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Regulatory Cooperation Between the European Commission and U.S. Administrative Agencies

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ARTICLES

REGULATORY COOPERATION BETWEEN THE EUROPEAN COMMISSION AND U.S. ADMINISTRATIVE AGENCIES

GEORGE A. BERMANN

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INTRODUCTION

This Article examines the policies and practices of the European Commission toward various forms of bilateral regulatory cooperation with administrative agencies of the United States. To place this Article’s findings in a proper perspective, it is essential to understand both (A) the selection of the European Community (E.C.) as an appropriate overseas regulatory jurisdiction for such cooperation and (B) the reasons for focusing on the European Commission among the various E.C. institutions. Those questions are taken up in this Introduction. Part I describes in some detail the organization and functioning of the Commission. Part II—the core of this Article—analyzes the Commission’s practices and policies on regulatory cooperation with U.S. agencies at all levels. Finally, Part III offers some general conclusions that may be drawn from this inquiry.

A. The European Community as U.S. Regulatory Counterpart

The European Community is, at the present time, the clearest candidate for partnership with the U.S. in a collaborative rulemaking process. The E.C’s political institutions enjoy substantial responsibility for making regulatory policy in a market that is of roughly the same size and economic importance as the U.S., that enjoys about the same level of economic development and standard of living as the U.S., and that is America’s single most significant trade partner. Because European industry is at the same time American industry’s single most important business competitor, regulatory policy in the U.S. and E.C. is a major determinant of those industries’ basic competitiveness.

Historically, much E.C. regulation has been predicated on the desirability of establishing a more fully harmonized regulatory environment, so that the factors of production—goods, persons, services and capital—may enjoy greater freedom of movement, resulting in a more fully integrated economic market. The term "internal market" refers to such an area. More recently, Member State leaders have enlarged the E.C.'s subject matter competence, so that policy in many sectors may be made at the E.C. level without express reference to its contribution to market integration. Newer regulatory competences, such as environmental policy, consumer protection, and worker safety and health, have been added to the few regulatory spheres that were specifically set out in the original treaties as belonging to the Community. Notable among the original regulatory spheres are competition law, agricultural policy and commercial policy. In these areas, the E.C. enjoys what may be called "autonomous" regulatory authority ("autonomous" in this context meaning without regard to market integration), as limited and defined in the Treaty of Rome. However, whether it is based on the Community's authority to legislate in the interest of the common market, on the one hand, or on the Community's "autonomous" regulatory authority, on the other, the legislation produced in Brussels is as fully regulatory as the rulemaking characteristic of U.S. administrative agencies in Washington, D.C. Because, as noted, the E.C.'s stage of economic and social development is roughly similar to that of the U.S., and because their political and cultural values are broadly comparable, the regulations adopted in the two capitals cover broadly the same range of issues and, within that range of issues, often pursue the same general policy ends.

B. The Role of the European Commission in Community Regulation

It is difficult to identify in the E.C. context the exact institutional counterpart of the U.S. executive branch and independent agencies, i.e., the agencies wielding national regulatory authority under the broad statutory delegations that Congress typically makes under the Commerce Clause. This is because regulatory authority at the E.C. level is shared by the

2. TREATY ESTABLISHING THE EUROPEAN COMMUNITY, [hereinafter E.C. TREATY], art. 7a.
3. Id. titles II, V, and VII (setting forth rules and policies on agriculture, competition, and commercial policy, respectively).
4. The Commission itself has remarked on the "growing parallelism between the US Administrations' priorities and policies, and those of the Community." COMMISSION OF THE EUROPEAN COMMUNITIES, COMMISSION PAPER ON E.C.-U.S. RELATIONS 4 (Apr. 6, 1993).
Council (comprising representatives of the Member States) and the Commission (the Community's chief executive body), with the European Parliament (directly elected by the citizens of the European Union) playing a role as well.

The Council has authority under the Treaty of Rome to adopt the most important regulatory texts provided for in the Treaty, though it may in principle do so only where based upon a prior formal Commission proposal.5 In many instances the Council, in accordance with the Treaty,6 has delegated that authority to the Commission,7 and the Treaty occasionally confers regulatory authority directly on the Commission.8 Furthermore, in practice, and in many cases by law, the Council and Commission obtain the advice of the European Parliament before adopting a regulatory text. Amendments to the E.C. Treaty introduced by the Single European Act in 1987 granted to Parliament a more direct and active, though still limited, legislative role in many important legislative areas.9 I refer mainly to what has come to be known as the "parliamentary cooperation procedure."10 Treaty amendments later adopted at Maastricht in 199211 granted to Parliament an effective right of veto over legislation in certain areas. When

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5. E.C. TREATY, supra note 2, art. 153.
6. Id. arts. 145, 155.
8. See, e.g., E.C. TREATY, supra note 2, arts. 10(2) (administrative cooperation in elimination of customs duties among Member States and setting up common customs tariff), 13 (abolition of charges having effect equivalent to customs duties between Member States), 22 (computation of common customs tariff), 33(7) (timetable for abolition of measures having effect equivalent to quotas), 45(2) (approximation of agricultural prices), 48(3)(d) (regulations on right of workers to remain in another Member State after employment), 90(3) (rules governing public undertakings and undertakings enjoying special or exclusive rights), 91(2) (rules on duty-free and limit-free reimportation of goods from another Member State).

In addition to the regulatory authority conferred on it directly by the Treaty, the Commission also has Treaty-based authority to issue individual decisions in important categories of cases. See, e.g., E.C. TREATY, supra note 2, arts. 17(4) (authorization to maintain customs duty), 25(1)(2) (finding of insufficient domestic production or other grounds justifying imports below common customs tariff), 26 (authorization to Member State to postpone application of common customs tariff), 37(3) (authorization to Member States to apply protective measures).

10. E.C. TREATY, supra note 2, art. 189c.
enacting measures under this "parliamentary co-decision procedure," the Council, in effect, needs Parliament's express or tacit approval.\[^{12}\]

Despite the fact that regulatory authority is ultimately vested in the Council and, in some cases, the Parliament, the focal point for any inquiry into E.C. regulatory cooperation with the U.S. is decidedly the Commission. This is because, under the E.C. legislative process, all regulatory measures—even those ultimately requiring adoption by the Council and possibly approval by Parliament—must be based on prior formal proposals of the Commission. Although the Council normally may not adopt such a measure without a prior Commission proposal, the Council may seek to modify the proposal before it is adopted. Because of its virtual monopoly on legislative initiative, the Commission has a clear advantage in setting E.C. regulatory priorities, in conceiving and studying the problems that need addressing at the E.C. level, in formulating regulatory solutions, and in proposing draft measures to that end. Even where the Commission lacks authority under the Treaty or under Council legislation to enact these measures on its own, the Commission itself in all likelihood will have conceived and elaborated the measures and initially put them into proposal form. In the case of E.C. agreements with third countries—a prospect of obvious relevance to international regulatory cooperation—the Commission has an even firmer treaty basis for the exercise of power; it has exclusive authority to negotiate international agreements, though it is ultimately subject to a negotiating mandate by the Council and subject to the Council's decision whether or not to approve them.\[^{14}\]

In appreciating the predominance of the Commission in any discussion of international regulatory cooperation by the E.C., it is also important to remember that the Commission is a standing body of persons permanently located in Brussels who, though named by the Member States themselves "by common accord," are duty bound to act in the Community interest and without instructions, formal or informal, from the Member State governments.\[^{15}\] The Council, by contrast, gathers in Brussels, or elsewhere, as and when there is legislative business to conduct; such business will typically be proposals from the Commission to be considered for adoption. Even then, only the Member State ministers whose portfolios are affected by the proposals will be the ones to assemble as the Council. In further

\[^{12}\] Parliamentary co-decision refers to the legislative procedure under which parliamentary opposition prevents a measure from being enacted.

\[^{13}\] E.C. TREATY, supra note 2, art. 189b.

\[^{14}\] Id. art. 228.

\[^{15}\] Id. arts. 157-58.
contrast, the Commission is supported by a permanent staff (of around 12,000) consisting of technical, legal, and policy personnel (plus administrative support of various kinds) based in Brussels. While the Council itself also has more or less permanent support of the same varieties, chiefly in the form of the Committee of Permanent Representatives (COREPER) of the Member States, its support is by no means of the same magnitude.

Thus, it is not only the Commission’s predominance in formulating regulatory policy that accounts for its crucial role in international regulatory cooperation, but also the Commission’s permanence and visibility in Brussels, reinforced by its larger staff. This means that the parties that are most likely to press for international regulatory cooperation—U.S. and other overseas regulators, as well as private economic interests seeking to promote regulatory harmonization, for example—will find the Commission and its various services a generally more accessible, receptive and effective listener. Indeed, this activity might be regarded as a species of the legislative lobbying activity of which the Commission is a frequent target. When the Council finally deliberates and votes, it does so in utmost secrecy. It also frequently acts on the basis of purely political and Member State-driven considerations, and in a spirit of political expediency rather than “neutral” policy assessment. For all these reasons, any serious consideration of international regulatory coordination in the making of Community policy, as a practical matter, will have to be paid at the prior policy-formulation stage, the stage at which the Commission is absolutely predominant; otherwise it is not likely to be paid at all.

Despite this Article’s focus on the Commission as the privileged E.C. participant in international regulation cooperation, it is important to bear in mind not only that much of that cooperation is subject to approval by the Council and to influence (if not in all cases approval) by Parliament, but also that the actual implementation of E.C. law, once it is made, remains primarily in Member State hands. With the principal exceptions of competition and state aid law, regulatory policy is carried out mostly by Member State personnel, in much the same way as the Member States carry out their own domestic policies. This is in contrast to U.S. administrative practice, in which much federally-made policy is also federally-implemented. In devising forms of international regulatory cooperation with the E.C.

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16. The Commission estimates that about 3,000 organized interest groups, employing 10,000 people, are located in Brussels. Commission of the European Communities, Information—Communication—Openness 79 (1994).

17. See generally Lobbying in the European Community 82-88 (Sonia Mazey & Jeremy Richardson, eds., 1993).
and notably with the Commission, U.S. agencies thus need to bear in mind that Member State administrations bear primary responsibility for putting Community policy into practice on a daily basis. It is true, of course, that the Commission oversees the Member States' performance in implementing directives and other Community law, and thus in a sense also participates in its enforcement. The fact remains, however, that implementation is primarily a Member State responsibility.

The E.C. is often dependent upon the Member States not only for the implementation of Community law, but also for its very transposition into national law. This is because a great deal of E.C. rulemaking takes the legal form of directive rather than regulation. Unlike a regulation (which legally binds the Member State administrations immediately and directly as of its entry into force), a directive requires that the relevant Member State legislators and regulators, by the deadline set out in the directive, make whatever legislative and regulatory modifications to existing national law are required to bring national law into conformity with the content of the directive. In other words, while E.C. regulations may require execution by Member State authorities, E.C. directives require both transposition and execution by those authorities. A U.S. agency that engages in international regulatory cooperation with the European Commission will therefore have a special interest, in the event that the cooperation culminates in the issuance of a directive, in exploring the extent to which that directive has been implemented into national laws and regulations in a faithful and timely fashion.

This Article's focus on the Commission is thus a reflection of that institution's central role in the E.C. legislative process. As one authority has written: "With an array of power resources and policy instruments at its disposal—and strengthened by the frequent unwillingness or inability of the Council to provide clear leadership—the Commission is at the very heart of the Community system." The Commission's yearly output of

18. Enforcement proceedings by the Commission against the Member States under Article 169 of the E.C. Treaty is the usual vehicle for this purpose.
19. See E.C. Treaty, supra note 2, art. 189 (regarding issuance of directive and creation of regulations).
20. Neill Nugent, The Government and Politics of the European Community 61 (2d ed. 1991). Nugent underscores the sense among senior Commission officials of "the lack of political direction from above" and "the amount of room for policy initiation that is available to them." Id. at 73.
legal instruments is around 600 proposals for Community legislation, all addressed to the Council, and in some cases also the Parliament.\(^{21}\)

I. THE EUROPEAN COMMISSION AND THE POLICY PROPOSAL PROCESS

For the reasons set out in the Introduction, the European Commission is the only E.C. institution that may realistically be expected to engage in sustained international regulatory cooperation with U.S. agencies on behalf of the E.C. Part I of this Article accordingly describes the Commission in some detail from an institutional point of view, and then outlines the process by which the Commission develops a regulatory idea and puts it into the form of a definitive proposal for adoption by the Council as a regulation or directive. It is during the course of this decisional process that E.C. regulators have their greatest opportunity to pursue international regulatory cooperation with U.S. and other overseas regulators.

