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**MISFITS: EU LAW AND THE TRANSFORMATION
OF EUROPEAN GOVERNANCE**

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**MISFITS: EU LAW AND THE TRANSFORMATION
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The analysis of European integration is informed by deeply-anchored views of the ways in which public policy unfolds at the European level. The interpretation of the treaties, shaped by decades of decisions of the European Courts, has given birth to a kind of vulgata that is rarely called into question. Interaction among the main institutional players — the Commission, Parliament and the Council — is held to be the key element in the decision-making process. Hence, *inter alia*, the importance of the concept of ‘institutional balance’ (discussed in the contribution of Lenaerts and Verhoeven in this volume). Adoption of legislative instruments is the integration technique *par excellence*: it was through the 300 or so directives contained in the 1985 White Paper on the Single Market that barriers to intra-Community trade were to be dismantled and, even today, legislative activity is the main parameter by which we measure the growth in the scope of EU activities.¹ Implementation of EU policies is constrained by choices made in the legislative phase; it is thus perceived to be of secondary importance and generally receives less attention. Classical views about institutional balance simply stress that, in theory, the implementation of EU policies remains in the hands of national administrations.

This legislative bias is equally pervasive in normative assessments of EU policies. One generally discusses legitimacy issues in relation to legislative activities: the classical description of the ‘democratic deficit’ rests entirely on the role played by legislative assemblies in decision-making procedures. The European Court of First Instance has also made the clear suggestion that alternative forms of legitimization – such as the participation of management and labour representatives in decision-making processes – mattered only ‘in the absence of the participation of the European Parliament in the legislative process’.

However, a gradual shift has occurred in European governance in the wake of the single market program. The European Union has assumed new tasks that are largely linked to what is increasingly referred to as ‘risk regulation’; that is, the assessment and management of risks that may result from natural events or human activities. It has also become apparent that – unlike the mere removal of trade barriers – managing a single market entails a degree of positive action that does not always fit within the neat legal categories inherited from the past. New actors have emerged, such as European administrative agencies and others, such as intergovernmental committees, have seen their roles deeply transformed. Scientific expertise has acquired an unprecedented level of importance. Traditional legal categories have therefore ceased to adequately reflect the actual operation of the EU’s machinery. How should one react to this mismatch between law and reality? Should one return to the purity of the classical model? Or has the time come to envisage a paradigmatic shift?

This contribution tries to address these issues. It is organized as follows. Section 1 highlights the main transformations occurring in European Union governance. The next sections try to demonstrate the growing gap that has emerged between new patterns of governance and traditional legal analyses. It does this by focusing on three sets of issues: comitology (section 2); the powers that can be conferred on specialized European

agencies and other bodies whose existence was not contemplated by the EC Treaty (section 3); and the role of scientific expertise (section 4). Section 5 returns to the discrepancy between legal perceptions and functional realities.

1. The Transformation of European Governance

The past fifteen years have seen a deep transformation in the way in which the European Union functions. Some elements affect the whole range of European activities, albeit to different degrees. A good example is the emergence of the European Parliament as a key actor in European policy-making. Other transformations can be seen as the result of a shift in the kind of tasks undertaken by the European Union.

While European integration has long been associated with market unification, there has been a significant expansion in the nature of EU activities. The EU has moved beyond the realm of economic regulation into areas such as environmental and consumer protection, and health and safety issues. Although this expansion process was initially founded on a rather tenuous legal base, it has been ratified by successive Treaty changes: the Single European Act, and the Maastricht and Amsterdam Treaties consolidated European intervention in the area of social or risk regulation. First, they explicitly recognized the competence of the European Community to deal with these issues, and second, they brought about a gradual shift to qualified majority voting that simplified decision-making. The reasons for this gradual Europeanization of regulatory policies are simple. The division of labour outlined in the Treaty of Rome – with the European Community focusing on economic integration while social regulation remained primarily under the Member States' control – resulted in de-regulatory pressures as the EC set out to dismantle non-tariff barriers to trade. It therefore emerged that the only way to reconcile market integration with ambitious social regulation programs, and to thus avoid trade distortions, was to develop such programs at the European level. Combined with the fact that European firms often prefer to comply with a single European rule rather than fifteen different rules, this element generated growing pressures in favour of the development of European regulation.

This transfer of powers from the national to the European level has been accompanied by a transformation in the conduct of European policies. The prototype of European interventions were primarily of a legislative kind; the 'approximation of laws' contemplated in the EC Treaty. Yet the classic dichotomy between legislation (assumed to deal with broad principles) and implementation (understood as the mere application of those principles) is particularly ill-suited to activities undertaken by public authorities in a risk regulation framework. By their very nature, the problems dealt with in such a framework cannot all be anticipated in the legislative phase; the precise nature of the hazards, the likelihood that they will materialize, and the kind of response they will require are often fairly uncertain. Not only will the technical nature of the likely problems require use of expert knowledge at various stages of the process but, equally importantly, implementation decisions often acquire a significant political salience. Consumers are more likely to show interest in an administrative decision about whether or not to

authorize the marketing of Viagra, than in a decision about the adoption of broad (legislative) principles spelling out the safety and efficacy conditions that a pharmaceutical product must satisfy before it can be licensed. In other words, risk regulation has led to the development of a new kind of function – ‘political administration’ – that is not easy to fit into the classic categories of public law. In an integrated market, this function must clearly be exercised in a uniform – though not necessarily centralized – fashion, lest dismantled legislative barriers are replaced by newly emerging administrative obstacles. At the very least, a convergence of scientific risk assessment and administrative practices is required.

