

ADMINISTRATIVE PROCEEDINGS INVOLVING EUROPEAN AGENCIES

EDOARDO CHITI*

I

INTRODUCTION

Between 1996 and 2002, 294,625 applications were submitted for Community trademarks and 168,190 were actually registered. In the same period, there were more than 10,000 applications filed for a Community plant variety right, and about 7,000 of these rights are currently in force. And between 2000 and 2002, out of 149 applications submitted to place a pharmaceutical product on the internal market, 113 authorizations were granted.

All these cases have required the intervention of a supranational office provided with a legal personality, known, in the jargon of European Community (EC) institutions, as the “European agency.” Contrary to what one might expect, the relevant administrative action is not carried out exclusively by such an office. Rather, the Community’s administrative function is exercised jointly by a plurality of supranational, national, and mixed authorities, according to a complex institutional design laid down by EC legislation.¹

The purpose of this Article is to reconstruct the peculiar features of proceedings involving European agencies by analyzing the relevant positive law, administrative practice, and case law. This is to ascertain, in part, what is distinctive about these proceedings, as compared to the other procedural models that are progressively emerging in the Community legal order. More generally, the study of proceedings involving European agencies aims at contributing to the discussion about the originality of European administrative law *vis-à-vis* the administrative traditions of the Member States.²

Before beginning this analysis, it is necessary to give a clear definition of what is meant here by “European agency” in order to delimit the exact scope of the inquiry. The expression “European agency” is often used by EC institutions and European scholars with reference to a wide range of organizational models that are not always homogeneous. For the purposes of this study, the phrase “European agency” refers to any Community office that is (a) endowed with legal personality and legal tasks by the

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* Professor of Administrative Law, University of Lecce.

1. Edoardo Chiti, *Decentralised Integration as a New Model of Joint Exercise of Community Functions: A Legal Analysis of European Agencies*, 10 EUR. PUB. L. REV. 1267 (2003).

2. Sabino Cassese, *Il diritto amministrativo europeo presenta caratteri originali?*, 53 RIVISTA TRIMESTRALE DI DIRITTO PUBBLICO 35, 50-51 (2003).

supranational, European legislation, (b) auxiliary to central Community administration, i.e., the European Commission, (c) constituted of a number of collegial bodies composed of representatives of various national and European authorities, and (d) characterized, in functional terms, as essentially aimed at realizing a technical or administrative decentralization ensuring at the same time the collaboration among a variety of national authorities, and between them and the supranational institutions.³ Accordingly, this analysis will not include proceedings involving highly specialized offices that closely assist the Commission, acting outside a systematic and structured relationship with national authorities.⁴ Nor will it consider proceedings before European authorities that are independent of Community central administration, governments of the Member States, and private power.⁵

II

PROCEDURALIZATION AND COMPOSITION OF THE COMPETENT OFFICES

A number of distinctive features characterize the proceedings involving European agencies. The first is that they combine supranational, national, and mixed administrations in the context of “common systems”⁶ created by Community laws regulating particular sectors.

As one might anticipate, these provisions have not delegated European agencies all the powers necessary to carry out the various administrative functions. Rather, these functions have been distributed among a plurality of European and national administrations, as well as among offices composed of representatives of both levels of administration. This requires composite tools, among which is the articulation of the administrative function in procedural sequences that ensure the interconnection and the interdependence between the various competent offices. For instance, Council

3. This is the case in the European Foundation for the Improvement of Living and Working Conditions, the European Centre for the Development of Vocational Training, the European Environment Agency, the European Training Foundation, the European Monitoring Centre for Drugs and Drug Addiction, the European Agency for the Evaluation of Medicinal Products, the Office for Harmonisation in the Internal Market, the European Agency for Safety and Health at Work, the Translation Centre for Bodies of the European Union, the Community Plant Variety Office, the European Monitoring Centre on Racism and Xenophobia, the European Agency for Reconstruction and the European Maritime Safety Agency. For an overall account of the subject see EDOARDO CHITI, *LE AGENZIE EUROPEE. UNITÀ E DECENTRAMENTO NELLE AMMINISTRAZIONI COMUNITARIE* (2002).

4. One such agency is the European Aviation Safety Agency and the “executive agencies” to be entrusted with certain tasks in the management of Community programs. On the latter, envisioned by Council Regulation 58/2003, 2002 O.J. (L 120) I, see Paul Craig, *A New Framework for EU Administration: The Financial Regulation 2002*, 68 *LAW & CONTEMP. PROBS.* 107 (Winter 2004).

5. The most prominent example is the European Central Bank, on which see the detailed analyses by CHIARA ZILIOI and MARTIN SELMAYR, *THE LAW OF THE EUROPEAN CENTRAL BANK* (2001). See also ALBERTO MALATESTA, *LA BANCA CENTRALE EUROPEA* (2003). A more recent example is provided by the establishment of the European Food Safety Authority. See Sabino Cassese, *La nuova disciplina alimentare europea*, in PER UN'AUTORITÀ NAZIONALE DELLA SICUREZZA ALIMENTARE, 13 *et seq.*, (Sabino Cassese ed. 2002). For a synthetic account on the growing tendency to establish independent authorities at the Community level see EDOARDO CHITI and CLAUDIO FRANCHINI, *L'INTEGRAZIONE AMMINISTRATIVA EUROPEA*, 78 *et seq.*, (2003).