A. The Commission Structure

The Commission is the E.C.'s principal executive organ. Functioning as a collegial body, the Commission consists at present of 20 members named by common accord among the Member States. Under the Treaty, each Member State has the right to one Commissioner\(^{22}\) and it is assumed that the five largest Member States will each supply a second Commissioner. The E.C. Treaty expressly requires, however, that Commissioners act in full independence of their governments and receive no instructions from them.\(^{23}\)

Under modified Treaty rules adopted by the Member States at Maastricht, and effective with the Commission term starting January 1995, the Member State governments first nominate, by unanimity, a candidate for president of the Commission.\(^{24}\) Because the nominee and the rest of the Commission will have to be approved by the European Parliament, the Member States are expected to consult with Parliament about the nominee at an early stage.\(^{25}\) In close consultation with the nominee, the Member

\(^{21}\) *Id.* It is estimated that the Commission produces an additional 200 or more communications, memoranda and reports per year. The number of instruments that the Commission definitively issues each year on the basis of its own decisional authority (Commission directives, regulations and decisions) is much greater, in the vicinity of 5,000. *Id.* at 78.

\(^{22}\) E.C. TREATY, *supra* note 2, art. 157(1).

\(^{23}\) *Id.* art. 157(2).

\(^{24}\) *Id.* art. 158(2).

\(^{25}\) *Id.*
State governments then proceed to nominate the other Commissioners. Although the presidential nominee does not have the right to name those Commissioners, his or her views are apt to be given serious consideration by the Member States.

Once the nominees have been designated, their names are submitted as a body for approval by the Parliament for renewable five-year terms, co-terminus with the Parliament's own term of office. The Parliament must express its approval or disapproval of the Commission as a whole, and no Commissioner may assume office until Parliament has approved the body as a whole. Once so approved, the new Commission is formally appointed by the Member States. The Commission remains formally responsible to the Parliament in that the latter may force the Commission's collective resignation at any time by passing a vote of censure by a two-thirds majority of votes cast, representing at least a majority of MEP's. To date, no motion of censure has passed.

The Commission as a whole, guided by the President, determines the allocation of responsibilities among the Commissioners. Each Commissioner will thus receive one or more "portfolios." Notwithstanding this specialization of Commissioners, no proposal may be adopted and sent in the Commission's name to the Council for enactment, unless approved by a majority of the full Commission.

Contrary to what one might suppose, the Commission's permanent staff is not organized by portfolio. Rather, the staff is arranged into twenty-four more or less permanent Directorates-General, designated by subject matter, and each headed by a Director-General. However, the Directorates-General are assigned to the Commissioner to whose portfolio their subject matters most closely correspond. The Commission may also set up

26. Id.
27. E.C. TREATY, supra note 2, art. 158(1).
28. Id. art. 158(2).
29. Id. art. 158(3).
30. Id. art. 144.
33. E.C. TREATY, supra note 2, art. 163 (stating that Commission "shall act by a majority of the number of members . . .").
34. COMMISSION R. OF PROC., supra note 31, arts. 17, 18; Spence, supra note 32, at 97, 100-101.
35. COMMISSION R. OF PROC., supra note 31, art. 12. Pursuant to the Commission's internal rules of procedure, "the Commission may assign to its Members areas in which they will have special responsibility for preparing the Commission's business and for implement-
temporary structures to deal with particular matters, as in the case of the Consumer Policy Service. Such a structure, however, may not in fact operate very differently from a subject-matter directorate.\textsuperscript{36}

The Directorates-General are further divided by subject matter into Directorates (headed by Directors), which in turn are subdivided into Units (headed by "heads of unit").\textsuperscript{37} It is normally within the various Units of the Commission—commonly referred to as the Commission’s "services" to distinguish them from Commissioners who actually make up the Commission—that responsibility for carrying out the Commission’s basic tasks is lodged. Alongside the sectoral Directorates-General are the Commission’s Secretariat-General (responsible for preparing and coordinating the work of the Commission as such),\textsuperscript{38} as well as the Commission’s Legal Service and other more specialized "horizontal" units.\textsuperscript{39}

Each Commissioner has a cabinet, consisting of a small number of advisors, freely chosen by the Commissioner.\textsuperscript{40} Often, but by no means invariably, the Commissioner chooses cabinet members from among persons of his or her own nationality. One member of the cabinet serves as chef de cabinet, or top personal assistant to the Commissioner. The chefs de cabinet often are able to reach final political agreement on a matter at their weekly meetings (typically Mondays), thus relieving the Commissioners from having to take up the matter at their own crowded weekly sessions (typically the following Wednesday). Special inter-cabinet committees (grouping the cabinet members of the various Commissioners working in the same area) also may meet in order to advance the various dossiers then under consideration.

The E.C. Treaty confers on the European Commission a wide variety of important tasks, including:

\begin{itemize}
\item \textsuperscript{*} Id. In fact, a Director-General may on occasion report to more than one Commissioner, depending on the matter at hand and, conversely, some Commissioners are responsible for more than one Directorate-General.
\item \textsuperscript{36} Id. art. 19.
\item \textsuperscript{37} Id. art. 18.
\item \textsuperscript{38} \textit{COMMISSION R. OF PROC.}, supra note 31, art. 15. The Secretary-General also functions as secretary to the Commission and is the only non-Commissioner to sit at the Commission table when it meets. Id. art. 8. He or she presides over weekly meetings of the Commissioners' Chefs de Cabinet (Mondays) and of the Directors-General (Thursdays). He or she is also responsible for Commission relations with the other Community institutions. Id. art. 15.
\item \textsuperscript{39} Id. art. 20.
\item \textsuperscript{40} The cabinet is the "personal staff" to the Commissioners. Id. art. 14.
\end{itemize}
(a) direct implementation of certain treaty articles;\textsuperscript{41} 
(b) promulgation of "tertiary" legislation in implementation of the Council's own "secondary" legislation;\textsuperscript{42} 
(c) negotiation of international agreements and conduct of external relations more generally;\textsuperscript{43} 
(d) direct enforcement of E.C. policy in the area of competition law and state aids to industry;\textsuperscript{44} 
(e) the grant or denial of Member State requests for various derogations from E.C. law obligations;\textsuperscript{45} 
(f) the prosecution of infringement actions against Member States for their E.C. law violations;\textsuperscript{46} and 
(g) representation of the Community interest in legal actions before the Court of Justice and the Court of First Instance.\textsuperscript{47}

Politically, the most important instrument of power of the Commission—and certainly the most critical one for purposes of regulatory cooperation with foreign government authorities—is the power to formulate and propose E.C. legislation. This particular function is described more fully in the following section.

\textbf{B. The Commission's Role in Initiating Legislative Measures}

This section examines the general procedural constraints on the Commission in its capacity as proponent of legislation for adoption by the Council as E.C. regulations or directives. Viewed from a U.S. perspective, the Commission and its Directorates-General appear to enjoy a high degree of autonomy in determining how to formulate a draft regulation or directive. Although the Council, Commission and Parliament must follow one or another fairly clear legislative procedure before a proposal may be enacted into law, the procedure by which the Commission formulates the initial proposal is relatively unstructured. The Commission has consider-
ABLE PROCEDURAL FREEDOM UNDER ITS OWN RULES OF PROCEDURE AND ITS MANUAL OF OPERATIONAL PROCEDURES when acting in this capacity.

1. Launching a Regulatory Initiative

Ideas for new legislative measures may originate anywhere in the Commission, whether in the office of one of the Commissioners or Directors-General, or from any point within the Units into which the Directorates-General and Directorates are further divided. Ideas may be generated not only by individuals or teams found within the Commission hierarchy, but also by the many outside persons and institutions with which the Commissioners, their staffs or the services interact. These include members of the other major institutions of the E.C. (notably the Council and Parliament), persons from different echelons within the Member State governments, and persons involved in the lobbying efforts conducted by private sector groups and public interest organizations.

The E.C. Treaty formally invites the Council to request the Commission to submit legislative proposals on a particular subject matter. As amended by the Maastricht Treaty, the E.C. Treaty extends this right of request to the European Parliament and, within limits, to the Committee of Regions, the European Monetary Institute, the Member States and the European Council. Other bodies, whether set up directly by the E.C. Treaty (as in the case of the Economic and Social Committee (ECOSOC) or the Monetary Committee) or, more often, pursuant to Council legislation, may also play this role. As a practical matter, however, the Commission itself determines whether a particular regulatory initiative will be pursued. It also determines the timing, the conceptual framework, and the content of the initiative.

2. The Role of the Commission Services

Once the Commission decides to pursue a legislative proposal on a given subject, the project is placed in the hands of a Commission official within the appropriate or "lead" Directorate-General. Usually a "working

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49. E.C. TREATY, supra note 2, art. 152.
50. Id. art. 138b.
51. Id. arts. 138b, 198, 198c, 109d, 109f(4).
53. Spence, supra note 32, at 104.
party," consisting of other Commission staff (most likely representing a number of interested services) and various outside experts and consultants, is assembled under that official's chairmanship. On other occasions, the process begins instead with a Commission "green paper," setting out general policy guidelines and serving as the basis for consultations with interested parties. The Directorate-General in which the project is undertaken typically draws up a Working Document describing the issues that the legislation is expected to address, and progressively amends that document as the legislative work proceeds. The legislative efforts can extend over months and even years. As part of a recent campaign to improve the "openness" and "transparency" of its regulatory processes, the Commission is seeking to widen and deepen its consultations with Member States (including national parliaments) and with private sector and public interest groups during the period in which its legislative proposals are taking shape. Nevertheless, the Commission reserves almost complete discretion over the quantity and timing of consultations to be had, the range of persons and institutions whose participation is to be engaged, and the intensity of that participation. The Commission's annual programme reflects the legislative projects undertaken by the Commission services.

The Commission has an extensive network of both permanent and ad hoc advisory committees which not only furnish the services with technical and policy advice on issues requiring special expertise, but which also provide them with early warning of the difficulties a policy initiative may encounter as it moves toward adoption as a proposal by the Commission, comment by Parliament and other bodies, and decision in the Council. A first category consists of "expert" committees composed of specialists of various sorts nominated by the national governments. Their advice is especially welcome because they may anticipate Member State objections. Expert committee members may even reappear in the Working Groups that will eventually advise the Council, should the measure later come before the latter for adoption. A second category consists of "consultative" committees organized and funded by the Commission to collect the views of different private economic groupings without the involvement of the

54. Id.
55. It is a general rule that only one Directorate-General should be the lead department. MANUAL OF OPERATIONAL PROCEDURES, supra note 48, § 8.1.2.
56. Id. § 8.1.1. "The Directorate-General responsible for the matter in hand takes the lead in drawing up the document in due form on the responsibility of the appropriate Member of the Commission." Id. § 9.2.
57. COMMISSION R. OF PROC., supra note 31, art. 4.
Member State governments. Their members are drawn heavily from among
the full-time employees of various economic associations and groups, such
as labor, industry or particular agricultural sectors. The extent of reliance
on such committees, and the extent of their influence, vary greatly among
Directorates-General.58

Assuming the legislative project is not shelved or subsumed under
initiatives taken by another Commission division, the effort, will in
principle culminate in a preliminary draft proposal. Although this proposal
may not be published officially, it is circulated among other Commission
services that may have an interest in it,59 as well as among the Member
States (including both their parliaments and their administrations) and
among relevant private and public organizations. Lobbying of the
Commission services on behalf of affected interests has become a common
feature of the process.60

3. From Preliminary to Final Draft Proposal

The transition of the proposal from preliminary to final draft depends on
the commentary received and the difficulty of the necessary compromises.
While the preliminary proposal will have taken fairly concrete shape by this
time, it is still widely open to comment and to change. At some point in

58. NUGENT, supra note 20, at 68-69.

59. The Commission’s Rules of Procedure call for departments involved in the
preparation of Commission decisions to work together as closely as possible. COMMISSION
R. OF PROC. supra note 31, art. 20, para. 1. More specifically, the department responsible
for a measure is required to consult with other departments associated or concerned with the
subject in sufficient time before submitting the measure to the Commission. Id. para. 2.
According to the Commission’s Manual of Operational Procedures, “[t]o ensure efficient
cooperation and optimum consultation, the lead department should make informal contact
with the other departments concerned as soon as it begins work on drafting a proposal.”
MANUAL OF OPERATIONAL PROCEDURES, supra note 48, § 8.1.1.