Interestingly, the years following the completion of the single market program have seen a marked decline in the volume of primary legislation (that is, of new legislative initiatives), adopted by European institutions, as is demonstrated by Figure 1. Although the total number of directives and regulations has remained fairly stable, this is largely due to the fact that implementation decisions – the functional equivalent to delegated legislation at the European level – often have the same form as primary legislation because Community law ignores any clear hierarchy of norms. The data shown in Figure 1 can therefore be read as confirming that a large number of EU decisions are now being made in the post-legislative phase.

Figure 1

Proposals for primary legislation introduced by the European Commission

Sources: Reinforcing Political Union and Preparing for Enlargement, Commission Opinion for the Intergovernmental Conference 1996, 1995, p.87, for years 1990-1995; COM (95) 512 final for year 1996; SEC (96) final for year 1997; for year 1998; [tp://europa.eu.int/comm/off/work/1999](http://europa.eu.int/comm/off/work/1999) <http://europa.eu.int/comm/off/work/2000> for year 2000.

This shift is far from being merely formal. It suggests that important decisions are now taken by other actors – technocrats (be they bureaucrats or scientific experts) instead of politicians – and according to procedures that do not necessarily allow for the degree transparency or citizen participation required by a democracy. The problem is compounded at the European level by the fact that risk regulation is at the crossroads between national and EU competencies, and intermediate structures had to be established in order to bridge the gap between the two levels. The evidence suggests that the importance of these structures is growing: ten European agencies have been created over the last decade to connect national administrations with a (modest) European structure, and the frequency of committee meetings appears to be increasing.

Europe is therefore confronted with a phenomenon akin to the emergence of what some American authors have described as a technocratic ‘fourth branch of government’. There are clear differences between the two shores of the Atlantic: in the EU, the distinction between legislative and executive functions is far from being as clear cut as that in the United States (where each function is given to a different branch of government). Similarly, US administrative law has struggled to define the proper status of *federal* agencies whereas European technocratic structures have a clear *multilevel* character, given their role as a connecting device between the EU and national administrations. Notwithstanding these differences, the growing importance of technocratic governance has given rise to serious legitimacy concerns in both cases. It has also represented an analytical challenge for legal systems that were accustomed to regard administrative decision-making as necessarily constrained by the will of the legislator. The *aggiornamento* is still to be done in the EU context: legal treatment of technocratic governance structures remains informed by a somewhat dated view of their role, as we shall now see.

2. Comitology: Intergovernmental Control or Deliberative Networks?

Government by Committees and Institutional Politics

The body of literature looking at the role of intergovernmental committees in the EU

system has expanded significantly in recent years. It is therefore sufficient to highlight a few elements of relevance to the overall argumentation of this contribution.

The Treaty of Rome was fairly elliptic with regard to the implementation of Community measures: Article 155 contemplated the possibility that the Council of Ministers would delegate to the Commission the right to adopt implementation measures. However, national governments have been wary of granting too much discretionary power to the Commission, and they have often obliged the latter to consult a committee of national representatives prior to making a decision.

Whereas the procedures regulating relationships between the Commission and those committees have varied a lot, there is broad agreement on a number of points. First, committees are viewed as a mere control device and are deprived of their own decision-making powers: the final word rests either with the Commission or, more rarely, with the Council. This enabled the Court to rule that the management procedure was not contrary to the institutional balance established by the Treaty. Second, committees are widely seen as the instrument of a principal-agent relationship between the Council and the Commission. In the same ruling, for instance, the European Court of Justice argued that '[t]he function of the management committee is to ensure permanent consultation in order to guide the Commission in the exercise of the powers conferred on it by the Council and to enable the latter to substitute its own decision to that of the Commission.' Finally, clear limits are supposedly assigned to committees' powers: according to the procedures established by the Treaty, 'basic elements' of the matter to be regulated must be decided by the Council itself. The committees are supposedly confined to implementation issues.

Such a view is symptomatic of a traditional understanding of the dynamics underpinning the integration process. Not only does it hold legislative procedures to be the most legitimate form of decision-making, but it attaches great importance to the necessity of achieving a balance of power between the Commission and national governments (which are implicitly regarded as unitary actors acting in a cohesive fashion).