6. See Sabino Cassese, *European Administrative Proceedings*, 68 *LAW & CONTEMP. PROBS.* 21, 22 (Winter 2004).

Regulation 40/94, establishing a Community trademark, provides a procedure for registering a Community trademark and a procedure for converting a Community trademark, or a Community trademark application, into a national trademark application.⁷ In both cases, the relevant powers are distributed between the Community office and national industrial property offices according to a criterion of complementariness based on the distinction between decisionmaking and the activities that serve to prepare or execute such decisions. Thus with regard to registration procedure, the offices of the Member States grant the Community office technical assistance, and the procedure concludes with a measure adopted by the supranational administration.⁸ The reverse happens in proceedings to convert to a national trademark application, since the decision on the admissibility of the request for conversion is taken by the competent national office, while the European body forwards the application and all the relevant information to the national office.⁹ The main element of such a process is the mutual assistance afforded by Community and national agencies to one another—that is, relationships in which one office performs tasks that are instrumental to a final decision taken by a second office. It is a reciprocal auxiliary relationship, since either body—the Community or that national office—can operate, according to the particular case, in the capacity of the other.¹⁰ Therefore, the distinction between decisionmaking and assistance activity is not a static relationship between center and periphery, in which the European office is the principal decisionmaker, assisted by national administration. Rather, the Community administrative outline is based upon two complementary and interdependent poles, both of which, according to the procedure, can play the role of main and of auxiliary subject.¹¹

In contrast, interdependence is accomplished in other cases through a more elaborate structure. One example is the centralized procedure of pharmaceutical product authorization, regulated by European Parliament and Council Regulation 726/2004. First, the different offices involved are made interdependent mainly through relationships giving them equal ranking. According to these relationships, established by several procedural provisions, an office is obligated to involve a second office in the proceedings when it exercises a given power.¹² Further, such relationships are established not only between Community offices and Member States' administrations, but also between these and mixed organizations, functional both to the development of a tech-

7. Council Regulation 40/94, art. 36 *et seq.*, 108 *et seq.*, 1994 O.J. (L 11) 1.

8. For instance, the national offices assist the Office for Harmonization in the Internal Market with secretarial activities when the application is filed with the industrial property office of a Member State; they also search their own register of trade marks to assist with Community trade marks applications. Council Regulation 40/94, art. 25(2), 39, 1994 O.J. (L 11) 1.

9. Council Regulation 40/94, art. 109(3), 1994 O.J. (L 11) 1.

10. On the notion of auxiliaryity, see MASSIMO SEVERO GIANNINI, *DIRITTO AMMINISTRATIVO* 317 (3d ed. 1993).

11. Even if the organizational relationships are arranged mainly through procedural means, this does not exclude the provision of some permanent and general relations concerning the activity of the subjects in all the procedures for the administration of Community trade marks. Council Regulation 40/94, art. 86-87, 1994 O.J. (L 11) 1.

12. For a detailed analysis of Council Regulation 2309/1993, 1993 O.J. (L 214) 1, on which the overall scheme for the new regime was laid down by Council Regulation 726/2004, O.J. (L 136) 1, see EDOARDO CHITI, *supra* note 3, at 201.

nical deliberation among experts on specific scientific issues, and to the congruence of national with supranational interests. Therefore, this case is different from the case of Community trademark administration. If in the latter instance each office is called to act as an auxiliary to the others in order to fulfill a Community interest, the centralized procedure of pharmaceutical product authorization represents a legally more complex construction, founded on the juxtaposition (in the context of a procedure regulated by Community law) of plural centers of reference. The resulting pattern is based on the presupposition that public health can be looked after only through the combination of plural and complementary points of view examining the different aspects involved. Scientific analysis is performed by transnational bodies, and the administrative evaluation is carried out by centers of reference representing the national and supranational interest, as well as by bodies that act as a composite of such interests.

These two examples show that Community legislation regulates procedure differently in each policy area. Beyond these differences, however, the European provisions share two elements. On the one hand, the function is proceduralized by European legislation setting down a number of procedural steps which require the intervention not only of Community administrations, but also of national and composite administrations. On the other hand, European legislation establishes a number of organizational relationships between the various public authorities with power in a particular area. These relationships are necessary for functional integration.

This outline identifies what is distinctive about proceedings involving European agencies, as compared to the other procedural models existing in the Community legal order. The concurrence, in various forms, of Community authorities, mixed offices, and national administrations renders such proceedings "composite proceedings."¹³

However, these administrative procedures are subject exclusively to Community law (contrary to most composite proceedings), which establishes and regulates in a very detailed way the participation of supranational and national agencies in rendering

13. The notion of composite proceedings has been initially worked out by CLAUDIO FRANCHINI, AMMINISTRAZIONE ITALIANA E AMMINISTRAZIONE COMUNITARIA. LA COAMMINISTRAZIONE NEI SETTORI DI INTERESSE COMUNITARIO, 174 (2nd ed. 1993). In these terms, it has been used by Guido Greco, who maintains that "the peculiarity of such institutions . . . is given not only by the joined participation (each time with heterogeneous roles and functions) of different authorities belonging to a different order, within a single procedure, but also and mainly by the different regime to which the single segments of the procedure are subject." Guido Greco, *Incidenza del diritto comunitario sugli atti amministrativi italiani*, in TRATTATO DI DIRITTO AMMINISTRATIVO EUROPEO 505, 594-95 (1997). As recently highlighted, various European proceedings can be correctly defined as composite. In particular, it is possible to qualify as composite "the proceedings in which, in different forms, the Commission and the national administrations concur, which excludes, therefore, those in which the States are involved as mere addressees of the Community action, such as in the case of Community measures concerning state aids." See Sabino Cassese, *supra* note 2, at 43. The problematic aspects of composite proceedings, concerning most of all the judicial protection of the concerned subjects, are discussed in particular by Mario Pilade Chiti, *Principio di sussidiarietà, pubblica amministrazione e diritto amministrativo*, in DIRITTO PUBBLICO, 505, 517-19 (1995); Mario Pilade Chiti, *I procedimenti composti nel diritto comunitario e nel diritto interno*, in QUADERNI DEL CONSIGLIO DI STATO, ATTIVITÀ AMMINISTRATIVA E TUTELA DEGLI INTERESSATI. L'INFLUENZA DEL DIRITTO COMUNITARIO 55 (1997); see Claudio Franchini, *Nuovi modelli di azione comunitaria e tutela giurisdizionale*, in DIRITTO AMMINISTRATIVO 81 (2000). For an updated discussion of the notion of composite proceedings, see Giacinto della Cananea, *The European Union's Mixed Administrative Proceedings*, 68 LAW & CONTEMP. PROBS. 197 (Winter 2004). For a general reconstruction of the matter and a functional typology of the proceedings involving a finality of composition, see Sabino Cassese, *supra* note 6.

the final determination. In contrast to many types of composite proceedings, these procedures do not introduce a new layer of procedure on top of pre-existing national procedure.¹⁴ Rather, this form of European legislation establishes a comprehensive procedure, involving and integrating a number of supranational and national authorities. It would be wrong, however, to confuse such proceedings with comitology committees.¹⁵ Although both are set down comprehensively and exclusively in Community law, the nature of the administrative bodies involved is very different. Comitology proceedings involve the Commission and committees composed of representatives of the Member States.¹⁶ In contrast, the proceedings considered here involve decentralized Community offices—European agencies. The European agency replaces the Commission, and national administrative agencies are involved directly, not only through the medium of a national representative as in comitology proceedings.