It is further provided that mention shall be made of any important files currently
under consideration or about to go before the Commission at the weekly meeting of the
several Directors-General. Id. § 8.1.2. The Manual also provides that, “the Directorate-
General responsible must involve from the outset all the other departments with an interest
in the topic in question or in some aspect of it.” Id. § 9.3.

60. There are reported to be around 3,000 special interest groups active in Brussels.
Sonia Mazey & Jeremy Richardson, The Commission and the Lobby, in THE EUROPEAN
COMMISSION 169, 180 (G. Edwards & D. Spence 1994). “Officials also know that they need
to mobilize the support of those interests directly affected by EC legislative proposals since
the legislation is otherwise unlikely to be adopted by the Council or implemented effectively.
Most groups therefore experience little difficulty in gaining access to Commission officials.”
Id. at 178.
the process, as the focus sharpens, the Commissioner who is responsible for
the Directorate-General in which this legislative activity is centered
becomes closely involved in revisions of the preliminary draft proposal.
Should the measure eventually come before the full Commission for
adoption as a proposal, it is this Commissioner who normally plays the
leading role.

Under the Commission's internal rules of procedure, the reworked
proposal is subject to a number of required consultations. These include
consultations with the other Commission services that are legitimately
interested, with the individual Commissioner in charge of the Director-
ate-General that is responsible (to the extent that he or she is not already
involved), and with any outside committee that is required under the Treaty
to be consulted at this stage. It is impossible to generalize about the
amount of change that these consultations are likely to produce. However
seriously their criticism may be taken, none of the bodies consulted is in a
position to insist that changes be made to the proposal. The furthest the
rules go in this direction is to provide that the service in charge must
consider and attempt to accommodate the views of the other interested
services within the Commission and, where unable to do so, at least
acknowledge those views in the final draft proposal. It is also customary
for the proposal to be submitted to the office of each of the other
Commissioners, where it is then assigned for study and discussion either to
a working group composed of the interested Commissioners or the
appropriate members of their cabinets. It is fair to say that the Working
Party—at this point in close contact over the matter with the responsible

61. COMMISSION R. OF PROC., supra note 31, art. 20. See Spence, supra note 32, at
105-107. Weekly meetings of the Directors-General and the Chefs de Cabinet of the
Commissioners, as well as meetings of the standing "Inter Service Groups," help ensure that
such coordination occurs.

62. These may include, among others, the Monetary Committee and the Economic and
Social Committee. See PHILIP RAWORTH, THE LEGISLATIVE PROCESS IN THE EUROPEAN
COMMUNITY 32-33 (1993) [hereinafter RAWORTH].

63. COMMISSION R. OF PROC., supra note 31, art. 20, para. 3. According to the
Commission's Manual of Operational Procedures:
The object of the coordination exercise should be to achieve as wide a consensus
as possible. In the event of disagreement, if the originating department feels it is
justified in adhering to its original proposal despite objections from the other
departments, it should explain its reasons and, if so requested, record the
differences of opinion when making its submission to the Commission.
Irreconcilable differences of opinion should be objectively recorded by the
department responsible in the document submitted to the Commission.

§ 8.1.1. See also id. § 9.3.
Commissioner and other Commission members or their staff—will endeavor to find some sort of common ground, though without undue sacrifice to the measure's central objectives or to its overall coherence.

4. Regulatory Impact Analyses

The Commission's proposal-making procedures require the preparation of several different "impact analyses." One such analysis is the so-called "small and medium-sized business impact analysis," required to be submitted to the Commission's Directorate-General XXIII (DG XXIII). Under the Commission's Manual of Operational Procedures, each text submitted to the Commission for adoption as a legislative proposal must be analyzed in terms of its economic impact on small and medium-sized businesses. This assessment is meant to cover not only the proposed rules' direct economic implications for small and medium-sized businesses, but also the compliance costs and administrative burdens that it would impose on them. In its review, DG XXIII may question the adequacy or accuracy of the analysis, and its questions may cause the responsible service to revise its analysis. DG XXIII does not, however, have authority to require that changes be made to the proposed measure.

The published procedures of the Commission also now require the responsible service to demonstrate, in a memorandum accompanying the final proposal, that it considered and rejected regulatory alternatives. Consideration of regulatory alternatives is meant to promote respect for the general principle of "proportionality." The principle, established by the jurisprudence of the Court of Justice and more recently affirmed in the

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64. Id. § 9.5.1.(ii). See also id. at Annex 20 (providing copy of impact assessment form).
65. MANUAL OF OPERATIONAL PROCEDURES, supra note 48, § 9.5.1.(ii).
66. Id.
67. Id.
68. Id.
69. "So as to avoid any initial bias, the originating department should at an early stage provide all the facts and general information on which its proposals are based, including any arguments in favor of alternative solutions. If several options are available, the originating department should give the reasons for its preference at the outset." Id. § 8.1.1.

Documents provided to the Commission in support of a proposed measure are required to provide "all the information required for assessing the political and/or economic context" as well as to mention "any alternative solutions . . . and their respective merits." MANUAL OF OPERATIONAL PROCEDURES, supra note 48, § 9.5.1.
Maastricht amendments to the E.C. Treaty, requires the E.C., in essence, to favor the least restrictive alternative.\textsuperscript{70}

As amended at Maastricht, the E.C. Treaty also expresses a general E.C. law principle of "subsidiarity," meaning that the E.C. should not take legislative action within fields of concurrent E.C. and Member State jurisdiction if action at the Member State level could adequately accomplish the E.C.'s objectives.\textsuperscript{71} Accordingly, the Commission's internal rules now require that the explanatory memorandum accompanying a final text for adoption as a Commission proposal contain a statement demonstrating that the proposal also is consistent with the principle of subsidiarity.\textsuperscript{72} Finally, under the E.C. Treaty, as amended at Maastricht, the Commission must ensure that all legislative proposals to the Council can be financed, so far as E.C. expenditures are concerned, from the E.C.'s own resources.\textsuperscript{73} The "fiche financière" which is required to accompany any proposal for adoption by the Commission, sets out the proposal's financial implications; as the E.C. has limited resources to be allocated among an increasing number of policy areas, this information will influence the Commissioners in their ultimate decision making.

5. **Legal Service Review**

Before it is finally submitted to the Commission for adoption, a legislative proposal must be submitted to the Commission Legal Service for formal legal review.\textsuperscript{74} This may not, however, be the first time in the long process of legislative development that the matter will have come before the Legal Service. The responsible Commission service is likely to have consulted the Legal Service previously on one or more issues of law

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\textsuperscript{70} E.C. TREATY, supra note 2, art. 3b, para. 3.

\textsuperscript{71} Id. para. 2.

\textsuperscript{72} Internal Commission procedures had already required that the explanatory memorandum contain a paragraph outlining the difficulties that Member States could expect to encounter in implementing any E.C. directive that was contemplated. MANUAL OF OPERATIONAL PROCEDURES, supra note 48, § 9.5.1(b).

\textsuperscript{73} E.C. TREATY, supra note 2, art. 201a. The Directorates-General responsible for budgets, personnel and administration must be consulted on all proposed measures that may have implications for budget and finances, personnel, or administration, respectively. COMMISSION R. OF PROC., supra note 31, art. 20, para. 2. See also MANUAL OF OPERATIONAL PROCEDURES, supra note 48 §§ 9.4.2., 9.4.3. Their statements on a proposed measure are required to accompany the measure when sent to the Commission for approval. Id. § 9.5.1.

\textsuperscript{74} COMMISSION R. OF PROC., supra note 31, art. 20, para. 2. See also MANUAL OF OPERATIONAL PROCEDURES, supra note 48, § 9.4.1.
which may have surfaced in the drafting process. The Legal Service’s final review of the text will focus on the measure’s legality, as measured by all relevant norms of E.C. law, both substantive and procedural. With the proliferation of legislative procedures under the Treaty—each providing different institutional roles for the Parliament, Council and Commission, as well as different voting majorities in the Council—the Legal Service has increasingly focused on the question of the “correctness” of the proposal’s “legal basis” in the Treaty, but its review covers the full range of legal issues that the proposal raises. In the end, the Legal Service gives a favorable or unfavorable opinion on the text in question. In the latter event, the Legal Service states its reasons in a note attached to the draft measure submitted for approval to the Commission.

6. Adoption of a Proposal by the Commission

At this point, the final draft proposal is conveyed to the responsible Commissioner, accompanied by (1) an explanatory memorandum containing any required impact analyses, (2) the opinion of the Legal Service, and (3) any committee opinions required by the Treaty. That Commissioner’s objective, presumably, is to have the draft adopted by the Commission acting as a collegial body; in any event, it is he or she who will move the proposal’s adoption. To that end, the draft is first submitted to the relevant cabinet committee—i.e., a committee chaired by the relevant cabinet member of the Commission President and consisting of his or her counterparts in the cabinets of the other Commissioners—with a member of the responsible Commission service also present. If the proposal is expected to be adopted under the Commission’s expedited “written procedure,” the cabinet members will not actually meet, unless of course agreement by written procedure is blocked. Assuming it is successful, the written procedure dispenses with the requirement of discussion and vote at a full meeting of the Commissioners. In all other cases, the final draft

75. “The Legal Service must be consulted as soon as possible on any proposals which involved legal drafting.” MANUAL OF OPERATIONAL PROCEDURES, supra note 48, § 8.1.1.
76. Id. § 9.4.1.
77. Also attached to the proposal will be the opinions of the Directorates-General for Budget, Financial Control, Personnel and Administration. See id. § 9.5.1.
78. COMMISSION R. OF PROC., supra note 31, art. 6.
79. Id. art. 10. The written procedure may be used only if the Directorates-General involved and the Legal Service are agreeable to that procedure. Id. A “written procedure” may also be used at the Cabinet level. Id. In other words, if there is previous agreement at the level of the Directorates-General, the cabinet members may themselves reach agreement without actually meeting.
proposal will be presented for discussion at such a meeting. Even then, the chefs de cabinet of the Commissioners, presided over by the Secretary-General, will meet in advance of the Commissioners' own meeting with a view toward reaching agreement on as many remaining issues as possible, so that the Commissioners themselves can focus strictly on matters of disagreement. The cabinets thus play a major role in Commission policy making. Among other things, they enable individual Commissioners to consider and determine how to vote on issues lying outside their main areas of responsibility and to deal directly and continually with lobbyists.

Under the chairmanship of the Commission's Secretary-General, the Commissioners meet at weekly sessions to reach their most important decisions, including the decision to adopt a proposal for legislation. These closed meetings may end with the proposal's adoption (with or without amendment), either by consensus or by an actual vote, with passage requiring an absolute majority vote of the Commissioners in favor. Often, however, the dossier will be remitted to the responsible Commission service for further work on one or more outstanding issues. In truth, the Commissioners have wide discretion over the draft proposal before them. "They may accept it, reject it, refer it back to the Directorate-General for redrafting, or defer making a decision."