Institutional politics have shown that this view was shared by almost all of the actors that are active on the European scene. The Commission has long fought against the most restrictive of the committee procedures, notably the *contre-filet* variant of the regulatory committee procedure, which it regarded as a burdensome interference in its implementation powers. The Single European Act's failure to simplify comitology procedures was one of the main reasons for the Commission's initial reservations concerning that Treaty. During the Delors years, the Commission made no secret of its loathing for comitology. For its part, the European Parliament has repeatedly declared its aversion to a system that it perceived to be an undue restriction of the Commission's regulatory powers. Of course, this a position was largely explained by the fact that it enjoys more influence over the Commission than over the Council of Ministers. Thus the Parliament has frequently used its powers to oppose overly stringent procedures: the first instance in which a Council's common position was rejected in co-decision procedures arose because of a dispute over the proper implementation procedure. Similarly, in the post-Maastricht years the European Parliament brought several cases before the Court of

Justice when it deemed its prerogatives to be threatened by decisions of other institutions. Conversely, the Member States' frequent insistence on imposing stricter procedures, notwithstanding their own commitment to favour advisory committees for internal market legislation, illustrates their unwillingness to give free reins to the Commission. Thus, all the main institutional actors appear to agree on a vision of comitology as a rather traditional mechanism of intergovernmental control.

Yet, turning to the actual operation of the system, there is no shortage of evidence to present a radically different picture of the very same phenomenon. While official discourse would lead one to expect systematic confrontations over the proper role of committees, day-to-day reality seems to have been much more consensual. Of the thousands of opinions submitted by committees in the period between 1993 and 1995, only six cases were referred back to the Council, and none of these led to a failure to decide. Moreover, accounts of committee members suggest that voting tends to be a rare event, and that the Commission – which chairs committee meetings – exerts considerable influence over their work. This might explain why the Commission has often been prepared to agree with the Council on the procedure to be chosen, notwithstanding its proud declarations to the contrary. Empirical works have depicted committees as peer structures in which the quest for consensus is a prevailing concern. In a now famous contribution, Joerges and Neyer have suggested a radically new vision of comitology as a forum for 'deliberative politics' in which all participants engage in the search for the common good.

Interestingly, there has been a change of attitude in recent years, even among European institutions. Once so critical of committees, the Commission has now adopted a more conciliatory tone. In its proposal for a new framework decision on comitology following the Treaty of Amsterdam, the Commission deliberately omitted any provision aimed at enhancing the transparency of comitology proceedings, lest (it was said) this might alter the quality of interaction with national officials.

B. Who watches the Watchmen? The Need for New Legal Constructs

The consensual nature of the exercise undoubtedly has positive aspects, if only because it lessens the risk of institutional conflicts and provides for the smooth functioning of the EU regulatory system. Yet it brings its own set of problems. In a period of widespread mistrust of technocratic structures of all kinds, consensual deliberations between well-intentioned experts who meet behind closed doors to avoid unwanted interference, may easily be resented as collusion between technocrats. If intergovernmental control mechanisms no longer fulfil the task for which they have been established, and if comitology has indeed evolved into a freewheeling transnational structure, the key question becomes: who controls this structure, and how? Hence, *inter alia*, a request for more transparency and for participatory rights in committee procedures.

Problems arise at different levels. The rather poor transparency of the committee procedures 'make it difficult to discern the part played by the committees in the formulation and eventual adoption of measures'. It also tends to complicate judicial

review of committees' work as they are deprived of decision-making powers of their own. True, the validity of the decisions eventually adopted by the Commission or the Council at the end of a comitology procedure can always be challenged: in recent years, the European Court of Justice has indeed started to look more closely at the functioning of committees, particularly when their procedural rules were allegedly violated. Needless to say, the indirect character of the review process, compounded by the more general difficulty experienced by private parties seeking annulment of Community decisions, reduces incentives to rely on litigation to ensure the proper functioning of committees.

Similar concerns have led to a gradual shift in judicial perceptions of the legal status of committees. This is exemplified by the *Rothmans* case. Under the access rule contained in Decision 94/90, a well-known cigarette manufacturer had requested to the Commission the minutes of the Customs Code Committee. The reasons for the application were simple: like all 'comitology' committees, this one did not have its own administration, budget, archives or premises, nor an address of its own (as the Court of First Instance subsequently noted). It therefore appeared natural to turn to the only permanent member of the network – the Commission – which chairs the Committee and performs secretarial duties. Yet Decision 94/90 provides that applications must be sent 'direct to the author'. The Commission thus rejected the application, arguing that it could not be regarded as the author of the minutes 'in the intellectual sense' because it was subject to the Committee's control even though, in practice, it held the pen for the Committee.

Although the Commission's decision merely reflected the traditional construction of comitology's role, it gave rise to an embarrassing situation. Committees are supposed to be an emanation of the Council, which does not generally hold copies of Committee documents. Thus, in practice, the Commission's conclusion amounted to an exclusion of comitology from the scope of rules regarding access to Community documents.