Other distinctive features can be discerned from administrative practice, features which further improve integration among the competent offices and many of which were not anticipated by the original legislation. The administration of new drug approvals is the most interesting case, since it shows the tendency of the roles of the various offices to overlap and blend rather than remain separate and distinct. For instance, the European Agency for the Evaluation of Medicinal Products takes part, through its experts, in all of the meetings both of the pharmaceutical committees assisting the Commission and of the working groups organized by such committees.¹⁷ Through this device, the scientific expertise of both the Agency and the pharmaceutical committees is integrated. Indeed, the opinions of the scientific committee internal to the Agency, usually adopted unanimously, are generally not the subject of further debate in the Commission's pharmaceuticals committees.¹⁸ Moreover, the officials and experts in the Agency establish informal contacts with pharmaceutical companies and associations representing consumers and patients. The administration of new drug approvals ensures the integration of the many European public bodies involved not so much through a rigid division and distribution of tasks as much as through a fusion of such tasks in a technical-bureaucratic continuum.

14. Guido Greco, *supra* note 13, at 592.

15. Council Decision 468/99, 1999 O.J. (L 184) 1 (laying down the procedures for the exercise of implementing powers conferred on the Commission); *see also* Case C-378/00, Commission of the European Communities v. European Parliament and Council of the European Union, 2003 E.C.R. I-937.

16. On the nature of the comitology committees, *see* Case T-188/97 Rothmans International BV v. Commission of the European Communities, 1999 E.C.R. II-2463; *see also* Case T-111/00, British American Tobacco International (Investments) v. Commission of the European Communities, 2001 E.C.R. II-2997.

17. OFFICE OF THE OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES, THIRD GENERAL REPORT—1997 ON THE ACTIVITIES OF THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS (1998).

18. OFFICE OF THE OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES, SIXTH GENERAL REPORT—2000 ON THE ACTIVITIES OF THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS (2001).

III

PROCEDURALIZATION AND COMPETITION BETWEEN NATIONAL AUTHORITIES

The above reconstruction of proceedings involving European agencies is not comprehensive. In particular, the new drug approval regime presents a number of anomalies. A medicinal product can be authorized either through the centralized Community procedure examined above or through a procedure known as “decentralized authorization” or “mutual recognition.” An authorization granted through the centralized procedure, is valid in all the Member States.¹⁹ The decentralized process operates as follows: (1) the national medicinal agency issues an authorization valid for its territory and based partly on national law, partly on Community law (Directives 2001/82 and 2001/83), (2) the national authorization is recognized by other Member States as valid for their territories too (Directives 2001/82 and 2001/83), and (3) in the event that other Member States deny mutual recognition to the national authorization, a proceeding to resolve the matter is held before the Community authorities (also regulated by Directives 2001/82 and 2001/83).

Contrary to what one might suppose, such a process does not lead to full competition between national and Community laws. The producers of pharmaceutical products cannot freely choose the procedure (centralized or decentralized) that they consider more convenient. Rather, they are bound by the criterion established by Regulation 726/2004. According to this law, the centralized Community procedure is compulsory for medicinal products developed through biotechnological processes, but optional for other pharmaceutical products constituting a significant innovation.²⁰ For all other products—the majority of commercial pharmaceutical products—the producer must obtain an authorization through the decentralized process. The authorization is valid only within the national territory, but following the authorization, the producer can begin the proceedings for recognition of the authorization in the other Member States. Therefore, pharmaceutical companies can choose between these two procedures only with respect to a circumscribed group of products, for which a centralized procedure is optional. The competition between legal systems is, instead, with regard to the relationships between various national laws. These legal systems compete within the decentralized authorization procedure. Therefore, although drug manufacturers cannot generally choose between the Community and the decentralized procedure, they can decide in which Member State to begin the decentralized procedure.²¹

A complex scheme is thus realized. First, the chosen pattern is an alternative to the model of full harmonization, insofar as the national regimes are maintained and the new supranational process coexists with them. Second, the companies active in

19. OFFICE OF THE OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES, SIXTH GENERAL REPORT—2000 ON THE ACTIVITIES OF THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS (2001).

20. Council Regulation 726/2004, art. 3(1-2), 2004 O.J. (L 136) 1.

21. For an enlightening discussion of the search for the most convenient regulatory regime, see Sabino Cassese, *L'arena pubblica. Nuovi paradigmi per lo Stato*, in RIVISTA TRIMESTRALE DI DIRITTO PUBBLICO 601, 637-41 (2001).

this sector of the internal market do not have the option of choosing, from case to case, between the Community and national regime. They are obligated to respect the rule fixed by the European legislation providing the procedure to be followed for the various types of products, and leaving the companies the option to choose only for a limited number of products for which the centralized procedure is optional. At the same time, European legislation, by partially harmonizing national laws, makes it possible for those being regulated, in the context of the decentralized authorization procedure, to choose the Member State and the national regulator considered most favorable to its interests.