Once the proposal is adopted, the Translation Service translates the text into all the E.C.'s official languages. The proposal is then published as

80. Id. art. 2.
83. COMMISSION R. OF PROC., supra note 31, art. 7. Also, Commission discussions must be kept confidential. Id.
84. Id. art. 6, para. 3.
85. NUGENT, supra note 20, at 63. According to one authority: "[W]hat makes the Commission work in practice . . . is the existence of a layer of procedures designed almost to ensure that real power remains outside the services and is focused in the Cabinet system. It is almost as if Commissioners and their Cabinets let the Services play the game of policy-making, consultation of interest groups and inter-institutional relations, while reserving both judgement and the exercise of real power to themselves.
Spence, supra note 32, at 113.
86. WEATHERILL & BEAUMONT, supra note 47, at 153.
an official document, accompanied by a revised explanatory memorandum.\textsuperscript{87} In keeping with the principle of subsidiarity, the memorandum, in relevant cases, will recite the Commission’s basis for concluding that action at the E.C. rather than the Member State level was necessary to achieve the E.C.’s regulatory objectives.\textsuperscript{88} The proposal is then ready for submission to the Council for action.\textsuperscript{89}

7. \textit{From Commission Proposal to Council Measure}

The legislative course of a measure following its submission by the Commission to the Council varies with the particular legislative procedure required to be followed under the relevant Treaty article. Depending on the applicable article, the Parliament either may be consulted or may enjoy the additional prerogatives entailed in parliamentary cooperation or parliamentary co-decision. Similarly, there may be either immediate Council action on the Commission proposal or, more likely, two readings in the Parliament and Council, and possibly (under the co-decision procedure) intervention by a Joint Conciliation Committee.\textsuperscript{90} How forcefully Parliament may influence the outcome depends on whether the parliamentary cooperation or parliamentary co-decision procedure is in effect.\textsuperscript{91}

For the reasons set out earlier, however, these stages of the legislative process—though politically and institutionally crucial—are not the ones that are likely to give priority to international regulatory coordination with U.S. or other overseas regulatory counterparts. Prospects for coordination are unlikely to surface for the first time during the Parliament’s or the Council’s political deliberations over the proposed text. Nor is new information about the parallel regulatory policies of other countries likely to be added to the legislative dossier at this point. In other words, any serious consideration of coordinating E.C. rules with rules of the U.S. will have to have been given by the Commission if it is to have any influence over the regulatory result at all. It is unrealistic to suppose that the Parliament or Council, which have fewer means and weaker political incentives than the Commission to explore the international regulatory

\textsuperscript{87} Id. at 108.
\textsuperscript{88} Id. at 108-09.
\textsuperscript{89} The Commission’s Secretary-General is responsible for ensuring official notification and publication of Commission instruments in the Official Journal of the European Communities, and for transmitting the documents to other Community institutions. COMMISSION R. OF PROC., \textit{supra} note 31, art. 15.
\textsuperscript{90} E.C. TREATY, \textit{supra} note 2, art. 189b.
\textsuperscript{91} Id.
dimension of a given problem, will introduce or advance this perspective if the groundwork for doing so has not already been laid.

In further appreciating the Commission's freedom to initiate legislative proposals, it bears emphasizing that under all the E.C.'s legislative procedures, the Commission has the right to modify or withdraw a proposed measure even after it has been put before the Council, unless it has been formally adopted by the Council. This has been a central feature of the E.C. legislative process from the very beginning and remains so today. Thus, the Commission may alter a proposal unilaterally, even while it is under active consideration by the Parliament or the Council, provided the Commission follows its own internal rules in so doing. The significance of this prerogative lies in the fact that, while the Council often is able to adopt the Commission's proposal by a qualified majority vote of its members, the Council, under most procedures, can adopt a different text (that is, different from the Commission's original or amended proposal) only if it acts to do so unanimously. The Commission's continual right to amend its proposals thus gives whatever its current policy preferences happen to be an ongoing advantage as far as adoption by the Council is concerned. Of course, if the Commission elects to withdraw its proposal altogether, the Council (or Council and Parliament, under the co-decision procedure) cannot then enact it in any version.

II. COMMISSION PRACTICES AND POLICIES ON REGULATORY COOPERATION WITH U.S. AGENCIES

The preceding parts of this Article sought to demonstrate how and why the Commission bears primary responsibility on the E.C. side for conducting whatever regulatory dialogue can be expected to develop with U.S. regulatory agencies. Part II of this Article examines the practices and policies of the Commission in this respect. It begins with a description of the legal and political framework within which such regulatory dialogue occurs. It then examines the Commission's policies and practices themselves, both at the "services" level and at the higher "political" level.

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92. E.C. Treaty, supra note 2, art. 189a(2).
93. Id. art. 189a(1).
94. See generally Raworth, supra note 62, at 26.
A. The Services' Basic Freedom to Cooperate with Overseas Governments

Although the matter has not been conclusively decided, most indications are that the Commission's various services are free to engage in at least some forms of direct bilateral cooperation with counterpart units of the U.S. government. The prevailing attitude thus resembles that of U.S. regulatory agencies, which likewise tend to assume that they need no express authorization from Congress or the President before engaging in international regulatory cooperation. Of the examples of U.S.-E.C. regulatory cooperation discussed in a later section of this Article, few have been expressly authorized at the top levels of government.

B. The Transatlantic Declaration

If the Commission services were to look for textual authority to conduct bilateral regulatory cooperation with U.S. agencies, they would find at least some such authority in the Transatlantic Declaration of November 22, 1990. This document—which, as its name suggests, is no more than a declaration—expresses a political commitment at the highest levels of the U.S. and the E.C. to collaborate in addressing and solving problems of common interest. The Declaration states in pertinent part that the U.S. and E.C. (including the Member States) "will inform and consult each other on important matters of common interest, both political and economic, with a view to bringing their positions as close as possible, without prejudice to their respective independence." Some, though by no means most, of the subjects mentioned in the Declaration directly implicate regulation. These include "technical and non-tariff barriers to industrial and agricultural trade, services, ... transportation policy, standards, telecommunications, [and]

95. See infra Part II.D.
97. Some European leaders have urged that political, economic, and security relations between the U.S. and the E.U. be placed within the framework of a formal treaty, rather than a mere declaration, evidently so that the U.S. might be held more closely accountable for various of its unilateral measures, chiefly in the trade sphere. See Euro Parliamentarians Urge Economic Treaty with U.S., EUROWATCH, at 5 (Mar. 21, 1994).
98. BULL. E.C., supra note 96, at 91.
The U.S. and E.C. also specifically agreed in the Declaration to engage in joint research and exchanges in science and technology, as well as in education and culture.\textsuperscript{99}

In concrete terms, the Transatlantic Declaration establishes a framework for "regular and intensive consultation" between U.S. and E.C. authorities.\textsuperscript{100} The chief institutional components of this framework include:

(a) biannual consultations between the Presidents of the Commission and the Council, on the one hand, and the U.S. President, on the other;
(b) biannual consultations between the E.C. Foreign Ministers and the Commission, on the one hand, and the U.S. Secretary of State, on the other;
(c) biannual consultations between the Commission and the U.S. government at the cabinet level; and
(d) other ad hoc consultations and briefings.\textsuperscript{102}

These meetings have been held with the intended regularity.\textsuperscript{103} At a July 1994 summit, however, the then President Delors, Chancellor Kohl (Council President) and President Clinton decided to improve the functioning of the transatlantic summits by having each of the three presidents name representatives to act as "personal contact points" for coordinating and facilitating work by experts in follow-up from, and preparation for, summit meetings.\textsuperscript{104} Notwithstanding the emphasis on high-level political meetings, the Transatlantic Declaration evidently envisages bilateral government contacts at all levels, including what may be considered the "grass-roots" agency level. The importance of developing "an effective working relationship at all levels" has been forcefully underlined by the Commission.\textsuperscript{105} Besides facilitating regulatory convergence, action at the agency level has the capacity to serve as "an early

\begin{itemize}
  \item \textsuperscript{99} Id.
  \item \textsuperscript{100} Id.
  \item \textsuperscript{101} Id.
  \item \textsuperscript{102} Id.
  \item \textsuperscript{103} COMMISSION PAPER ON E.C.-U.S. RELATIONS, supra note 4, at 8-9.
  \item \textsuperscript{104} U.S.-E.C. Summit Marks New Stage in an Expanding Partnership, U.S. REPRESENTATIVE TO THE EUROPEAN UNION, LETTER FROM BRUSSELS, at 6 (Aug. 10, 1994).
\end{itemize}
warning system in order to detect and to resolve trade issues before they develop into political problems.\textsuperscript{106}

The Transatlantic Declaration appears to have generated U.S.-E.C. cooperation chiefly in non-regulatory fields, thus fields lying beyond the scope of this Article. As was probably the signers' intent, discussions held under the Declaration's banner thus far have related mostly to (a) the coordination of U.S. and European foreign policies toward third countries (typically in relation to discrete international crises) and (b) the negotiation and resolution of direct bilateral trade disputes between the U.S. and E.C., notably over allegations of unfair trade practices.\textsuperscript{107} Meetings held pursuant to the Transatlantic Declaration accordingly have dealt with such foreign relations issues as the Iraqi invasion of Kuwait, unrest in Central America and Africa, civil wars in the former Yugoslavia, and developments in the former Soviet Republics and in the other countries of Central and Eastern Europe. The meetings also have focused on trade issues, and, more particularly, on the difficulties associated with concluding the GATT Uruguay Round. In the naturally more confrontational field of international trade policy, each side has adopted the practice of periodically setting out in writing its trade grievances against the other. For its part, the Commission (through the Directorate-General for External Relations) publishes an annual report listing alleged U.S. barriers to trade and investment, and other unfair practices.\textsuperscript{108}

In point of fact, the distinction between trade disputes, on the one hand, and regulatory harmonization, on the other, is not always a sharp one. The Commission’s annual report on U.S. trade and investment barriers explicitly recognizes that trade and investment barriers result from not only the direct exercise by governments of distinct and overtly protectionist trade instruments (taxes, tariffs, customs, quotas, subsidies, dumping and procurement policies), but also from their exercise of conventional regulatory powers.\textsuperscript{109} The 1992 report specifically noted that divergent economic regulations among trading partners, each adopted for valid


\textsuperscript{107} Official accounts of the summits held under the Declaration clearly reflect an emphasis on foreign affairs and bilateral trade relations. See, e.g., COMMISSION OF THE EUROPEAN COMMUNITIES, 27TH GENERAL REPORT supra note 1, at 252-55 (discussing Western Economic Summit).

\textsuperscript{108} SERVICES OF THE EUROPEAN COMMISSION, 1995 REPORT ON U.S. BARRIERS TO TRADE AND INVESTMENT 65 (May 1995).