In such conditions, adherence to the traditional view of committees would have ended up frustrating the principle of transparency to which European institutions have given so much importance in recent years, as Sweden, a notoriously transparency-minded government, promptly argued before the Court. Thus the Court preferred to rule that 'for the purposes of the Community rules on access to documents, "comitology" committees come under the Commission itself, (...) which is responsible for rulings on applications for access to documents of those committees.' In order to avoid a situation in which it would be nearly impossible to hold the actual authors of a decision accountable, the Court of First Instance decided to adopt a radically new reading of the role of Committees. A stroke of the pen transformed them from control bodies into structures subordinate to the very institution they were supposed to control.

Rothmans is an interesting ruling in several respects. First, it is symptomatic of the paradigmatic shift in the perception of committees. The Court was faced with a tension between classical constructions in which committees are viewed as a control device, and the actual operation of the bureaucratic machinery where the dividing line between the various actors is somewhat fuzzy. Second, it illustrates a difficulty inherent in the emergence of transnational bureaucratic structures at European level: keeping them

under control is made more difficult by the discrepancy between their legal status and their actual role. To avoid creating a black hole in which important decisions could be made without any control, the Court had no choice but to opt for an innovative reading of the situation, in which ‘comitology’ committees and the Commission are depicted as forming part of the same network-like structure. This concession to pragmatism is noteworthy as, in other areas, traditional legal constructs have stood in the way of an acknowledgement of the changing conditions in which European governance structures now operate.

3. European agencies: Delegation v. Accountability?

The Growth of European Agencies

Quantitatively and qualitatively, the mushrooming of specialized European agencies is one of the most interesting developments in the functioning of EU bureaucracy in the post-Maastricht years.

To better illustrate this, a general remark is in order. The Commission is by far the largest sector of the EU’s administration: in 1999, the number of authorized staff totalled 21,438 persons (including temporary agents), compared to 4,102 in the European Parliament and 2,671 in the Council of Ministers. However, the staffing of both the Council and Parliament – although starting from a much more modest base – recently appears to have grown at a faster rate than that of the Commission. This is noteworthy, given the expansion in the scope of EU policies registered at Maastricht and Amsterdam. As indicated above, the growing role of the EU in the field of risk regulation does not merely entail the adoption of legislative rules; it also requires an elaborate apparatus for scientific assessment, as well as decisions about risk management that must be taken at the European level. One might thus have expected this evolution to be reflected in a sizeable growth of the Commission, but this does not appear to have been the case. Between 1995 and 2000, Commission staff (including clerical and logistical support staff, as well as translators) increased from 15,836 to 17,087. In roughly the same period, ten European administrative agencies with a total staff of 1,045 were created. These covered areas ranging from the environment, or health and safety at work, to racism and xenophobia, and reconstruction in Kosovo. These figures provide a simplistic, yet arguably telling, picture of the contradictory trends at work. On the one hand, national governments keep enlarging the range of missions entrusted to the Union; on the other hand, they are reluctant to accept parallel growth in the means with which the Commission (symbol of the loathed Brussels Eurocracy) is endowed. It is known that the tension between these two logics has resulted in the managerial inadequacies – massive outsourcing, absence of control, and ultimately corruption – depicted in the report of the independent experts that prompted the resignation of the Santer Commission. However, beyond these pathological episodes, the same structural contradictions have also played a key role in the emergence of some kind of functional decentralization within the EU bureaucracy.

Most of the agencies created in recent years appeared as responses to the growing need for administrative assistance in the preparation of EU policies and their implementation. The existing agencies can be grouped in three broad categories:

information agencies, whose main function is to gather information and to liaise between national authorities and EU administrations;

implementation agencies, entrusted with the duty of implementing the EU regimes in highly specialized areas such as trademarks or plant variety rights;

management agencies, which assist the Commission in the management of EU programmes.

The trend towards the establishment of specialized administrative structures seems to have been encouraged by the criticisms levelled at the Commission's managerial capabilities in recent years. The establishment of agencies for food safety, aviation safety and maritime safety is currently contemplated, and others are said to be following. This might be seen as an indication that the evolution towards a greater devolution of administrative responsibilities to European structures is fairly uncontroversial. However, the situation is more complex.

Following the lead of Giandomenico Majone, some scholars have been arguing that the establishment of specialized agencies was a positive development in its own right, likely to improve the effectiveness and the credibility of European regulatory policies. However, reactions within the relevant policy communities have shown far less enthusiasm. Commission officials have warned against a development that might lead to the establishment of rival structures and that they thus view as a threat to their institution. Commission President Romano Prodi was most explicit in this respect. In a speech before the European Parliament on 3 October 2000, he made a vibrant plea in favour of the necessity of preserving the Commission's authority over specialized agencies. On their side, national administrations have often insisted on retaining a measure of control over the work of agencies.