In terms of the project of this Article—reconstructing the features of European agency proceedings—this scheme reflects a double regulatory technique. On the one hand, the centralized procedure aims at ordering the intervention of each office in the process of protecting the public interest. This aim is pursued through a procedure based on the joint participation of national, Community, and mixed administrations, but regulated by detailed European legislation. On the other hand, the centralized procedure coexists with the decentralized or mutual recognition procedure, differing from the centralized proceedings in two respects. First, integration of the competent offices is combined with competition between national public powers, so that these are at the same time called to both collaborate and compete with each other. Second, the procedural sequence does not fall under the category of composite proceedings, and is instead made up of a number of connected proceedings. This is because the procedure that chronologically and logically precedes a particular outcome determines the annulment of the subsequent proceedings; but the result of these subsequent proceedings is not conditioned on a positive outcome in the previous proceeding.²²

Understandably, these two patterns are qualitatively distinct from both the pursued aims and the modes through which these aims are accomplished. Their co-occurrence in some of the systems coordinated by the European agencies allows them to maintain that the administrative proceedings perform the function of ensuring the interconnection and interdependence between the various competent offices. But the overall structure laid down by the Community legislation presupposes, in some cases, a certain degree of competition between national public powers. When this happens, the action of the administrations (supranational, national, and mixed) is ordered not in a single Community procedure, but in several (national and Community) interconnected proceedings. In this situation, the public national powers perform dual roles: administrators (as co-authors of the administrative activity), and parties (in case of a conflict whose composition is attributed to the supranational authorities).

The competition between the public powers of the various Members States is rich with consequences. It suggests, for instance, the possibility for the regulated entity to exploit the opportunities resulting from multiple regulators, by establishing implicit

22. On the difference between composite proceedings and procedural sequences made up of interconnected proceedings, see della Cananea, *supra* note 13.

“alliances” with some authorities and by using the possibilities offered by Community law to the detriment of other regulators (and other regulated entities).²³

The importance of competition between national public powers, however, should not be exaggerated. First, competition occurs only in limited circumstances, such as cases in which the procedure gives order to the intervention of the various administrations without creating possible conflicts between them that are quantitatively prevailing. Second, even if it is not a real anomaly of the system, the competition between Member States’ public powers is conceived as a sub-optimal solution, resulting from a political compromise aimed at avoiding an excessive strengthening of the center (the Community) to the detriment of the periphery (the national legal orders). A wider application of the centralized authorization procedure would be preferable to such a solution. This interpretation is corroborated by the administrative practice.

The data collected during the first years of the Community’s legislation on pharmaceutical products illustrates that, in cases in which the centralized procedure is optional—allowing pharmaceutical companies to choose between two possible procedures—the companies prefer the Community centralized procedure rather than the procedure of mutual recognition.²⁴ That is, when it is possible to choose between the two procedures, Community law is considered more convenient by the producing companies.

However, with regard to the decentralized procedure, recent studies²⁵ have shown a hierarchy in the preferences of the producing companies, which tend to choose certain Member States (in particular, the United Kingdom, Sweden, Holland and Denmark) over others (Greece and Luxembourg). Such studies have hypothesized that the choice of the Member State in which the procedure is started is due to specific characteristics of the national administrative system—in particular, the technical knowledge

23. The “games with the rules” typical of the exercise of the regulatory function and connected with the multiplication of the regulators and with the competition among regulatory regimes are discussed by Sabino Cassese, *Dalle regole del gioco al gioco con le regole*, in *MERCATO CONCORRENZA REGOLE*, 276 *et seq.*, (2002).

24. As a matter of fact, for the products for which the centralized procedure is only optional, between 1995 and 2000, 113 were applications for the authorization through the centralized procedure, while 73 were through the procedure of mutual recognition. The statistical data have been collected by the Commission in its Report on the experience acquired as a result of the operation of the procedures laid down in Council Regulation 2309/93, 1993 O.J. (L 214) 1, Council Directive 75/319, chpt. 3, 1975 O.J. (L 147) 1 and in chpt. IV of Council Directive 81/851, chpt. 4, 1981 O.J. (L 317) 1, worked out in October 2001 and forthcoming. However, it should be considered that a comparison of the percentage of applications through the two procedures in the single years shows that the preference for the centralized procedure is not constant: the centralized procedure was preferred in 80% of cases in 1995, 49% in 1997, and 77% in 2000. *Id.*

25. See CAMERON MCKENNA AND ANDERSEN CONSULTING, “CAMERON-MCKENNA-ANDERSEN REPORT” (2000), assessing the functioning of the authorization procedures between 1995 and 1999, available at <http://pharmacos.eudra.org> (last visited Oct. 28, 2004); see also the EFPIA SURVEY ON THE MUTUAL RECOGNITION PROCEDURE (2000), available at <http://pharmacos.eudra.org> (last visited Oct. 28, 2004); see also EVALUATION OF THE OPERATION OF THE COMMUNITY PROCEDURES FOR THE AUTHORISATION OF MEDICINAL PRODUCTS, elaborated by the Commission, available at <http://pharmacos.eudra.org> (last visited Oct. 28, 2004); see also the report by the MUTUAL RECOGNITION FACILITATING GROUP, ANALYSIS OF WITHDRAWALS IN THE MUTUAL RECOGNITION PROCEDURE (2001), available at <http://pharmacos.eudra.org> (last visited Oct. 28, 2004).

and experience of the competent administration, as well as the rapidity of its action.²⁶ On the whole, however, the decentralized procedure is not considered satisfactory to either the involved companies (that complain about increases in already expensive product costs), or the Commission (because of market fragmentation that results from the small likelihood that decentralized procedure will be used to obtain authorizations in all the fifteen Member States).²⁷

IV

THE PROTECTION OF INTERESTED PARTIES

Having examined the composite function among the competent administrations, it is now necessary to investigate the regulation of proceedings involving European agencies—specifically, those proceedings involving the procedural protection granted both to the parties to the proceedings and to third parties. The regulation of the Community trademark again supplies an example. Community trademark regulation provides a wide range of procedural guarantees for the applicant as well as for third parties, both in the specific and general parts of the basic law (Regulation 40/94).