\textsuperscript{109} Id.
domestic reasons, resulted in significant barriers to trade, and it urged that an "in-depth bilateral dialogue of the type envisaged by the Transatlantic Declaration" be conducted to reduce these barriers. 110

A third category of affairs contemplated by the Transatlantic Declaration covers general cooperation in law enforcement, including such high-profile activities as combating terrorism, international crime and international traffic in drugs. 111 Law enforcement, however, also has its more routine aspects. Two notable cooperation agreements on law enforcement—in the securities and competition law areas—are taken up in a later section of this Article. 112

The Transatlantic Declaration is in fact sweeping enough to encompass transatlantic governmental coordination in virtually any domain in which it might be desirable. 113 Miscellaneous global issues such as overpopulation, nuclear proliferation, unemployment and slow economic growth have all figured on its agenda. More recently, the Commission specifically endorsed the general phenomenon of international regulatory cooperation as an important form of activity to be pursued under the Transatlantic Declaration. 114

C. Legal Limits on Formal Regulatory Cooperation

As the preceding discussion implies, the Commission services enjoy substantial freedom to determine whether and how to act in concert with overseas regulatory authorities. To that extent, their initiatives are governed by political rather than legal considerations. Nevertheless, the Court of Justice's recent ruling in France v. Commission, 115 decided in the context of the U.S.-E.C. competition law agreement, suggests that the Commission is subject to at least certain procedural requirements when it enters into binding legal agreements for regulatory cooperation with other govern-

111. BULL. E.C. vol. 23, No. 11, point 1.5.3, at 91 (1990).
112. See infra part II.D.1.c.i. (discussing mutual assistance in enforcement).
113. Thus, the ministerial meeting held in Brussels in November 1990 resulted in two joint U.S.-E.C. declarations on bilateral cooperation. These announced the establishment of new working parties to foster cooperation in science and technology, on the one hand, and in higher education and continuing training, on the other. BULL. E.C. vol. 23, No. 11, point 1.4.11 (1990).
To the extent that an agreement of this sort obligates the Community toward third party governments, and thus exposes the E.C. to liability under international law, it must be considered as constituting a binding international agreement whose negotiation, signing, and ratification are subject to the specific treaty-making procedures set out in the E.C. Treaty. Therefore, although it may engage in exploratory discussions without any formal mandate or negotiating directive from the Council, the Commission must eventually report to the Council and, in any event, seek a formal mandate before making any formal international legal commitment.

Moreover, the Council alone may ratify a binding international agreement on behalf of the E.C. In reaching the conclusion that the Commission had overstepped its powers by entering into the agreement on its own authority, the Court in France v. Commission rejected several impressive arguments by the Commission, namely:

(a) that the agreement contemplated purely "administrative" cooperation between U.S. and E.C. authorities, rather than cooperation in substantive policymaking, and was thus a mere "administrative arrangement";

(b) that the agreement by its own terms expressly reserved to the signatories the right to withhold cooperation when required by their respective competition law principles;

(c) that the obligations created under the agreement (exchange of information, cooperation, coordination) were extremely limited, and were imposed exclusively on the Commission and not on other E.C. or non-E.C. actors;

(d) that performance by the Commission of its obligations under the agreement would not entail additional budgetary expenditures;

(e) that the Commission could have achieved similar results through a purely oral and informal understanding with the Americans, but had preferred a more visible framework.

116. Id. at 6-7.
117. Id. at 7.
118. Id.
120. Id. at 6.
121. Id. at 7.
122. Id.
123. Id.
(f) that the agreement fell within a sphere—competition policy—in which the Commission enjoys the broadest of policymaking responsibility in the E.C. law context.\footnote{124}

Under the Court's ruling, arguably, the Commission lacks authority to commit itself to following any particular form of cooperation with foreign authorities, including consultation in the preparation of draft regulatory texts or even the sharing of underlying data, without observing the treaty-making procedures laid down in the E.C. Treaty. Under this reading, the Commission may cooperate as fully as it wishes with overseas authorities, without observing any prior formalities, but may not, on its own, obligate itself to do so. Only by entering into a "mere" joint declaration or "gentlemen's agreement," rather than a binding international agreement, may the Commission escape the E.C. Treaty's procedures for treaty-making.\footnote{125}

D. Commission Practices and Policies on Regulatory Cooperation with U.S. Agencies

Even if the Transatlantic Declaration furnishes an overall political framework for regulatory dialogue with the U.S., it provides very little day-to-day machinery for the conduct of that dialogue. Thus, responsibility for determining whether and how to conduct regulatory cooperation with U.S. agencies—and for actually carrying it out—essentially rests with the Commission services themselves. This is consistent with the view that, subject to the strictures of France v. Commission, international regulatory cooperation is a fully appropriate activity for the services to pursue. The first part of this section thus focuses on bilateral regulatory cooperation at the services level. On the other hand, a measure of responsibility for general oversight and coordination of activity at the service level has been assumed by the Unit for Relations with the U.S.A. (organized within the Commission's Directorate-General for External Relations, or DG I) and by a bilateral "Sub-Cabinet Group" headed (for the E.C.) by the Director-General of DG I and (for the U.S.) by the Under Secretary of State for Economic Affairs.\footnote{126} I examine the oversight and coordination functions of these bodies in the concluding part of this section.

\footnote{125} Id.  
\footnote{126} Id.
1. Regulatory Cooperation at the Services Level

Various Commission services have embarked on programs of international regulatory cooperation with U.S. administrative authorities. In most cases, they have acted on their own initiative, out of a belief on the part of officials within the service in question that such cooperation would promote a legitimate Commission objective within that service's sphere of responsibility. The services tend to undertake such initiatives in one of three situations: (a) as a direct rulemaking strategy, (b) as a means of addressing bilateral trade conflicts, and (c) as a means of aiding programs of mutual assistance in enforcement.

a. Regulatory Cooperation as a Direct Rulemaking Strategy: Programmatic Cooperation

In a number of cases, Commission officials have mounted programs of regulatory cooperation with U.S. agencies because, like their U.S. counterparts, they viewed such cooperation as a strategy that might be of use in carrying out their essential rulemaking responsibilities. Typically, they consider some form of institutionalized dialogue with counterpart U.S. agencies to be helpful in establishing the relevant regulatory standards within their sphere of responsibility or in promoting a more fully integrated world market (to the benefit of producers and consumers alike) in the goods and services in question. I call efforts of this sort "programmatic" because they correspond to performance by the Commission of one or more of its central regulatory tasks.

As the following illustrations will show, it is not essential that such cooperation be conducted with the United States on an exclusively bilateral basis.\(^{127}\) Nor do all service-initiated cooperative programs necessarily exhibit the same degree of commitment or intensity. That commitment or intensity may be measured according to:

(a) whether participants commit to collaborating,
(b) whether they meet at regular intervals, with agendas,
(c) whether the collaboration entails the occasional sharing of information and exchange of views, on the one hand, or a determined effort to reach common positions, on the other,
(d) whether the determined effort entails a further commitment to implement what is agreed upon,

\(^{127}\) Truly multilateral cooperation is beyond the scope of this report, but trilateral cooperation certainly is not.
(e) whether deliberations are preceded by joint research and study,
(f) whether what is contemplated are minimum standards or maximum standards or both,
(g) whether and to what extent formal interventions in each other’s domestic rulemaking processes are envisaged, and
(h) whether participants engage in systematic follow-up on questions of implementation.

Those Commission services that have chosen to engage in programmatic cooperation with counterpart U.S. authorities have mostly steered away from high-intensity, high-commitment forms of programmatic cooperation. Thus, very rarely do any of the programs entail (a) the creation of full joint study teams, (b) the parallel initiation of identical regulatory proposals, or (c) a program of formal written intervention in the other’s regulatory processes, to name just a few of the hallmarks of what may be considered to be high-intensity cooperation.

i. Pharmaceutical Regulation

In 1991, the regulatory authorities and industry associations in the E.C., U.S. and Japanese pharmaceutical sectors agreed to cooperate in what has been described as “a very ambitious programme of harmonisation of quality, safety and efficacy testing requirements to avoid unnecessary repetition of costly and unethical testing in humans or animals.”

The following revised terms of reference for this program, known as ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), reveal its breadth and comprehensiveness:
- To provide a forum for constructive dialogue between regulatory authorities and the pharmaceutical industry on the real and perceived differences in the technical requirements for product registration in the [three regions];
- To identify areas where modifications in technical requirements or greater mutual acceptance of research and development procedures could

128. FERNAND SAUER, THE EUROPEAN UNION AND INTERNATIONAL PHARMACEUTICAL HARMONISATION (Apr. 1994). The primary objective was “to reach consensus on the steps needed to achieve greater harmonization of technical requirements for medicinal products, through an active process of discussion, debate and review of science by international experts of the highest calibre.” Martin Bangemann, Welcome Address, in PROCEEDINGS OF THE FIRST INTERNATIONAL CONFERENCE ON HARMONISATION 2 (Brussels 1991) (P.F. D’Arcy & D.W.G. Harron, eds., 1991) [hereinafter BRUSSELS HARMONISATION CONFERENCE].
lead to a more economical use of human, animal and material resources, without compromising safety;
- To make recommendations on practical ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for registration.129

The ICH program is guided by a Steering Committee, which draws its membership from the three regulatory authorities and the industry cosponsors, and is supported by a Secretariat located in the international pharmaceutical regulatory body, IFPMA.130 In November 1991, 1,200 government and industry experts attended the first major ICH conference, held in the presence of observers (notably Canada, the EFTA and the WHO) in Brussels.131 The second conference, attended by 1,500, took place in Orlando, Florida, in October 1993. A third major conference was held in November 1995 in Yokohama, Japan. Between conferences, however, experts' meetings are held at approximately four-month intervals in one of the three regions.132 Oriented by the ICH Steering Committee, the working parties discuss and draft trilateral guidelines and position papers on issues of a more or less technical character, with a view toward their eventual adoption. The ICH Steering Committee has established the following five-step process for this purpose:

**Step 1:** Preliminary discussion by expert working groups mandated by the Steering Committee, culminating in a preliminary draft reviewed by experts until consensus is reached and the draft is in a position to be forwarded to Steering Committee.133

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129. PROCEEDINGS OF THE SECOND INTERNATIONAL CONFERENCE ON HARMONISATION I (Orlando 1993) (P.F. D'Arcy & D.W.G. Harron, eds., 1993) [hereinafter ORLANDO HARMONISATION CONFERENCE]. The ICH has placed an emphasis on safety and efficiency: A truly streamlined regulatory review process will bring the benefits of cost-effective medicines to patients around the world. Toward that end, we must work to make uniform the nature and extent of the evaluation of new medicines in areas of non-biological analytical testing, animal pharmacology and safety, and human efficacy and safety. And we must work to standardise the format and content of the regulatory submissions that document our scientific findings. *Id.* at 17. (opening remarks by William C. Steere, Jr., Chairman and CEO of Pfizer, Inc.).

130. *Id.* at 2.

131. Like its successor conference, the conference was sponsored jointly by the U.S., E.C., and Japanese pharmaceutical regulatory bodies and the U.S., E.C., Japanese and international pharmaceutical manufacturers associations. *Id.* at 1.

132. The U.S., Japan, and the E.C. comprise the three regions.

133. ORLANDO HARMONISATION CONFERENCE, *supra* note 129, at 5.
Step 2: Upon Steering Committee recommendation, the draft is submitted to the three regional agencies for formal consultation under their normal consultation procedures, including outside groups.134

Step 3: After comments are collected, a designated Rapporteur (in consultation with experts) analyzes the comments and amends the draft, which is then referred to an ICH Expert Working Group.135

Step 4: A final draft is endorsed by the Steering Committee which recommends it for adoption by national regulators.136

Step 5: The transposition of recommendations into domestic law.137

Thus far, four ICH harmonized guidelines have been adopted as final and have been transposed into law by the authorities in Europe, the U.S. and Japan.138 They deal with: (a) reproductive toxicity in animals, (b) clinical studies among the elderly, (c) stability testing of new active substances, and (d) dose response information to support drug registration.139 A fifth guideline on clinical safety data management is nearly final.140 Ten additional ICH guidelines are under outside consultation and another six are at the working group stage.141

ii. Foodstuffs Regulation

The bilateral U.S.-E.C. cooperation in food standards regulation appears to be somewhat less formal and less intensive than the cooperation in the pharmaceutical area.142 This may be because discussions between the U.S. Food and Drug Administration (FDA) and the Commission Foodstuffs Unit serve chiefly (1) to pave the way for the U.S. and E.C. to take joint positions on proposed amendments to the worldwide Codex

134. Id.
135. Id.
136. Id. at 6.
137. Id. at 6.
138. ORLANDO HARMONISATION CONFERENCE, supra note 129, at 8-9.
139. Id. at 6.
140. Id.
141. Id. at 6-7.
142. Conversation with Robert Hankin, Deputy Head of Unit, Foodstuffs Legislation and Scientific and Technical Aspects, European Commission, DG III (Industry). All conversations cited to herein were conducted with the author while in Brussels, Belgium, between the dates of October 4 and 28, 1995.
Alimentarius,\textsuperscript{143} and (2) to afford advance warning of trade disputes emerging in the agricultural sector. In addition, of course, the bilateral meetings permit an exchange of views on certain issues that happen not to have been addressed thus far by the Codex, as well as on some very broad issues of principle and regulatory philosophy. The FDA-E.C. Commission dialogue, inaugurated in 1986, is conducted informally on an annual basis. The host country prepares the agenda and ultimately the first draft of a press release. No joint-rulemaking as such has been undertaken within the framework of this cooperation, however, and it is not envisaged in the near future.