All this has led to the establishment of a system of checks and balances aimed to ensure that agencies will not emerge as structures that are likely to be too autonomous in their operations. All existing agencies are therefore governed by administrative boards composed of national representatives, to which an expert appointed by the European Parliament is occasionally added. Great care has also been taken to ensure the smooth co-operation of European agencies with their national counterparts, particularly for those agencies that enjoy autonomous decision-making power (such as the Trademark Office) or that are entrusted with the responsibility to prepare decisions to be made by the Commission, as is the case for the European Agency for the Evaluation of Medicinal Products (EMA). Last, but not least, agencies' powers have generally been defined fairly strictly. Most of them have been denied any decision-making power of their own. The regulation establishing the Lisbon Drug Monitoring Centre made it explicit that '[t]he Centre may not take any measure which in any way goes beyond the sphere of information and the processing thereof'. Whereas the Commission's initial proposal foresaw the possibility that the EMA would make autonomous decisions about certain procedural matters – such as the format of the application for marketing authorizations –

the regulation that was ultimately adopted denied the Agency even this limited degree of autonomy. Even the above-mentioned ‘implementation agencies’, which were given narrowly-defined executive powers to implement specialized EU regimes, are subject to a legality control by the Commission.

A more relaxed attitude seems to have emerged in recent times. Council Regulation 2454/1999 of 15 November 1999 has granted to the European Agency for Reconstruction in Kosovo wide powers to manage external aid programmes, which appears to encroach upon the Commission's budgetary powers ex Art. 274 EC. The Commission proposal for the establishment of a European Aviation Safety Agency also envisages the possibility that the latter might adopt non-binding ‘guidance material’; coupled with the power to issue individual decisions, this comes close to an independent regulatory power, as has been shown by the Commission's experience in the field of competition policy. Recent proposals also suggested that the administrative boards of yet-to-be-created agencies might not include representatives of the Member States. This seems to reflect a hope that the credibility of these new bodies will thereby be strengthened.

Notwithstanding these signs of greater openness, a strong anti-delegation bias seems to prevail. The explicit conferral of regulatory powers on autonomous agencies is perceived to be encroaching on the Commission's own implementation powers. Even more symptomatically, although Commission President Romano Prodi had initially called for the establishment of a ‘strong’ regulatory body at the EU level in the wake of manifold food scares, the Commission's own proposal did not even suggest providing the European Food Authority with autonomous power to adopt individual decisions.

3.2 Meroni and the non-delegation doctrine

This reluctance to delegate decision-making powers to decentralized bodies is allegedly based on the rather restrictive case law of the European Court of Justice. As early as 1958, the Court's famous *Meroni* ruling set out a series of conditions that had to be met if delegations of power were to be admissible. The Court admitted that it “cannot be excluded” that power might be delegated to bodies whose existence was not contemplated by the Treaties, if doing so appears compatible with the regulatory powers conferred on the institutions (in the case at hand, the High Authority of the Coal and Steel Community). However the ruling also specified that such delegation is permissible only when “it involves clearly defined executive powers the exercise of which can, therefore, be subject to strict review in the light of criteria determined by the delegating authority”, whereas delegation of “a discretionary power, implying a wide margin of discretion” is to be excluded in all cases. The Court justified this restrictive position by stressing that the balance of power between European institutions is “a fundamental guarantee granted by the Treaty in particular to the undertakings and associations of undertakings to which it applies”. It added that the delegating authority could not confer any powers other than those that it had itself received under the Treaty. Delegated powers are thus to be subject to the conditions that would have applied if the delegation had not taken place; treaty

rules on publicity, the giving of reasons, and judicial review, cannot be evaded by transferring powers to outside bodies.

Although given in the framework of the ECSC Treaty, this ruling is generally considered to be valid within the wider Community legal order. However, this view appears to neglect the important differences that exist between the institutional settings created by the various treaties establishing the European Communities. The Coal and Steel Community was a largely integrated system in which the High Authority had been endowed with important regulatory powers. In contrast, the Treaty of Rome is regarded to be a mere “framework agreement” that establishes a system in which broad objectives are to be reached gradually through legislative decisions. These basic elements are important in order to assess the relevance of the Meroni precedent in the context of what is now the European Community.

The factual situation that gave rise to the Meroni dispute is worth recalling. Article 53 ECSC confers power upon the High Authority to make financial arrangements common to several undertakings. On that basis, the High Authority adopted a decision establishing a financial arrangement for ensuring a regular supply of ferrous scrap. The implementation of this agreement was entrusted to two private law funds established in Brussels, which enjoyed broad autonomy in the operation of the equalization scheme. The Court therefore concluded that the High Authority had delegated a power it enjoyed by virtue of the Treaty. Situations of this kind are rather rare in the EC context, where decisions taken by the European institutions are usually to be implemented by national administrations. Assuming implementation powers are to be given to some administrative agency, those powers would rarely be taken away from a Community institution; they would instead be removed from national administrations. Indeed, prior to the establishment of EMEA or OHIM, marketing authorizations for medicinal products were delivered, and trademarks were registered, by national bodies rather than the Commission.