Regarding single procedures, trademark registration procedures grant both the parties to the proceedings and third parties a wide series of procedural rights. These range from the right to be informed to the right to submit written observations and give notice of opposition to trademark registration.²⁸ Regarding the principles common to the various proceedings, procedural phases before the Office that call for giving or obtaining evidence must be adversarial in nature. The parties have to be informed of a witness or expert hearing before the Office, and have the right to be present and to put questions to the witness or expert.²⁹ Above all, the decisions of the Office—which have to state the reasons on which they are based—“shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments.”³⁰

In addition to these provisions, Article 79 of Regulation 40/94 provides that in the absence of procedural provisions in either Regulation 40/94, the implementing regulation, the fee regulations, or the rules of procedure of the Boards of Appeal, the “Office shall take into account the principles of procedural law generally recognized in the Member States.”³¹ This reference in Article 79 should not at all be underestimated,

26. See Sabino Cassese, *supra* note 21, at 638-40. The analysis of the administrative practice allows a more accurate interpretation of the legal regime. On the one hand, it reveals the dynamics primed by a regulatory framework based on the competition among national legal regimes and, though to a lesser extent, between these and European law. On the other hand, it shows the shortcomings of the current legislation and the desirability of an extension of the scope of application of the centralized procedure.

27. See Commission, *supra* note 24. The preference of the European institutions for the centralized procedure has led to the extension of its scope of application by Regulation 726/2004. *Supra* note 20.

28. The most complex case concerns opposition, since it opens an adversarial procedure between the parties on the registration of the trade mark. Regulation 40/94, art. 42, *supra* note 11. For an analysis of the provisions concerning the registration procedure and the other proceedings regulated by Regulation 40/94, see EDOARDO CHITI, *supra* note 3, at 133 *et seq.*

29. Regulation 40/94, art. 76, *supra* note 11.

30. *Id.* at art. 73.

31. *Id.* at art. 79.

since it implies that the Office can, on the one hand, recall the principles already singled out by the Court of Justice (such as the “rights of the defence,” including the equality of arms, the right to be heard, the right to be informed and the right to be represented or assisted), and, on the other, enrich such a catalogue, even if only within the area of Community trademarks.³² Among the principles to which the Office might refer, the principles of administrative law established by the Council of Europe in its study concerning the relationship between administrative authorities and private persons should be included. These principles add to the list of the European Court of Justice the following: the right to make representations to an administrative authority and to submit facts, evidence, and arguments; the duty to complete the different procedural stages within a reasonable time; the public administrations’ duty to notify the individuals concerned of the administrative act; and the duty to implement within a reasonable time those administrative acts that grant a right or safeguard a private individual’s interest.³³

The Community trademarks example is not an isolated case. Granting interested parties several remarkable procedural rights is common to all the provisions governing proceedings involving European agencies—both when they give rise to Community, but polycentric, proceedings (as in the case of proceedings to grant a plant variety right), and when they provide connected proceedings (as in the case of decentralized procedures authorizing pharmaceutical products). More precisely, such provisions are specific applications of the so called “interest representation model,”³⁴ where they impose “a regulation model founded on the participation of interests, so as to ensure decisions grounded on the knowledge of facts and on a reasonable and justified balance of the interests.”³⁵

In this sense, we see a clear connection between the effectiveness of both procedural protections and Community law, since the protection of private actors in the proceedings is functional to guarantee not only their subjective positions, but also the

32. With specific reference to the Community order, see HANS PETER NEHL, *PRINCIPLES OF ADMINISTRATIVE PROCEDURE IN EC LAW* (1999); among the oldest studies, see Albrecht Weber, *Il diritto amministrativo procedimentale nell’ordinamento della Comunità europea*, in *RIVISTA ITALIANA DI DIRITTO PUBBLICO COMUNITARIO* 393 *et seq.*, (1992); Valentine Korah, *The Rights of the Defence in Administrative Proceedings under Community Law*, in *CURRENT LEGAL PROBLEMS* 73 *et seq.*, (1980); for a theoretical perspective on the matter, see CHRISTOPHER BELLAMY, *LEGAL PROTECTION OF INDIVIDUALS, THEIR FUNDAMENTAL RIGHTS AND THEIR RIGHTS OF DEFENCE*, in *LES SANCTIONS COMME MOYENS DE MISE EN OEUVRE DU DROIT COMMUNAUTAIRE*, KÖLN, BUNDESANZEIGER 115 *et seq.*, (1996).

33. COUNCIL OF EUROPE, *THE ADMINISTRATION AND YOU – A HANDBOOK*, (1997). Less detailed, but interesting all the same for its comparative approach, the study of the Italian Consiglio di Stato on the principles of administrative law common to the Member States see *IL DIRITTO AMMINISTRATIVO NEI PAESI CEE: PRINCIPI COMUNI. ATTI DEL COLLOQUIO FRA CONSIGLI DI STATO E GIURISDIZIONI AMMINISTRATIVE SUPREME DELLA CEE* (1994).

34. The main features of the model are, on the one hand, the attention devoted to the emerging of interests that might influence public decisions, and on the other hand, the fact that instead of being hierarchically ordered by the legislation, such interests are compared in the framework of the administrative law procedure. See Luisa Torchia, *I modelli di procedimento amministrativo*, in *IL PROCEDIMENTO AMMINISTRATIVO: PROFILI COMPARATI*, 33 *et seq.*, (Luisa Torchia ed. 1993) (a synthesis of the model); Richard Stewart, *The Reformation of American Administrative Law*, in *HARV. L. REV.*, 1667 *et seq.*, (1975); Richard Stewart, *Madison’s Nightmare*, in *U. CHI. L. REV.*, 335 *et seq.*, (1990); STEPHEN BREYER, CASS SUNSTEIN, AND RICHARD STEWART, *ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT AND CASES* (5th ed., 2002).

35. Sabino Cassese, *supra* note 2, at 47.

full emergence of facts and interests and, therefore, the full effectiveness of administrative implementation of European legislation. This arrangement, based on a consideration of all the interested parties' opinions, is functionally complementary to the co-participation of national, supranational and mixed authorities in the exercise of a Community function.

In contrast with what happens in other areas involving the action of the European Community, these cases do not involve a system founded on the balance between *command and control* on the one hand, and on the other a game of preferences in which national governments are captured together with private actors.³⁶ The provisions under discussion instead give rise to a less flexible model, and one based on a clearer distinction between public activities and private powers. On the one hand, Community, national, and composite authorities work jointly for the exercise of a Community function, according to a scheme in which the need for cooperation predominates over competition between public powers (which is therefore marginal and not considered an optimal mechanism for the working of the European administration). On the other hand, in their role as interested parties, private subjects are called to act in two ways: to supervise public powers' actions and to contribute to the completeness of facts and interest identification and representation in the activities of this transnational "network" of public powers, which stands before them unified, even though this network is based on the participation of structurally separate offices.