\textit{iii. Science and Technology}

Although the two examples just given illustrate differences in both the form and intensity of cooperation, both focus on rather discrete regulatory issues. Programmatic cooperation can also be much more diffuse, however. This describes well the dialogue that has recently been launched in the area of science and technology. A U.S.-E.C. joint consultative group on science and technology, chaired jointly by the Assistant to the U.S. President for Science and Technology and the E.C. Commission Vice-President, held its first meeting in February 1991, and a second the following year.\textsuperscript{144} Its aim is to conduct high-level consultations on science and technology issues and a general exchange of information. Its meetings provide an overview of U.S. and E.C. science policy priorities and a review of ongoing cooperative research and development (R&D) activities.\textsuperscript{145}

\textsuperscript{143.} The Codex Alimentarius, participated in at present by 144 countries, is designed to protect the health of food consumers and to promote fair practices in the food trade. It is promulgated jointly by the FAO and WHO. \textsc{Codex Alimentarius Commission Procedural Manual} (7th ed. 1989) [hereinafter \textsc{Codex Alimentarius Manual}]; \textit{see also} Sub-Cabinet Meeting (Brussels, Feb. 2, 1994) (discussing the objective and means of achieving regulatory cooperation).

\textsuperscript{144.} \textit{See} \textsc{Bull. E.C}. vol. 23, No. 11, points 1.3.86, 1.4.11 (1990) (describing creation and activities of Joint Consultative Group on Science and Technology). The agreement establishing the Joint Consultative Group specifically contemplated creation of a joint task force on biotechnology research which would report to the Joint Consultative Group. \textit{Id.} point 1.3.86. \textit{See} \textsc{E.C. Treaty} supra note 2, art. 152 (allowing "the Commission to undertake any studies the Council considers desirable for the attainment of common objectives").

\textsuperscript{145.} Commission of the European Communities, Press Release, \textsc{E.C./U.S. Consultations on Science and Technology RAPID} (Feb. 27, 1991).
b. Regulatory Cooperation as a Means of Addressing Bilateral Trade Conflicts: Problem-Solving

A second and quite different approach to U.S.-E.C. regulatory cooperation may be described as more problem-solving than programmatic in nature. This situation arises when a U.S. agency or a Commission service considers a particular case of regulatory divergence to be problematic from a bilateral trade point of view. Sometimes it believes the other's standards to be protectionist in intent or exclusionary in effect; sometimes it simply observes that the regulatory divergence is costly to its private sector and thus prejudicial to its trade interests. In these situations, the dialogue tends to proceed more in an atmosphere of negotiation than in an atmosphere of neutral scientific inquiry, with strategies of competition predominating over strategies of cooperation. In fact, the line between simple regulatory harmonization (of which the cases in the previous section may be considered examples) and the settlement of trade disputes can become highly blurred. For this reason, it would be a mistake to exclude these programs from the scope of international regulatory cooperation.

i. Meat Import Restrictions

A perfect illustration of regulatory cooperation arising out of conventional agricultural trade disputes is the coordination of health standards for fresh beef and pork. For years, the U.S. meat industry had complained that the E.C. was improperly restricting U.S. exports through its so-called Third Country Meat Directive, which set strict hygiene and inspection standards for foreign meat plants.\(^{146}\) In May 1991, amidst claims that increasing numbers of U.S. slaughterhouses were being unjustifiably "de-listed" for export to the E.C.,\(^ {147}\) the U.S. and E.C. agreed to make a systematic scientific comparison of their regulatory requirements to determine whether they were basically equivalent.\(^ {148}\) A joint group of U.S.-E.C. veterinary officials conducted the study from November 1991 through April 1992.\(^ {149}\) It showed that while most of the safeguards were basically equivalent, they

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147. Id. In fact the E.C. eventually banned all imports of U.S. pork (in November 1990) and beef (in January 1991). Id. The National Pork Producers Council and American Meat Institute then filed petitions under section 301 of the 1974 Trade Act, and the USTR initiated an investigation. Id. at 49-50.
148. Id. at 50.
149. THE YEAR IN TRADE 1992, supra note 146, at 50.
were accompanied by certain unnecessary legal and administrative requirements which effectively precluded recognition of that equivalence. By May 1992, the parties managed to reach agreement on the remaining equivalency issues. After further negotiations, and further reliance on veterinary experts, the two sides entered into a formal agreement by which they undertook to introduce, within six months from that time, whatever legal and administrative changes were necessary to ensure the mutual recognition of health and safety findings. The accord also provided for: (1) a program of reciprocal site visits of veterinary inspection facilities, (2) acceptance of a principle of "regionalization" in the control of animal diseases, which would require the U.S. to recognize that certain individual Member States were free of specified animal diseases, and (3) agreement by the E.C. to "consider on the basis of mutual agreement, the possibility of approving plants certified by FSIS as being in compliance with E.C. requirements prior to visits by reviewers," a practice evidently then already adopted by the U.S. Interestingly, the parties agreed that this accord "will bind reviewers of both parties and will constitute a satisfactory resolution of the current dispute involving the third country Directive."

**ii. Copyright Protection**

Another instance of international regulatory cooperation undertaken to resolve a bilateral trade dispute is the "dialogue" between the U.S. Patent and Trademark Office (Department of Commerce), on the one hand, and the copyright and neighboring rights division of the Commission's DG XV (Internal Market and Financial Services), on the other. Within that dialogue, priority has been given to the elimination of regulatory disparities considered by either side as constituting unfair competition. A good example is the current negotiation over harmonizing computer software copyright protection. Sometimes the parties address problems that are only emerging, with a view toward preventing full-scale trade disputes. The

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150. *Id.*


152. *Id.* at 3-4.


154. Conversation with Paul Vandoren, Head of Unit, Copyright and Neighboring Rights, and Unfair Competition, DG XV (Internal Market and Financial Services).
joint research and negotiation currently underway to develop computer hardware devices to block the illicit copying of documents illustrate such "early warning" efforts.\textsuperscript{155}

iii. Telecommunications

A further illustration of problem-solving regulatory cooperation is the current program of cooperation between the U.S. Federal Communications Commission and the Commission's DG XIII (Telecommunications) on telecommunications issues. Highly informal dialogue seeks to bring about greater mutual understanding of overall telecommunications strategies—the "U.S. National Information Infrastructure" and "European Information Society," respectively.\textsuperscript{156} It specifically aims, however, to identify and eliminate those regulatory features on either side that have a discernible protectionist effect. This program, which has been described as having a strong bargaining flavor,\textsuperscript{157} permits U.S. and E.C. authorities to intervene formally and in writing in opposition to proposed regulatory action by the other side.\textsuperscript{158} The first meeting of the so-called EU-U.S. Dialogue on the Information Society took place in Washington, D.C., in November 1994. Participation has since been broadened to include also Directorates-General I, III and XV (for the Commission) and the Departments of State and Commerce, and the United States Trade Representative (USTR) for the U.S.

iv. Air Transport

Another trade dispute that has given rise to problem-solving regulatory dialogue concerns restrictions on access to airline-owned computerized
reservation systems. The U.S. Department of Transportation and the DG VII (Transport) have had discussions over the possible protectionist purpose or effect of such systems.\textsuperscript{159} Like many others, these discussions have raised general differences of principle, such as the choice between "national treatment" and "reciprocity" as the applicable standard of international comity. On the other hand, the dialogue over computer reservations systems is not limited to dispute resolution. Much of it is programmatic as well, and thus represents cooperation as a direct rulemaking strategy, as discussed in the previous section. More specifically, the Department of Transportation and DG VIII have taken the dialogue as an opportunity to discuss the structuring of new regulatory provisions on computer reservations systems.\textsuperscript{160}

\textit{v. Public Procurement}

When trade-related problems transcend sectoral boundaries or raise very specific allegations of protectionism, they may require bilateral negotiation at a political level higher than the individual agency or Commission service. The government procurement agreements reached between the U.S. and E.C. in May 1993 and April 1994 exemplify such initiatives. The 1993 public procurement agreement sought to open a combined procurement market valued at U.S. $200 billion.\textsuperscript{161} Negotiated between Commissioner Sir Leon Brittan and U.S. Trade Representative Mickey Kantor, the agreement provided for nondiscrimination and openness in contracts for public works, goods, and certain services awarded by central administrative bodies. The agreement became effective on May 25, 1993, for a period of two years, in the form of a Memorandum of Understanding between the U.S. and the E.C.\textsuperscript{162}

The agreement further provided for a jointly financed, but independent, study of public procurement opportunities between the two sides, as well

\textsuperscript{159} Conversation with Jonathan Scheele, Head of Division, E.C. Commission, DG VII (Transport).

\textsuperscript{160} Letter from Charles Ries, Minister Counselor for Economic Affairs, United States Mission to the European Communities (Mar. 12, 1995).


\textsuperscript{162} The Memorandum of Understanding was concluded for the Community through Council Decision 93/323/EEC of May 10, 1993, concerning the conclusion of an Agreement in the form of a Memorandum of Understanding between the European Economic Community and the United States of America on government procurement, O.J. (L 125) (May 20, 1993). \textit{See also} COMMISSION OF THE EUROPEAN COMMUNITIES, 27TH GENERAL REPORT \textit{supra} note 1, at 253; BULL. E.C., vol. 26, No. 4, point 1.3.30 (1993).
as additional negotiations over "a balanced comprehensive agreement on procurement." The negotiations culminated in a further government procurement agreement of April 13, 1994, signed at Marrakesh, Morocco. Although the latter agreement did not resolve all of the remaining issues (notably government-owned telecommunications issues), it had the effect of nearly doubling the bidding opportunities available on each side. It did so chiefly by permanently covering the electric utility sector and opening up procurement by subcentral government entities.

Whether dialogue over specific claims of protectionism constitutes a form of regulatory cooperation is ultimately a matter of definition. While some might place it in a different category, there is good reason to consider regulatory cooperation and trade negotiations as closely related, rather than strictly parallel, processes.

c. Regulatory Cooperation in Aid of Mutual Assistance in Enforcement

Commission units and U.S. agencies sometimes undertake regulatory cooperation to enhance their conduct of routine investigative and enforcement activities. It may be tempting to dismiss the information-sharing and other forms of cooperation that take place under such agreements as purely administrative in nature. However, because enforcement decisions are the way in which regulatory policy is made in many fields, investigative and enforcement cooperation has a strong regulatory component and performs many of the same purposes as bilateral cooperation in standard-setting. Some agencies also have found that, while mutual assistance in enforcement requires a minimum of substantive regulatory convergence, enforcement cooperation may in turn give impetus to further cooperation in rulemaking.

163. Memorandum of Understanding, supra note 162, art. 5.
i. Securities and Anti-Trust Enforcement

In September 1991, the U.S. Securities and Exchange Commission (SEC) and the European Commission announced their intention to cooperate in oversight of the international securities markets.\(^{168}\) The joint statement (by then SEC Chairman Richard C. Breeden and E.C. Commission Vice-President Sir Leon Brittan) called for a regular dialogue on both policy and enforcement issues.\(^{169}\) More specifically, it contemplated both consultation and an exchange of information between the parties on matters of common interest, including trends in the securities markets and their regulation. This understanding has apparently been implemented with some success.