The concept of delegation is therefore quite ill-suited to such situations; as the Court pointed out in *Meroni*, such a concept makes sense only in relation to powers “which the delegating authority itself received under the Treaty”. *Europeanization* would be a better description of a process in which powers are transferred vertically (from the national to the EU level) rather than horizontally (from Community institutions to specialized agencies).

Yet, it is through the prism of delegation that the legal community has examined the legality of European agencies. This may be partly due to the problem of making sense of a novel type of structure that is difficult to frame within existing categories because of its network-like character. But less innocent interpretations are also possible. The alleged inflexibility of the legal system has often been invoked – not least by the Commission and its legal service – against any attempt to confer autonomous powers on specialized agencies, regardless of how limited this delegation might be.

The example of the EMEA is again quite significant. Even though Regulation 2309/93 entrusted the Agency with the management of some procedures for the authorization of pharmaceuticals, its powers stop short of actual decision-making. The

measures to be adopted in this framework must therefore be taken by the Commission acting under the supervision of two ‘comitology’ committees (the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products). This limitation is largely viewed as a consequence of the non-delegation principle defined in *Meroni*. Decisions about whether or not to grant a marketing authorization for a given pharmaceutical are indeed complex; they involve difficult choices and a balance must be found between a variety of objectives ranging from health and safety to industrial concerns. As such, they clearly fall into the category of “discretionary decisions” contemplated in *Meroni*. But even in this case, the *Meroni* precedent is not as restrictive as one might have thought, for it explicitly contemplated the possibility that the High Authority “grant agencies the power to draw up resolutions the application of which belongs to the High Authority, the latter retaining full responsibility for the same”. The Court argued that in such a case there is actually no delegation because the High Authority remains in charge. Thus, a system in which the EMEA would have been granted the power to adopt marketing authorizations would have been perfectly in line with the *Meroni* doctrine, provided that the Commission retained the power to disallow those decisions. In other words, even accepting that the *Meroni* precedent was relevant for the new agencies — a questionable view, as has been seen — other control devices that are more respectful of agency autonomy might have met the demands of the Court of Justice. Another option was chosen nonetheless. This clearly suggests that, in addition to legal concerns, considerations of political opportunity obviously played a role in the definition of agencies’ power.

The difference between the current system, in which decisions are prepared by the agency and formally adopted by the Commission, and the kind of delegation contemplated here, might appear tenuous. Yet keeping an arms’ length between agencies’ operations and the Commission might offer advantages of two kinds.

First, it would significantly increase the transparency of the system. Although all marketing authorizations are Commission decisions under the present rules, the Commission systematically rubber-stamps EMEA recommendations – apparently without even discussing them — since a written procedure is followed. Thus, while EU institutions appear, in principle, to stick to a very strict non-delegation doctrine, in practice they have been content to adopt a far more relaxed attitude. This is easily understandable: given the technical character of the decisions in question, the Commission is naturally inclined to follow expert advice. But why portray a substantively expert decision as a ‘political’ decision? Wouldn’t the situation be clearer if the respective responsibilities of scientists and politicians were more clearly delineated? The Commission appears to fear the emergence of potential competitors. However, it should appreciate that the present situation’s ambiguity creates risks. One day the Commission might be called upon to bear the responsibility for decisions in which it played a merely formal role. The risk is not simply political. Risk regulation and litigation have developed in parallel in several countries, as citizens aggrieved by decisions of public authorities tend to bring the matters before administrative or even criminal courts. Politicians and public officials are increasingly being sued for their

alleged wrongdoings. It would therefore be in their interest to assist in the clarification of everyone's responsibilities.

Second, a clearer delegation of authority to agencies might have the advantage of reducing the risk of undue political interference in what constitutes primarily technical decisions. This does not mean that all political considerations should be precluded. Indeed, many scientific decisions do involve political dimensions: a decision about whether or not to authorize the morning-after pill will necessarily entail ethical considerations in addition to efficacy concerns. Other decisions will have distributive implications that are not for experts to determine. But a clearer demarcation between these two kinds of logic would make it more difficult for all kinds of economic interests and political concerns to hide behind pseudo-scientific arguments, as frequently happens. Of course political bodies would retain the right to disallow the experts, but they would be forced to do so openly. This would force them to give reasons for their deeds. Paradoxically, the development of delegation might therefore enhance accountability, instead of reducing it as is often feared.

4. Structuring the Interface between Scientific Expertise and Political Decisions

One of the peculiarities of risk regulation is that it often requires decisions to be made in a context of uncertainty. The problem is not merely that those decisions will have to be based on the recommendations of experts who are expected to master the technical complexity of the issues. The very nature or extent of the risk will sometimes be disputed: it has taken long debates for the existence of a greenhouse effect to be accepted by experts. In other cases, the controversy will concern the kind of measures to be adopted in order to tackle a given problem. Political leaders are usually unlikely to be confronted with undisputed recommendations by the scientific community. Hence the question: how is the interface between scientists and policy makers to be structured?