This is clear with respect to those hypotheses—representing the central structure of the overall procedural arrangement—in which the European regulation provides proceedings that are composite but minutely regulated by Community law. However, this conclusion is not undermined by the existence of connected procedures. If it is true that in similar hypotheses a more complex game between regulators and regulated is possible, it is also true that there are fewer actual cases in which this more complex game plays itself out. In practice, such a game takes place very rarely. When it does, it does so in a way that cannot be compared to the models of functioning of other areas in the European order.

Finally, the model of "interest representation" is not always sufficiently worked out. The most significant example concerns pharmaceutical products regulation, in which the procedural design turns out to be much less developed than the example concerning Community trademark administration.

Consider first the scarce consideration given to consumers, patients, and interested parties other than the applicant. To them, the European regime dedicates few provisions, providing little encouragement—providing, for example, that "the Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the health professions."³⁷ Moreover, the Agency must publish an assessment report on the

36. This is what happens, for example, in the sector of competition law. For a discussion of this specific type of functioning of the European administration see Sabino Cassese, *supra* note 2, at 42-43.

37. Regulation 726/2004, art. 78, *supra* note 20. Such provision, already envisioned by Regulation 2309/93, has been enforced in three main ways: first, through conferences attended by representatives of industry, national authorities, and Community institutions; second, through annual meetings with the representatives

given medicinal product for human use, drawn up by the scientific committee, and must outline the reasons for its opinion in favor of granting authorization after deleting of any information of a commercially confidential nature.³⁸

The lack of non-applicant interests and procedural rights makes salient a distinguishing feature of the overall regulatory model. In contrast to the experiences of other legal systems in corresponding areas, the Community scheme adopts an exclusively technical approach regarding the risk factor, since the relevant criterion for the analysis of risk is the potential hazard to human beings and ecosystems associated with a given action.³⁹ In other words, risk is defined as the sum total of the expected physical damage and/or of other undesirable effects on persons or ecosystems, calculated on the basis of a scientific study of the relationship between a potentially hazardous agent and its harmful effects observed in persons or other living organisms. The goal of this approach is the identification of possible hazards, and the specification of their probability. The technical analysis of risk factors, performed by scientists operating in the context of Community pharmaceutical administration, is thus not followed by a broader consideration of a cost-benefit analysis, nor is it mediated through processes able to furnish social or cultural interpretations of the undesirable events.

From a more strictly legal standpoint, the greatest gap in the current regulatory framework is that of “equal access of groups to knowledge of what government is doing and contemplates doing and equal access of groups to the discussion leading up to the regulatory agencies’ decisions.”⁴⁰ While recognizing the possibility of multiple options,⁴¹ the question of equal participation cannot be evaded by Community lawmakers: “while equalizing participation in regulatory decision-making may not guar-

of industry, health professions, consumers, and patients; finally, through the promotion of a dialogue with pharmaceutical companies in the initial stages of the research programmes, usually arranged several years before the application of the commercial authorization. In addition to the previous regime, Regulation 726/2004 also provides the possibility that the committees of the Agency “shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organizations and health-care professionals’ associations.” Regulation 726/2004, art. 78(2), *supra* note 20. On the participation of the interested parties in the activities of the Community public powers, see the general studies by Deirdre Curtin, “*Civil Society and the European Union: Opening Spaces for Deliberative Democracy*,” in COLLECTED COURSES OF THE ACADEMY OF EUROPEAN LAW 185 (1999); Lothar Maier, *Institutional Consumer Representation in the European Community*, in EUROPEAN CONSUMER POLICY AFTER MAASTRICHT 89 (Norbert Reich and Geoffrey Woodroffe eds. 1994); Wolfgang Streeck, *Community, Market, State—and Associations? The Prospective Contribution of Interest Governance to Social Order*, in European University Institute Working Papers, 94 (1984).

38. Regulation 726/2004, art. 13(3), *supra* note 20; see also the decision concerning the rules for the access to the documents held by the European Agency for the Evaluation of Medicinal Products, adopted by the Executive Director (Dec. 3, 1997). Available at http://europa.eu.int/agencies/emea/index_en.htm (last visited, Nov. 11, 2004).

39. See the classification by Ortwin Renn, *Concepts of risk: a Classification*, in SOCIAL THEORIES OF RISK 53 (Sheldon Krinsky and Dominic Golding eds. 1992).

40. Martin Shapiro, *Equality and Diversity*, in EUR. REV. PUB. L., 371, 387 (1999).

41. Cf., the debate on the possible codification of principles and rules of administrative procedure in Community law; see Carol Harlow, EUROPEAN ADMINISTRATIVE LAW AND THE GLOBAL CHALLENGE, 17-19 (European University Institute Working Papers—RSC, 98/23), see also Carol Harlow, CODIFICATION OF EC ADMINISTRATIVE PROCEDURES? FITTING THE FOOT TO THE SHOE OR THE SHOE TO THE FOOT (Jean Monnet Chair Papers, European University Institute - RSC, 1995). See also Mark Shapiro, *Codification of Administrative Law: The US and the Union*, in EUR. L. JOUR., 26 (1996).

antee that regulation will yield net substantive gains in economic and social equality, unequal participation will almost certainly guarantee that such gains will not occur.”⁴²

V

ALTERNATIVES TO THE PROCEDURALIZATION OF THE EUROPEAN ADMINISTRATIVE FUNCTION

The proceduralization of the European administrative function constitutes a specific technique of administrative integration. Community legislation has not concentrated the exercise of a certain administrative function in a single body characterized by a particular nature. Rather, it has distributed the attributes necessary to carry out the Community function among a plurality of offices (supranational, national, and mixed), whose integration derives from Community proceedings regulating the time and modalities of the connections among various competent administrations.

Proceduralization of the administrative function also serves a different purpose. Applying the “interest representation” model, proceduralization encourages private subjects to take part in the action of the transnational “network” of public powers, with a view toward controlling the activity of those public powers, as well as toward guaranteeing that recognition and representation of facts and interests are complete.