A similar development is the 1991 agreement between the U.S. and the Commission government for cooperation in competition law enforcement.\(^{170}\) Under the agreement, the parties undertook to notify each other of cases of common interest,\(^{171}\) to exchange information,\(^{172}\) to guarantee the confidentiality of such information, and to conduct regular consultations.\(^{173}\) They further agreed to cooperate when dealing with related cases and, within the limits established by their respective laws, to take account of the other's important regulatory interests.\(^{174}\) The agreement is particularly innovative in its adoption of the principle of "positive comity," according to which both sides may request the other to take action to stop anticompetitive activity adversely affecting their business interests. The

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169. At the time, the SEC already had a memorandum of understanding with the U.K., France and the Netherlands, but these memoranda more specifically targeted cooperation in the exercise of investigative powers. U.S., European Commission Sign Cooperation Pact, REUTERS, Sept. 23, 1991, available in LEXIS, Nexis Library, WIRES File.

170. E.C.-U.S. Agreement on the Application of their Competition Laws, 30 I.L.M. 1487 (1991) [hereinafter Competition Agreement]. The agreement was signed in Washington by Sir Leon Brittan (then Vice-President of the Commission) for the E.C., and William Barr (then acting U.S. Attorney-General) and Janet Steiger (FTC chair) for the U.S. This agreement was, of course, the subject of the Court of Justice ruling in France v. Commission. See supra notes 115-26 and accompanying text (discussing implications of France v. Commission).

171. Competition Agreement, supra note 170, art. II.

172. Id. art. III.

173. Id. art. VIII.

174. Id. art. IV.
other side then must consider and, where possible, act favorably on that request.\textsuperscript{175}

\textit{ii. The Mutual Recognition Agreement}

A similar initiative that has not yet reached fruition is the conclusion of a "mutual recognition agreement" (MRA) between the U.S. and the E.C.\textsuperscript{176} The projected agreement arose out of proposals for the U.S. to allow non-U.S. entities, and for the E.C. to allow non-E.C. entities, to test products for conformity assessment purposes with a view toward certifying them as being in compliance with local health, safety, environmental and more purely technical requirements. The MRA is expected to be developed on a general basis, but with industry-specific annexes.\textsuperscript{177} If achieved, it will not only ease the enforcement burdens on national enforcement agencies, but, in accordance with their principal purpose, also promote bilateral trade in goods.

The MRA negotiations are in some sense an outgrowth of earlier frictions over access by U.S. producers to E.C. procedures for product testing and certification—frictions associated with fears of a "fortress Europe." As part of the 1992 "internal market" program, the E.C. had become heavily involved, both directly and through existing standards bodies, in the establishment of E.C.-wide standards.\textsuperscript{178} Fearing loss of access to this large and potentially protectionist market, the U.S. pressed the E.C., on behalf of U.S. business to facilitate the latter’s involvement in setting E.C. standards and in certifying compliance with them.\textsuperscript{179} As a result of negotiations between then Secretary of Commerce Mosbacher and Commission Vice-President Bangemann, the Commission in May 1989 agreed to establish procedures for involving U.S. business in these


\textsuperscript{177} \textit{Id.}

\textsuperscript{178} The chief European standards bodies are CEN (European Committee for Standards) and CENELEC (European Committee for Electrotechnical Standardization). \textit{PROGRESS REPORT ON E.C./U.S. RELATIONS} 11 (July 1993).

\textsuperscript{179} \textit{PROGRESS REPORT ON E.U./U.S. RELATIONS, supra} note 164, at 11.
activities. The Commission also agreed to enter into discussions over eventual mutual recognition arrangements on product safety and quality. Negotiations are ongoing, with periodic progress reported. While formal requests by the U.S. government and U.S. industry for observer status in European standards bodies largely have been denied, requests for simple participation in the committee work of those bodies are commonly granted. In any case, representations to CEN and CENELEC can be made through the American National Standards Institute (ANSI).

2. Commission-Wide Oversight and Coordination of Regulatory Cooperation

While bilateral regulatory cooperation between the U.S. and the E.C. tends to develop most effectively at the individual agency or unit level, both sides have felt the need for some sort of oversight and coordination mechanism. It is important that the kind of initiatives described in this report not run at cross-purposes with one another or with more general "political" orientations at higher levels of government. This section of the Article deals with the general oversight and coordination functions performed for the Commission by the Unit for Relations with the USA (organized within Directorate-General I—External Relations) and by the U.S.-E.C. "Sub-Cabinet Group." Neither of these units was established with only regulatory cooperation in mind; their spheres of activity are as broad as U.S.-E.C. relations generally. Bilateral regulatory cooperation, however, has emerged as one of their concerns.

a. The Unit for Relations with the USA

Within the Commission’s Directorate-General for External Relations (DG I) is a Directorate B for relations with North America, South Africa,
Australia and New Zealand. In turn, within that Directorate is a Unit for Relations with the U.S.A. (U.S.A. Unit), whose function is to oversee and coordinate relations with the U.S. on all political and economic matters for which the European Union is competent. While the U.S.A. Unit commonly deals with the kind of direct international trade issues (e.g., GATT negotiations, North-South economic relations, anti-dumping, sectoral trade agreements, export promotion schemes) that lie at the core of DG I’s sphere of responsibility, it has given the notion of political and economic relations with the U.S. a very broad construction. Because U.S. and E.C. regulation of economic activity affects bilateral trade (including international economic efficiency and competitiveness), the U.S.A. Unit considers regulatory harmonization in all areas to be within its purview. In other words, while neither DG I nor its U.S. Affairs Unit is primarily responsible for making sectoral regulatory policy on behalf of the Commission, both have an interest in the consequences that such policy may have on U.S.-E.C. economic relations.

The result is that the U.S.A. Unit not only performs the function of coordinating and overseeing the steps that the various Commission services take by way of regulatory cooperation with U.S. agencies within the political and economic arena in which the E.C. is competent, but also assumes affirmative responsibility for promoting such steps. The Unit’s principal vehicle for these efforts is its E.U.-U.S. Interservice Group. This Group gathers representatives from most of the Directorates-General, as well as from the horizontal Commission services (Secretariat-General, Legal Service, Statistical Office, Forward Studies Unit), for periodic discussion of both specific initiatives and overall philosophy.

One of the initial undertakings of the E.U.-U.S. Interservice Group was preparation of a sector-by-sector inventory of issues subject to bilateral cooperation, whether current or projected.184 Discussion items have included the interconnection of telecommunications systems, information security, regulation of global mobile telecommunications, customs cooperation, registration of maritime carriers of dangerous goods, computerized airline reservation systems, licensing of foreign aircraft repair stations, waste shipment regulation, toxic release regulation, integrated pollution prevention and control systems, safety and roadworthiness standards for vehicles, sanitary and phytosanitary regulation, and immigration policy.185 The E.U.-U.S. Interservice Group basically discusses and

185. Id.
determines the appropriateness of bilateral regulatory cooperation with U.S. agencies in these and other specific areas, particularly with a view toward resolving issues that might otherwise lead to bilateral trade disputes. Deciding where cooperative efforts are likely to be fruitless is considered as important as deciding where they are likely to be fruitful. The E.U.-U.S. Interservice Group has performed a periodic "stock-taking" of progress toward regulatory cooperation between the various services and their U.S. agency counterparts. The resulting documents record, once again sector-by-sector, the specific meetings that have occurred and the concrete steps that have been taken. Given the Group's Commission-wide membership, this periodic assessment naturally receives wide circulation and publicity within the Commission.

With regard to regulatory cooperation with the U.S. more generally, the U.S.A. Unit has issued a "Background Paper on Regulatory Convergence." The Unit's most salient conclusions are that:

1. many regulatory divergences result not from protectionist motives, but as an unintended consequence of measures taken for valid domestic reasons;
2. regulatory convergence is more attainable if the polities involved share common economic and regulatory objectives;
3. complete regulatory convergence—in the sense of identical regulation—is ordinarily neither possible nor desirable;
4. on the other hand, elimination of mutually incompatible regulations is essential;
5. regulatory cooperation is desirable irrespective of the specific level at which it occurs or the intensity of the cooperation;
6. bilateral regulatory cooperation is compatible with continued participation in multilateral arrangements;
7. mutual understanding of administrative systems is essential to the mutual confidence required for regulatory cooperation;
8. mutual understanding is also essential to mutual acceptance of the other's tests and certifications of compliance; and

186. Id.
(9) potential divergences should be identified at as early a stage as possible so that they may in fact be avoided.189

b. The "Sub-Cabinet Group"

To give international regulatory cooperation with the U.S. greater visibility and support (and to allow resolution of issues that might otherwise erupt into full-scale trade disputes), the U.S. and the E.C. have placed this activity in a more politically prominent setting, namely a "Sub-Cabinet Group" headed, for the E.C., by the Director-General of DG I, currently Horst Krenzler and, for the U.S., by the Under-Secretary of State for Economic Affairs, currently Joan Spero. The holding of Sub-Cabinet meetings goes back to the early 1980's, though only under the Bush Administration were they placed on a regular basis. The first meeting of the Sub-Cabinet Group during the Clinton Administration took place in April 1993 in Brussels, followed by a second meeting the following July in Washington, D.C. These were the first occasions on which international regulatory cooperation appeared as such on the Sub-Cabinet agenda.190

In February 1994, the U.S.-E.C. Sub-Cabinet Group formally endorsed bilateral regulatory cooperation. The Sub-Cabinet Group underscored the importance of regulatory cooperation in reducing regulatory disparities and facilitating trade, and thus enhancing the transatlantic relationship. To this end, it specifically advocated greater access to information on the respective rulemaking processes and a greater use of international standards in domestic legislation.191 Thereafter, in May 1995, the Sub-Cabinet Group issued a text on "transatlantic regulatory cooperation," which formalized the program.192 The text urges U.S. and E.C. authorities to explore ways of cooperating in their regulatory and enforcement activities, "while still allowing [them to] meet their legitimate health, safety, consumer protection, and environmental objectives, and other broadly shared policy goals."193 According to the text, such cooperation "can help regulators better address

189. BACKGROUND PAPER, supra note 188, at 1-3, 6.
192. E.U.-U.S. Sub-Cabinet Text on Transatlantic Regulatory Cooperation, May 5, 1995, H. Krenzler and J. Spero signed the text for the European Commission and U.S. Administration, respectively. The full text may be found as an annex to PROGRESS REPORT ON E.U.-U.S. RELATIONS, supra note 164.
193. E.U.-U.S. Sub-Cabinet Text, supra note 192.
their programmatic and enforcement responsibilities, improve relationships with regulated industries, minimize unnecessary barriers to trade, and provide better health, safety and environmental data to assist regulatory decisions.\textsuperscript{194} The forms of cooperation urged include sharing technical information and infrastructure, consulting in the development of regulations, early warning of divergent regulatory initiatives (particularly those having trade implications), and establishing mutual conformity assessment, testing and certification regimes.\textsuperscript{195} The text commits the Sub-Cabinet Group to enhancing the visibility and credibility of regulatory cooperation by bringing successful examples of such cooperation to the attention of "the wider regulatory community."\textsuperscript{196}

A series of Progress Reports on E.C.-U.S. Relations published by DG I in collaboration with other interested DG’s and Commission offices reflects the progress made in the many aspects of U.S.-E.C. relations that fall within the purview of the Sub-Cabinet Group.\textsuperscript{197} At first "regulatory convergence," and later "regulatory cooperation," figured as rubrics in these reports, alongside rubrics covering other aspects of the relationship: trade, investment flows, foreign policy, burden-sharing, "fortress Europe," GATT, etc. The reports broadly reaffirm the value of bilateral U.S.-E.C. regulatory cooperation:

Many problems faced by EC or US exporters/investors on each other’s market are not the deliberate result of protectionist inspired legislation but rather the unintended outcome of measures adopted for valid domestic reasons or of the differences which exist between the regulatory systems in the EC and the US. . . . The fact that the EC and the US share a fundamentally similar approach to the question of the market economy and that their citizens and consumers express similar concerns regarding the quality of products and health and environment protection, should however, make it feasible to encourage convergence in regulations and in the legislation on which they are based.