A. Giving Science a Say

The most obvious response to this question takes the form of a mandatory requirement to consult experts before a decision is made. The Treaty of Amsterdam's insertion of a provision obliging the Commission to 'tak[e] account of any new development based on scientific facts' in its harmonization proposals can easily be construed as an obligation to consult scientific experts. Similarly, even before this provision was adopted, the European Court of Justice had declared, in a widely noticed ruling, that:

'[t]he drafting and adaptation of Community rules governing cosmetic products are founded on scientific and technical assessments which must themselves be based on the results of the latest international research (...) Since the purpose of consulting the Scientific Committee is to ensure that the measures adopted at Community level are necessary and adapted to the objective, pursued by the Cosmetics Directive, of protecting human health, consultation of the Committee must be mandatory in all cases.'

While the innovative character of this ruling has been challenged, its objective is beyond dispute: it is meant to enhance the quality of Community rule-making through procedural requirements. This would initially appear to be compatible with a classic view of the division of labour between policy-makers and scientists: the former are supposed to make the best possible decisions on the basis of the evidence they have at their disposal, while the latter must assist them by giving advice. This basic distinction has influenced much of the current thinking about risk regulation at the EU level. Thus, in its recent proposal for the establishment of a Food Safety Authority, the European Commission insisted on the necessity of drawing a clear line between risk assessment (a scientific task to be carried out by the Authority) and risk management (which must remain in the hands of the Commission because it entails policy choices).

However, the boundary between scientific arguments and political concerns is not always easy to draw in decisions entailing very complex technical assessments, particularly those involving scientific controversy. Policy-makers will sometimes come under attack simply for having followed experts' recommendations. For instance, in the *Bergaderm* case, the Commission was taken to Court for a decision to ban an allegedly carcinogenic substance on the basis of a scientific committee's controversial assessment. At other times, scientific evidence might be biased by the experts' national origins. Thus, in its report about the European Union's handling of the BSE crisis, the European Parliament's inquiry committee drew a rather bleak picture of the functioning of the Scientific Veterinary Committee. It noted *inter alia* that '[the] preponderance of UK scientists and officials (...) meant that the SVC tended to reflect current thinking within the British Ministry for Agriculture, Fisheries and Food.' Neither the efficiency nor the fairness of the policy process can therefore be guaranteed by a mere consultation mechanism. Like it or not, it is necessary to open the black box and look at the way in which scientific deliberations are organized.

B. Structuring Scientific Deliberations

The very importance of scientific assessments in contemporary public policy means that scientific deliberations cannot be left to develop in an autonomous fashion. The 'benign neglect' with which this crucial phase of the policy process was considered largely stemmed from a tendency to regard science as a universal, boundary-free world that was entirely governed by the quest for the truth (in contrast to policy processes dominated by sectoral interests of various kinds). The reality is somewhat more complex. We have seen that scientists can be 'captured' by sectoral interests. More fundamentally, science is controversial, by definition. Whereas policy-makers expect scientific assessments to provide them with clear-cut answers, we have known since Karl Popper that there is no such thing as a stable and definitive truth in scientific discussions. More often than not, policy-makers will be confronted with conflicting views and uncertainty. The quality of scientific deliberations therefore assumes an enhanced level of importance. The legitimacy of scientific assessments will ultimately depend on the way in which those deliberations are organized. How have the various 'experts' been selected? What

measures have been taken to ensure their independence or the pluralism of the debate? Have the different views expressed in the deliberation process been given adequate consideration?

The 1997 reform of scientific committees operating at the EU level made some important steps in that direction. The selection procedure has been tightened by setting up a Scientific Steering Committee that is vested, *inter alia*, with the power to ensure the selection of the ‘most suitable candidates’ for all scientific committees. Scientific experts are to operate with absolute independence and are to declare all possible conflicts of interests. Rules of procedures, agendas, minutes and opinions of the Scientific Committees must be made publicly available. To avoid some of the deviations noticed in the functioning of the Standing Veterinary Committee during the BSE crisis, provision is also made for minority views to be included in the minutes. These are all welcome developments because they foster the transparency of the debate, thereby improving the credibility and the legitimacy of scientific assessments.

However, one might wonder whether this suffices. Given the importance assumed by scientific assessments in many decision-making processes, it might be argued that it is crucial to the quality and the fairness of those processes that adequate consideration be given to the widest possible range of views. The Court of Justice has previously ruled that ‘respect for the rights guaranteed by the Community legal order in administrative procedures is of (...) fundamental importance’ where the Community institutions are engaged in complex technical evaluations. Among these guarantees, the Court mentioned ‘the duty of the competent institution to examine carefully and impartially all the relevant aspects’ of the issue, and ‘the right of the person concerned to make his view known and to have an adequately reasoned decision.’ This ruling applied to an individual decision and not to rule-making activities, yet the clear rationale was that the quality of experts’ deliberations is of crucial importance when European institutions tend to follow experts’ recommendations mechanically. ‘In those circumstances’, the court noted, ‘the group of experts cannot properly carry out its task unless it is composed of persons possessing the necessary technical knowledge (...) or the members of that group are advised by experts having that knowledge.’ Moreover, the Court made it clear that the debate had to address all relevant issues; this is why ‘the person concerned must be able to explain his position to the group of experts or to comment on the information before the group.’ While some of these guarantees may be better adapted to the level of risk management than to risk assessment, they also appear to be relevant to the latter. The same ethos should lead one to conclude that scientific bodies are subject to a ‘duty of care’ in their operations that should lead them to give adequate consideration to all of the views put forward. In any event, the Court of Justice made it very clear that the need for legal guarantees did not apply merely to the ‘political’ level of the regulatory process, but also to preparatory stages.