Let us now briefly consider cases in which the activity carried out by the administrations coordinated by the European agencies is not proceduralized. The examination of the relevant provisions turns out to be useful, allowing alternatives to the proceduralization of the administrative function to be defined as a mechanism of administrative composition. Among the cases so far considered, these non-proceduralized activities are quantitatively prevailing. In most instances, rather than distributing the activity among a plurality of subjects, Community legislation has provided that the activity shall be carried out by a complex organization,⁴³ sometimes defined as a “network.”⁴⁴ This is expressly defined, in functional terms, as the totality of the activities required to accomplish the Community administrative function. In structural terms, it is defined in reference to the totality of the competent offices. Within the framework of such complex administration, the contextually established European agency is assigned the task of coordinating the different competent offices, as well as of specifying and planning their activities. In order to perform this coordination and planning function, non-binding legal instruments are provided, aimed at achieving in a non-coercive way expected standards of behavior for the different competent offices.⁴⁵

Differently from the hypotheses so far examined, therefore, the unified character of the administrative system is not the result of a provision for administrative proceed-

42. Martin Shapiro, *supra* note 40, at 377.

43. Or, using a different terminology, within such a complex organization.

44. See, e.g., Council Regulation 1210/90, art. 4, 1990 O.J. (L 120) 1, as amended by Council Regulation 933/99, 1999 O.J. (L 117) 1 and Council Regulation 302/93, art. 5, 1993 O.J. (L 36) 1, as amended by Council Regulation 3294/94, 1994 O.J. (L 341) 1.

45. This is the case, for example, of the work program adopted by the European Environment Agency and the European Monitoring Centre for Drugs and Drug Addiction. See Regulation 1210/90, art. 8(4-5), *supra* note 44. See also Regulation 302/93, art. 8(3-4), *supra* note 44.

ings and for a complex set of organizational relationships between the various responsible offices. Rather, it derives from an explicit characterization of the relevant Community legislation and from the provisions assigning the European agency specific coordinating and organizational tasks, to be accomplished through “soft law” measures.

The peculiarity of this legal structure lies not so much in the legally non-binding nature of the instruments conferred on European agencies—which orient the activity of the offices they refer to on a non-compulsory basis—as much as in the use of these kinds of instruments, giving rise to a series of operative relationships that allow the development functional complementariness and interdependence among the various competent bodies.⁴⁶

Furthermore, the tools under examination bring into being a set of conditions at once limiting and enabling the involved administrations, for the purpose of making possible cooperative behavior, to the extent that the aim is to reach an agreement on the interpretation of a specific situation or on the mutual coordination of the respective plans of action.

It is on these grounds that it is possible to clarify the reasons for the recourse to similar legal instruments. They seem to find their functional foundation in the peculiar nature of the performed activity, which is characterized by the totality of the interpretative processes arising among the offices assigned the task of producing information, and eluding the cohesive force produced by the traditional organizational and procedural tools.⁴⁷

In addition to this, the complexity of these interpretative processes accounts for the tendency to multiply the hypotheses in which the single offices engage in forms of voluntary cooperation. In other words, order and stability in the administrative network are sought and possibly obtained not only by European agency’s adoption of non-binding measures provided under Community law itself, but also by the development of a panoply of “soft law” instruments that are not specifically contemplated by Community law, and that are aimed at integrating the measures adopted by the supranational body in order to facilitate the effective coordination of the competent offices.⁴⁸

46. The administrative order resulting from recourse to this technique is therefore at once spontaneous and externally determined. It is spontaneous because the relationships underlying it are freely developed in the interactions between the various offices and cannot be pre-defined by the Community legislation. It is externally determined because such relationships take place within the context of a series of non-binding measures adopted by the European agency in accordance with the establishing Community regulation. Moreover, such administrative order has an empirical nature and may be continuously modified and readily adapted to changing conditions.

47. From the perspective of administrative science, the point is further developed in Edoardo Chiti, *supra* note 1; see also Les Metcalfe, *Etablissement de liens entre les différents niveaux de gouvernance: intégration européenne et mondialisation*, in *REVUE INTERNATIONALE DE SCIENCES ADMINISTRATIVES* 139 (2000).

48. This tendency is particularly clear with reference to the administration of environmental information, where the adoption by the European Environment Agency of the work program constitutes the general framework within which a great number of organizational and procedural mechanisms of voluntary cooperation are set up by the single components of the “network.”

Under other profiles, however, the technique of administrative integration through non-legally binding acts seems closer to the technique based on proceduralization of the administrative function, and on the organizational relations among the competent offices. Coordination and planning powers by the Community body tend to produce forms of hierarchical ordering between the various subjects, which makes incorrect the usual political representations of the “network” as a mainly horizontal decisional space.⁴⁹

These two techniques are not necessarily exclusive. They can complement each other depending on the peculiarity of the activity to be carried out. The pharmaceutical products regime illustrates such an example. On the one hand, this regime is structured around the administrative function’s proceduralization and the establishment of a series of organizational relationships among the administrations assigned to accomplish the relevant tasks. On the other hand, it is based on various forms of spontaneous cooperation involving those administrations, which result in a partial modification of the design established by Community legislation.

The non-proceduralization of administrative activity is relevant not only with reference to the mechanisms of administrative integration; it also has to be evaluated with regard to the interests at stake. From this point of view, information production can immediately assume the connotation of an activity instrumental to the development of various administrative functions. It can be aimed at allowing a more effective exercise of decisionmaking powers by the competent authorities in particular policy areas. In specific cases, however, the information process acquires the features of an autonomous public function carried out for the social community, both to enable it to assess the action of the public powers, and to encourage or discourage the behaviour of some actors.⁵⁰

In both cases, however, the information process can be used to regulate private subjects’ behavior, even through different modalities. Sometimes, in fact, the competent public powers work out and publish data with a warning or persuading function to induce the private companies to orient their behavior toward specific purposes (such as environmental protection). In other circumstances, the information process is univocally directed towards the analysis of a technical matter, and toward assisting a certain authority its decisionmaking powers. Such an analysis thus acquires the character of a real opinion.

