, Materials and new Production Technologies
   - Energy
   - Environment (including Climate Change)
   - Transport (including Aeronautics)
   - Socio-economic Sciences and Humanities
3. The programme committee for the execution of the specific programme 'Ideas' implementing the 7th Framework Programme (2007-2013) of the European Community for research, technological development and demonstration activities
4. The programme committee for the execution of the specific programme 'People' implementing the 7th Framework Programme (2007-2013) of the European Community for research, technological development

and demonstration activities

5. The programme committee for the execution of the specific programme 'Capacities' implementing the 7th Framework Programme (2007-2013) of the European Community for research, technological development and demonstration activities
   - Research Infrastructures (DG RTD and DG INFSO)
   - Research for the benefit of small and medium seized enterprises (SMEs)
   - Regions of Knowledge, Research Potential and Support for the coherent development of research policies
   - Science in Society
   - Activities of International Co-operation

**Information society and media (DG INFSO)**

1. Advisory Committee on information systems security (SOG-IS) - on hold
2. Committee for the implementation of a multi-annual Community programme to make digital content in Europe more accessible, usable and exploitable (eContentPlus) (2005-2008)
3. Committee for the implementation of a multi-annual Community programme on promoting safer use of the Internet and new online technologies (Safer Internet Plus) (2005-2008)
4. Communications Committee (COCOM) - framework directive 2002/2I/EC (COCOM)
5. Electronic Signatures Committee
6. Radio Spectrum Committee (RSC) - Decision n° 676/2002/EC (RSC)
7. CIP-ICTC (b) the Committee for the ICT Policy Support Programme, called the ICT Management Committee (JCTC)
8. MEDIA 2007
9. FP7 ICTC - The programme committee for the execution of the Specific programme "Cooperation" implementing the Seventh Framework Programme (2007-2013) of the European Community for research, technological development and demonstration activities - Information and Communication Technologies (Configuration ofDG RTD FP7 committee)

**Fisheries and maritime affairs (DG FISH)**

1. Committee on Structures for Fisheries and Aquaculture
2. Committee for Fisheries Products
3. Committee for Fisheries and Aquaculture
4. European Fisheries Fund Committee

**Internal market and services (DG MARKT)**

1. Accounting Regulatory Committee
2. Advisory Committee on Public Procurement (ACPC)
3. European Banking Committee (EBC)
4. Committee for application of the legislation concerning common rules for the development of the internal market of Community postal services and the improvement of quality of service
5. Committee of Senior Officials on Public Health (CSOPH)
6. Committee on fees, implementation rules and the procedure of the boards of appeal of the Office for Harmonisation in the Internal Market (trade marks and designs)
7. Committee on the second general system for the recognition of professional education and training
8. European Securities Committee
9. Insurance Committee
10. European Financial Conglomerates Committee
11. Audit Regulatory Committee
12. Committee on the Prevention of Money Laundering and Terrorist Financing
13. Committee on the recognition of professional qualifications

**Regional policy (DG REGIO)**

1. Committee on the regulation establishing an Instrument for Structural Policies for Pre-Accession (ISP A)
2. Coordination Committee of the Funds

**Taxation and customs union (DG TAXUD)**

1. Committee for implementation of an action programme for customs in the Community (Customs 2007) (2003-2007)
2. Committee for monitoring trade in substances used for the illicit manufacture of narcotic drugs or psychotropic substances (precursors)
3. Committee for mutual assistance on recovery of claims (assistance)
4. Committee on economic outward processing arrangements for textiles - on hold
5. Committee on excise duties
6. Committee on the export and return of cultural goods
7. Committee on the movement of air or sea passengers' baggage (principles) - *on hold*
8. Customs Code Committee
   - Counterfeit and pirated goods
   - Customs procedures with economic impact
   - Customs valuation
   - Customs warehouses and free zones
   - Duty-free arrangements
   - Tariff and statistical nomenclature
   - Economic tariff questions
   - Favourable tariff treatment (end-use of goods) - *on hold*
   - General legislation
   - Movement of air or sea passengers' baggage (technical problems) - *on hold*
   - Origin
   - Repayment
   - Single Administrative Document
   - Transit
9. Standing Committee on Administrative Cooperation
10. Community programme to improve the operation of taxation systems in the internal market (FISCALIS 2003-2007)

**Education and culture (DG EAC)**

1. Programme for the enhancement of quality in higher education and the promotion of intercultural understanding through cooperation with third countries (Erasmus Mundus) (2004 to 2008)
2. eLearning Committee
3. Committee Europe for citizens
4. Committee of the integrated action programme in the field of lifelong learning
5. Committee "Youth in Action"
6. Culture Committee
7. European Year of Intercultural Dialogue 2008

**Health and consumer protection (DG SANCO)**

1. Tobacco Products Regulatory Committee
2. Committee for the implementation of the Community action programme on public health (2003-2008)
3. Committee of the General Product Safety Directive (200l/95/EC)
4. Committee for Community actions in support of Consumer Policy (2004-2007)
5. Committee on the decision to set up a network for the epidemiological surveillance and control of communicable diseases
6. Regulatory Committee on the quality and safety of blood
7. Standing Committee for Community protection of plant variety rights