5. Conclusion: Lost Boundaries

EU law remains influenced by a fairly traditional view of the way in which the

integration process unfolds. EU policies are still largely seen as an exercise in international diplomacy in which the convergence between would-be “national” interests – expressed by national governments and mitigated by the influence of enlightened technocrats (the Commission) – plays a key role. They carry a somewhat dated vision of public policy: the legislative stage is supposed to be decisive, and the control of elected representatives is expected to be the main way in which to ensure the legitimacy of policy choices.

These assumptions are being shaken by the evolution of European governance. The boundaries between law-making and implementation, or between scientific advice and policy-making, have become difficult to discern. The point is not that these classical concepts have become entirely obsolete, but that they are no longer sufficient to make sense of the way things work, let alone to regulate the policy-making process. Functional needs have led to the emergence of new actors – scientists, bureaucrats, interests representatives – whose influence is often essential. Decision-making processes have evolved. The idea that a clear-cut response can be given to the problems faced by modern society is increasingly challenged by the technical complexity of the issues to be addressed. Those are mighty problems for any society; at the European level, they are compounded by the necessity to involve a plurality of actors – national and European – at all stages of the policy process.

In combination, these trends have led to the emergence of transnational bureaucratic networks and to a strengthening of the administrative stages of the decision-making process at the expense of the legislative component. Constitutional principles have often been invoked as a brake in this process. The European Court of Justice has tried to preserve the primacy of legislative procedures by assigning limits to what can be delegated to technocratic bodies such as ‘comitology’ committees or specialized agencies. Basic principles (such as the concept of ‘institutional balance’) have been instrumentalized by those who tried to oppose the above-mentioned trends, not least in the European Commission. The stubborn insistence on a non-delegation doctrine has often been presented as a defence against a technocratic drift, and an attempt to preserve the ‘political’ character of basic decisions against the evils of technocracy. However, the reality is somewhat more complex. The EU’s legislative processes are heavily technocratic. Moreover, despite many protests to the contrary, one has accepted – in fact, if not in law – that basic decisions are made by technocratic bodies of various kinds, the choices of which are duly rubber-stamped by the ‘political’ powers that be. EU law is then used as a façade to hide a reality that is deemed to be unacceptable.

Law is said to protect normative values. Are these better served by this exercise in camouflage? It seems hard to believe. Are decisions that are made (de facto) by committees and agencies more amenable to judicial or parliamentary control simply because they are formally attributed to the European Commission? Hardly so. On the judicial plane, the rule of law ethos that led the European Court of Justice to declare itself competent to review the legality of decisions taken by the European Parliament (at a time this was not foreseen by the Treaty) would lead it to similarly accept jurisdiction to review the acts of any delegated body. For its part, the European Parliament has given

ample evidence of its ability to transform its budgetary powers as an instrument of political control, even in areas in which it was granted no formal powers. Specific mechanisms of parliamentary oversight can also be established.

Given the technical complexity of the decisions that are taken by delegated bodies, it is unlikely to be of much help to advocate a return to the status quo ante. Indeed, insisting on a principle of non-delegation ill-serves exactly the constitutional principles it is supposed to assist; hiding the identity of the organization actually responsible for decisions will sooner or later give rise to delicate liability issues. Those who are attached to the primary rule of constitutionalism – according to which all powers must be controlled – would be better inspired to acknowledge the evolution that has taken place. This is not tantamount to granting carte blanche to experts. Political institutions would still retain the right to define the basic objectives to be reached and the means to be used for that purpose. As indicated above, they might be given the power to overrule decisions that they deem to be incompatible with those objectives. However, the formal recognition of the role played by experts would enable one to insist on the necessity of consolidating the basic guarantees that surround decision-making at their level. Ensuring transparency, participatory rights, the pluralist character (and therefore the quality) of scientific deliberations, and fair behaviour on the side of public authorities, are all essential elements in the construction of a legal order that tries to reconcile the functional necessities of our time with individual rights and democratic principles. Important steps have already been made in this direction in the new framework decisions on comitology, following the Ombudsman's initiatives on transparency, and on the codes of conduct to be adopted by all EU bodies. With their rulings on transparency and principles of good administration, the European Courts have also actively promoted higher control standards. This trend could be strengthened by a clearer recognition of the transformations that have taken place within European governance.