These remarks raise a problem concerning administrative development. If these observations prevent us from considering studies produced by information networks (and coordinated by European agencies) as technical evaluations resulting from research activity that “is, as such, informal,”⁵¹ the lack of formalized procedures, rules, and principles of administrative action result in surprising gaps under a dual point of view.

49. For an account of this phenomenon in the environmental information sector, see EDOARDO CHITI, *supra* note 3, at 301 *et seq.*

50. From the perspective of political science, this point is made by Giandomenico Majone, *The New European Agencies: Regulation by Information*, in *JOUR. EURO. PUB. POL.*, 262 (1997).

51. MASSIMO SEVERO GIANNINI, *supra* note 10, vol. II at 39.

Environmental information is also affected by risk management—as we can see in the pharmaceutical products regime—in particular regarding interested party participation in the proceedings.

Regarding risk management, there are a number of ambiguities specifically involving the production of information. The area of drugs and drug addiction provides a concise, illustrative example. The Community legal regime in this policy area assigns the role of gathering and managing aggregate (rather than individual) data to the European Monitoring Centre for Drugs and Drug Addiction.⁵² The Centre is thus designed as an office for the study of drugs and drug addiction as a whole, rather than as a branch of police administration responsible for the collection, analysis, and publication of information about individual cases. In practice, however, the data collected often refer to single cases, insofar as the sources of such information are hospitals, courts, prisons, and police stations, all of which transmit the relevant data to the members of the Reitox organization in individual form. Surprisingly, the Community provisions regulating this sector do not in any way regulate the procedures used for conveying information from the source to the recipient: there are no provisions regarding the anonymity, analysis, the selection of data in the information production process. Community legislation has therefore failed to develop an adequate corpus of procedural provisions to regulate the various steps through which each individual case is transformed into aggregate data within the information chain. This specific case shows, more generally, that the production of information is problematic looked at in a number of perspectives; and that issues regarding procedure deserve much greater attention than they receives now under the current legal framework—taking a cue from European statistics, an area in many ways analogous to that of Community information agencies and regulated by a sophisticated set of provisions.

VI

CONCLUSION

This Article has examined, and attempted to reconstruct, the regulation of proceedings involving European agencies. In the context of this attempted reconstruction, five aspects of this procedural arrangement are significant.

First, the proceduralization of the administrative function is instrumental to stabilizing the cooperation between plural competent offices (national, supranational, and mixed), through modes that are subtracted from the negotiation of the single authorities. This implies a specific type of administrative proceeding, which can be considered “Community” in nature. At the same time, however, it is based on the participation of structurally distinct authorities. In some a few, minor cases, however, integration of the competent offices combines with competition between national public powers. Both are thus called to collaborate and compete with each other. Such a

52. Cf. Regulation 302/93 *supra* note 44, as amended by Regulation 3294/94, art.1(5) and 6(2) note 43, according to which the Centre shall not collect any data making it possible to identify individuals or small groups of individuals and shall refrain from any transmission of information relating to specific named cases and shall not publish or make accessible to the public personal data.

different structure is reflected in a distinct procedural technique, characterized by the plurality of national and Community proceedings connecting them.

Second, proceduralization of the administrative function applies the “interest representation model.” Under this model, in order to ensure that fact and interest identification and representation are complete, a relatively elaborate system of consultation mechanisms and private actor participation is at the center of the administrative activity carried out by the complex administration established by the relevant legislation.

Third, these two elements are functionally complementary: they are combined in a framework structured along two main guidelines. On the one hand, Community, internal, and composite authorities work jointly for the exercise of a Community function, according to a scheme essentially aimed at satisfying the requirements of cooperation between public powers. On the other hand, private actors, in their role as interested parties, are called to take part in the action of this complex but unified administration, both of controlling the action of the public powers and guaranteeing that identification and representation of facts and interests will be complete.

Fourth, the proceduralization of the administrative function is not a necessary element to the regulation of European agency activity. Many regulations (in particular, those concerning agencies responsible for coordinating transnational information networks) leave out administrative proceedings provisions and are based on alternative modes for the development of their activities.

Fifth, these pieces of Community legislation lay down an effective and original technique of integration among the variety of competent offices. This shows that the proceduralization of the administrative function concerning the ordered development of the activity actually has possible alternatives, including cases in which the number of the public powers involved is large. The absence of formalized procedures and principles of procedural activity, however, translates into a lack of both procedural guarantees and a real “interest representation model,” which would be useful in the areas in question, given the character of the carried-out activity.

To conclude, let us revisit the question posed at the beginning of this Article: can the distinct aspects of proceedings involving European agencies be considered a confirmation of the tendencies highlighted by the most advanced legal science, with regard to the development of a real European administrative law? The answer is no.

A new element, unknown in the traditions of the Member States’ administrative laws, can be singled out in European administrative law: the development of a specific version of the “interest representation model,” characterized by the involvement in the dialogue and in the debate not only of private actors, but also of States, “reduced to the rank of centers for the care of private interests.”⁵³

On the contrary, in the context of the procedural regulation examined in this Article, the “interest representation model” takes on a different connotation. It stands, first of all, as a mechanism aimed at guaranteeing the consultation and the participation of private parties in the processes of administrative enforcement of Community legislation, with a function both of controlling the action of the public powers and of

53. See Sabino Cassese, *supra* note 2, at 51.

guaranteeing the completeness of the identification and representation of facts and interests. Then, such a mechanism parallels the functional and structural integration of a plurality of public powers (national, supranational, and mixed) in a unified administration by sector, in which the element of the competition between public powers is fairly limited.

This creates a simpler and at the same time less original aspect than the one typical of the paradigm of “public arena.” Simpler, because national administrations and private actors are not called to compete on an equal footing in supporting their own interests and can exploit only marginally the differences of level in the regulation. Less original, because it is characterized by two elements—composition and cooperation on the one hand, and participation on the other—that have undoubted precedents in the national administrative systems. This demonstrates the rich variety of European administrative law, the simultaneous presence in it of both original and traditional institutions, and the sensitive balance between innovation and dependence on the national legal traditions.