The dialogue set up between the Commission services and the appropriate US regulatory agencies has helped to increase the knowledge of each others’ regulatory systems and move slowly to an increasing acceptance of the validity of the motivation behind differing regulations. . . .

...[F]urther progress along these lines will depend on the level of commitment from both the US Administration and the Commission, to identify relevant areas for future regulation at as early a stage as possible, and to consult and cooperate

\textsuperscript{194} Id.
\textsuperscript{195} Id.
\textsuperscript{196} Id.
\textsuperscript{197} The first such report (no. 0) appeared in May 1993, followed by reports in July 1993 (no. 1), December 1993 (no. 2), March 1994 (no. 3), July 1994 (no. 4), January 1995 (no. 5), July 1995 (no. 6) and December 1995 (no. 7).
in drafting legislation on the two sides of the Atlantic which avoids the creation of additional problems for Transatlantic business.\footnote{198. PROGRESS REPORT ON E.C./U.S. RELATIONS 6-7 (May 1993). In a later progress report, the Commission further remarked that: "[t]he E.U. regards regulatory cooperation as a dynamic process which, if pursued consistently, will contribute to a build-up of good will and understanding of mutual concerns and, which, if successful in one sector, will encourage progress in others." PROGRESS REPORT ON E.C./U.S. RELATIONS 12 (Mar. 1994).}

At their February 1994 meeting, the U.S. and E.C. representatives agreed to launch a "pilot" program of bilateral regulatory cooperation.\footnote{199. European Commission, Office of Press and Public Affairs, E.U.-U.S. Sub-Cabinet Meeting, Feb. 2, 1994, Joint Operational Conclusions (Feb. 4, 1994). See also PROGRESS REPORT ON E.U./U.S. RELATIONS 7 (Mar. 1994).} Under this program, a handful of areas—for example, pesticide regulation, global mobile satellite telecommunications standards, security systems for information, and packaging waste—would be selected for close and monitored regulatory cooperation between the U.S. and European authorities. It was hoped that, besides teaching some general lessons about international regulatory cooperation, an examination of the successes and failures among these initiatives would stimulate further cooperation in still other areas. Toward the end of 1994, however, it became clear that the designation of certain sectors as "pilots" for regulatory cooperation purposes had come to be viewed as problematic, particularly on the U.S. side. Among the apparent reasons were: (1) an aversion to the publicity associated with that designation, (2) fear of an attendant loss of autonomy on the part of the agencies or units primarily involved, and (3) an unwillingness of agencies to take trade considerations strongly into account in fulfilling their regulatory objectives. At its September 1994 meeting, the Sub-Cabinet Group abandoned the idea of a formal set of "pilot" programs of regulatory cooperation.

Priority instead was given to the development of general principles governing the practice of U.S.-E.C. regulatory cooperation, including such "horizontal," or cross-sectoral, issues as access to information in the respective rulemaking processes and the link between international standards and internal legislation. This reorientation thus far has resulted in the above-mentioned formal text on Transatlantic Regulatory Cooperation.\footnote{200. See supra notes 192-96 and accompanying text (discussing text).} Rather than identify "pilot" sectors in advance, the Sub-Cabinet Group chose to encourage regulatory cooperation very broadly and to bring examples, once proven successful, to the attention of the widest possible regulatory audience.\footnote{201. See supra text accompanying note 196.}
The U.S. Mission to the European Communities in Brussels plays an important role in preparing and following up on the Sub-Cabinet meetings. The Mission's work in this respect is headed by the Minister-Counselor for Economic Affairs. Regulatory dialogue between U.S. and E.C. authorities appears to be a priority for the current U.S. Head of Mission, with regulatory differences that have generated trade frictions receiving the greatest attention.

CONCLUSION

An examination of the Commission's policies and practices reveals a high degree of support for bilateral regulatory cooperation with U.S. administrative authorities. Up to the present, the decision whether to engage in some kind of systematic dialogue with U.S. agencies has been left to the discretion of the individual Commission services. In some sectors, the dialogue has become heavily institutionalized. Pharmaceutical regulation is perhaps the best example. There, the participants have undertaken to establish joint agendas, joint research teams and, to a certain extent, common standards. In most other sectors, the dialogue is less comprehensive and less intense. At present, a good deal of regulatory cooperation is conducted in a trade negotiation climate, that is to say, with a view toward resolving regulatory differences that have developed into identifiable trade disputes. With the recent emphasis on "early warning" efforts, however, regulators on both sides have sought to identify and resolve, at an early stage, those regulatory differences that have the capacity to ripen into full-fledged disputes.

Recent "horizontal" developments in the Commission have increased the likelihood that the U.S.-E.C. dialogue will proceed in a more cooperative than competitive vein. This is due largely to the development within DG I of the Unit for Relations with the U.S.A., whose objective it is to encourage and to monitor agency-level cooperation throughout the services. At the same time, the Sub-Cabinet Group has given such efforts a high political profile and a high degree of political support. The 1990 Transatlantic Declaration provides a specific textual basis for both the agency-level and the horizontal initiatives that I have described.

Considering the relatively short period during which U.S. and E.C. officials have engaged in deliberate regulatory cooperation, the scale of activity is impressive and the prospects for expansion are great. The

202. At present, Mr. Charles Ries is Minister-Counselor for Economic Affairs, U.S. Mission to the European Communities.
pattern however, is extremely uneven. In this conclusion, I explore some
of the reservations that the E.C. may have about launching a more
comprehensive and more intense cooperation with the U.S. agencies. I then
turn to ways in which, whatever its level or intensity, the Commission’s
commitment to regulatory cooperation with U.S. agencies might be
increased.

A. Possible Reservations About U.S.-E.C. Regulatory Cooperation

1. Do U.S. Agencies and E.C. Commission Divisions Bring Comparable
   Political Authority to the Dialogue?

   Although in many areas the Commission can only propose, rather than
adopt, regulatory action, it nevertheless effectively speaks in international
fora as the E.C.’s executive branch. Moreover, while divided and
subdivided into a large number of separate services, many of which
undertake separate international initiatives, the Commission ultimately
speaks and acts as a “college.” U.S. agencies—whether organized in the
executive branch or in independent regulatory agency form—are often
unable to instill the same degree of institutional confidence on the part of
their international interlocutors. Not only are they incapable of binding the
President or the Congress, or even state and local governments, but they
may not be able to bind the large number of other organizationally separate
agencies whose policies affect the issues under discussion. At least some
Commission participants in regulatory cooperation activities with the U.S.
have found the U.S. authorities to be unable to commit themselves to a
regulatory course of action even after joint discussions and study between
the U.S. and E.C. have pointed decisively in that direction.203 Moreover,
there seems to be doubt over the commitment of certain U.S. agencies to
the cooperative enterprise—doubt fueled by those agencies’ alleged
tendencies to deviate from international standards and to adopt new
regulatory policies on a unilateral basis.

2. Does U.S.-E.C. Cooperation Present Special Logistical Difficulties?

   On the operational level, E.C. officials engaged in bilateral regulatory
cooperation with U.S. authorities report only modest difficulties. There is
evidently some uncertainty as to which “side” should take the lead on a

203. Conversations with Dr. Alexander Schaub, Deputy Director-General, European
Commission, DG III (Industry), and with Robert Hankin, Deputy Head of Unit, Foodstuffs
given issue or ensure that momentum is maintained. Subject to that reservation, however, Commission officials report that harmonization has not been significantly more logistically difficult to achieve with the U.S., or with Japan, than among the E.C. Member States themselves.\textsuperscript{4} The consensus, moreover, is that whatever problems are encountered—language differences, comparability of technical standards, or differences in regulatory environment, for example\textsuperscript{5}—tend to diminish over time and with experience.

3. How Do Differing Attitudes Toward Transparency Affect Conduct of the U.S.-E.C. Regulatory Dialogue?

Over time, and particularly with the Commission’s increased attention to issues of openness and transparency, what might have been a significant stumbling block to cooperation has largely been avoided. E.C. regulators suggest that while E.C. law still imposes fewer procedural strictures on regulatory policy making than does American law, the disparity has diminished. More important, the procedural precautions that U.S. law may impose—precautions that lie beyond the scope of this Article\textsuperscript{6}—are not generally viewed as incompatible, or even very difficult to square, with E.C. administrative practice. Nor does transparency appear to be irreconcilable with the effective conduct of international regulatory cooperation.\textsuperscript{7}

\begin{itemize}
\item \textsuperscript{204} Conversation with Patrick Deboyser, Deputy Head of Unit, Pharmaceuticals, DG III (Industry).
\item \textsuperscript{205} According to a leading figure in international pharmaceutical harmonization, “one of the main impediments to the promotion of mutual acceptance of foreign clinical data is the differences among ethnic groups and the environments in which they live.” Osamu Doi, \textit{Role and Public Health Responsibilities of the Authorities}, in \textsc{Proceedings of the First International Conference on Harmonisation}, 18, 24 (Brussels 1991). \textit{See also} William C. Steere, Jr., \textit{Opening Remarks}, in \textsc{Orlando Harmonisation Conference}, supra note 129, at 16, 19.
\item \textsuperscript{206} \textit{See generally} George A. Bermann, \textit{Regulatory Cooperation with Counterpart Agencies Abroad: The FAA’s Aircraft Certification Experience}, 24 \textsc{Law & Policy in Int’l Bus.} 669 (1993).
\item \textsuperscript{207} \textit{See Proceedings of the First International Conference on Harmonisation Statement by ICH Steering Committee, Tokyo, Oct. 1990}, point 5 (Brussels 1991); David Kessler, Keynote Address, before the Second International Conference on Hamonisation, in \textsc{Orlando Harmonisation Conference}, supra note 129, at 22, 27.
\end{itemize}
B. Commission Prescriptions for More Effective U.S.-E.C. Regulatory Cooperation

Although I have concluded that the prospects for bilateral regulatory cooperation between the U.S. and E.C. are quite good from a political and administrative point of view, the process can be improved. The following are the recommendations that are most commonly advanced in Commission circles for promoting the process:

1. Coordination From An Early Stage Lessens the Chance That Regulatory Divergences Will Arise in the First Place

As the Commission's emphasis on "early warning" implies, it is easier to avoid future regulatory divergences than to eliminate existing ones. To begin with, the parties are less likely to have taken firm regulatory positions. Moreover, it is less likely that one party will find itself dramatically closer in time than the other to adopting the agreed upon standards. Sharp differences in rates of progress toward a common goal can in fact be a cause of friction in international regulatory cooperation efforts.

2. A Useful Initial Step is to Establish a Complete Inventory of the Licensing, Testing and Other Regulatory Requirements Prescribed By Law

E.C. regulators claim to have learned that, if they intend to launch a broad and lasting program of cooperation with a U.S. agency, rather than merely defuse a specific regulatory dispute, they should initiate the process by drawing up an inventory of existing regulatory requirements. A comparison may reveal that regulatory differences are not as extensive or profound as they were thought to be. Even if it reveals substantial differences, however, a joint inventory affords a useful basis for prioritizing the convergence efforts that are worth making and for maintaining an appropriate balance of mutual concessions as convergence proceeds.

208. See Fernand Sauer, Report on Progress Since ICH I: The European Community Regulatory Perspective, in ORLANDO HARMONISATION CONFERENCE, supra note 129, at 60, 61.

3. **Private Industry Can Provide an Enormous Stimulus to International Regulatory Cooperation**

Major actors in the private sector may be well situated to identify the practical differences in regulatory requirements among regions and to assess the economic and trade consequences that those differences entail. They also may be able to support the scientific research, data collection and data analysis that will provide the raw material for eventually arriving at joint solutions. For all these reasons, regulators have found that encouraging relationships between U.S. and E.C. industry and giving them appropriate access to government-to-government cooperation is very useful in promoting the enterprise. While inclusion of industry in the cooperative enterprise inevitably introduces administrative complications and transparency issues, it is nevertheless decidedly advantageous overall.