8. Standing Committee on plant health (SCPH)
9. Standing Committee on propagating material and ornamental plants
10. Standing Committee on propagating material and plants of fruit genera and species
11. Standing Committee on seeds and propagating material for agriculture, horticulture and forestry (SCS)
12. Standing Committee on the Food Chain and Animal Health -
    Section: "Phytopharmaceuticals - Legislation"
    - Section: "Phytopharmaceuticals - Pesticide residues"
    - Section: "Animal health and animal welfare"
    - Section: "Animal nutrition"
    - Section: "Biological safety of the food chain"
    - Section: "Toxicological safety of the food chain"
    - Section: "Controls and import conditions"
    - Section: "General food law"
    - Section: "Genetically Modified Food & Feed and Environmental Risk"
13. Standing Committee on Zootechnics (SCZ)
14. Consumer Protection Cooperation Committee (Reg. (EC) No 2006/2004)
15. Tissues and Cells Committee
16. Consumer Financial Programme Committee 2007 -2013 (CFPC)

**Justice, freedom and security (DG JLS)**

1. Committee Article 6 Visa
2. Committee for the Framework Programme for civil judicial cooperation
3. Committee for the implementation of Daphne Programme
4. European Refugee Fund Advisory Committee
5. SIS II Committee
6. Committee on the service in the Member States of judicial and extrajudicial documents in civil and commercial matters
7. Committee on legal aid in cross-border disputes in civil and commercial matters
8. Advisory Committee concerning jurisdiction, recognition and enforcement of judgments in civil and commercial matters - Brussels I
9. Crime Victims Committee
10. Committee on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
11. EURODAC Committee
12. DUBLIN II Committee
13. Prevention, Preparedness and Consequence Management of Terrorism and other Security related Risks
14. Prevention of and Fight against Crime
15. Criminal Justice
16. Solidarity and Management of Migration Flows

**External relations (DG RELEX)**

1. Committee on certification and control of imports and exports of rough diamonds for the purpose of the implementation of the Kimberley Process certification scheme
2. Industrialised Countries Committee

**Trade (DG TRADE)**

1. Advisory Committee on the implementation of activities relating to the Community market access strategy
2. Committee for administering the double-checking system without quantitative limits in respect of the export of certain steel products covered by the EC and the ECSC Treaties for the NIS countries (Ukraine, Russian Federation and Kazakhstan) having a steel agreement with the European Union (2000-2001)
3. Committee on common rules for exports of products
4. Textile Committee (conventional regime)
5. Committee on common rules for imports of textile products from certain third countries (autonomous regime)
6. Committee on defence against obstacles to trade which affect the market of the Community or a non-

member country (TBR)
7. Committee on harmonisation of the provisions concerning export credit insurance for transactions with medium and long-term cover
8. Generalised System of Preferences Committee (GSPC)
9. Management Committee on quantitative import or export quotas
10. OCT Transhipment Committee (Committee has never met so far)
11. Access to Medicines Committee
12. Committee on trade retaliation

**Enlargement (DG ELARG)**

1. Committee on certain procedures for applying the Europe Agreements with the CEEC's and the Republic of Slovenia and the free trade agreements with the Baltic countries (safeguard)
2. Committee on economic assistance to certain central and eastern European countries and for coordinating aid to the applicant countries in the framework of the pre-accession strategy ("PHARE")
3. CARDS: Committee for the implementation of Community Assistance to Reconstruction, Development & Stabilisation for Albania, Bosnia and Herzegovina, Croatia, Serbia and Montenegro (including province of Kosovo) and Fyrom
4. IPA Committee

**Europe Aid (AIDCO)**

1. Committee on development co-operation with South Africa (meets under the EDF Committee, III accordance with the basic rules in force)
2. Committee on Food Security and Food Aid
3. Human Rights and Democracy: Committee for implementation of development cooperation operations which contribute to the general objective of developing and consolidating democracy and the rule of law and to that of respecting human rights and fundamental freedoms
4. MED: Committee on financial and technical cooperation between the Community and Mediterranean non-member countries
5. ONG: Committee on co-financing operations with European non-governmental development organisations in fields of interest to the developing countries
6. PVD-ALA: Committee for management of financial and technical assistance to and economic cooperation with the developing countries in Asia and Latin America
7. TACIS: Committee for the implementation of the provision of assistance to the partner States in Eastern Europe and Central Asia
8. AENEAS Committee (Committee for the implementation of the programme for financial and technical assistance to third countries in the areas of migration and asylum)
9. Committee on European Development Fund (EDF)
10. ENPI Committee (European Neighbourhood and Partnership Instrument)
11. DCI Committee (Development Cooperation Instrument)
12. IFS Committee (Instrument for Stability)
13. INSC Committee (Instrument for Nuclear Safety Cooperation)
14. EIDHR Committee (Democracy and Human Rights Committee)

**Humanitarian Aid (DG ECHO)**

1. Humanitarian Aid Committee (HAC)

**Eurostat (ESTAT)**

1. Committee on statistics relating to the trading of goods between Member States
2. Committee on statistics relating to the trading of goods with non-member countries
3. Committee on the harmonisation of gross national income at market prices (GNI)
4. Committee on the harmonisation of the compilation of gross national product at market prices (GNP)
5. Confidentiality of Statistics Committee
6. Standing Committee for Agricultural Statistics (SCAS)

7. Statistical Programme Committee (SPC)
8. Balance of payments committee
9. Committee on Infrastructure for Spatial Information in the European Community (INSPIRE)

**Budget (DG BUDG)**

1. Advisory Committee on the Communities' Own Resources (ACOR)
2. Regulatory Committee for Executive Agencies (RCEA)

**European anti-fraud office (OLAF)**

1. Committee on mutual assistance in customs and agricultural matters

**Informatics (DG DIGIT)**

1. Pan-European eGovernment Services Committee (PEGSCO)