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The changing role of science in regulatory decision-making in the European Union

Paper presented at the fifth biennial ECSA conference,
held in Seattle from 29 May to 1 June 1997

REVISED DRAFT VERSION
Comments very welcome*

Introduction

Expert advice to policy-makers is everything but a new phenomenon. Throughout the ages, governments of every type and denomination have consulted people and organisations which were considered the producers, preservers and guardians of specific kinds of knowledge, whether engineers, astrologists, military strategists or economists. What is particular about the second half of this century is therefore not so much the existence of expert policy advisors as such, but the growing importance of one specific community as a source of knowledge and expert information in policy-making processes: the scientific community (Brooks et. al., 1987).

These introductory remarks refer to a development that is thoroughly studied and documented in contemporary scholarship. It is almost equally well-established that not every country receives, processes and uses expert policy advice in the same manner. In other words, policy styles differ according to -- to name but a few influences -- historical developments, institutional arrangements, and the different substantive urgencies which policy-makers are confronted with. This paper started as a reaction to one of the works which discuss the difference in use and integration of scientific expertise into policy decision-making between European countries and the United States, more in particular in the area of environmental and health and safety policy. It asks whether the emergence and maturing of a new level of policy-making in Europe, the European Union level, affects the way in which scientific expertise is used for the development of public policy and, if so, whether these changes could be expected to render this new policy-style more or less similar to the US model of integrating expertise into decision-making. In this analysis, particular attention is paid to the role of the European Court of Justice in re-shaping European styles of health and environmental science-policy decision-making, both at the EU and at the Member State level. If, as the paper argues, an approximation of styles is indeed to be expected, it becomes important for the European Union to look with renewed interest at the current problems faced in the United States relating to the acceptance of science as a prevalent input into public policy, to anticipate an emergence of similar issues in Europe and to consider possible solutions.

1. European and American science policy styles

During the 1980s and early 90s, a number of political scientists and legal scholars made comparative analyses of European and American modes of regulatory decision-making. One of these studies, a joint effort by Ronald Brickman, Sheila Jasanoff and

Thomas Ilgen, compared chemical substances control policies in four different countries: France, Germany, the United Kingdom and the United States (Brickman et. al, 1985). Since the focus of this widely acclaimed study -- the control of chemical substances -- represents one of the policy areas where the involvement of scientific expertise into the decision-making process is one of the most prominent characteristics, and because of the technical and scientific complexity of the field to be regulated (*see* Cranor, 1993; Rodricks, 1992; Uth, 1990), the authors' study in my opinion provides a fertile basis for analysis of science-policy issues on a more general level.

Brickman, Jasanoff and Ilgen's work pointed at some interesting differences between Europe and America in the use and reliance on scientific expertise and evidence in the development of chemical policies and decision-making.

First, the study indicated that US regulatory authorities tend to be much more demanding with respect to the quantity of scientific data on which regulatory decisions should be based. Not only do American funds for scientific research, and in particular research commissioned by US regulatory agencies, by far exceed the resources allocated for similar purposes in Europe, but furthermore are the requirements for scientific input and evidence as a basis for regulatory decision-making considerably more extensive and stringent in the US than in Europe (Brickman et. al., 1985). The US EPA's (Environmental Protection Agency) test rule programme, developed under the Toxic Substances Control Act, is a clear case in point: the agency's policy under this programme *"[was] to review 95 percent of all published material on a chemical, going back as far as thirty to fifty years."* In Europe, this kind of in-depth analysis is generally not required or performed (Krämer, 1992).

A second significant difference which is documented in Brickman, Jasanoff and Ilgen's analysis, refers to the degree of "formality" of scientific advisory procedures: European regulatory bodies are more prone to acquire expert opinions relying on informal channels of information than their American counterparts. Americans, in contrast, adhere more closely to formalised procedures and stick to officially recognised advisory channels in the development of regulatory decisions. This view is shared by David Vogel, who called the US approach *"[t]he most rigid and rule-oriented to be found in any industrial society"* (Vogel, 1986). When comparing the US to British environmental policy development, Vogel was struck by the greater degree of flexibility and willingness of UK environmental regulatory authorities informally to consult experts. Moreover, British regulatory bodies appeared to have an entirely different attitude towards industry (the usual addressee of environmental regulatory decisions), demonstrating a disposition to seek its advice informally, to negotiate with industry in a co-operative and non-confrontational manner, and to by-pass the need to impose "hard" rules and rigid standards through reliance on "softer" instruments such as voluntary agreements and self-regulation by industry.

Additionally, due to, *inter alia,* the above-described less formal approach to regulatory decision-making, the dividing line between scientific and other, *e.g.* economic considerations is sometimes blurred in European countries and, consequently, scientific considerations are not as clearly singled out and delineated in European regulatory decisions. On the whole, a more casual approach to incorporate scientific as well as policy-oriented factors into expert advice -- and consequently into policy decision-making -- prevails (Brickman et. al., 1985; Barker & Peters, 1993, 1.b, Murswieck, 1993). As far as the US is concerned, not only are the requirements for integrating scientific expertise into US policy decision-making quantitatively more rigorous (see above), they are also more rigid and formalised: decisions explicitly refer to their scientific "foundations," which form the predominant basis for their justification, and agencies go to great lengths to dispel any hint of discretionary decision-making (Wagner, 1995).

2. Explaining the difference: means, motives and dispositions

In reply to the question: "What explains the differences in the use and integration of scientific expertise in regulatory decision-making in Europe and the United States?" this paper proposes the following, almost embarrassingly simple, answer: US regulatory authorities use more scientific data and stick more closely to the formal, rigid procedural rules for regulatory decision-making because they need to. In contrast to their European counterparts, who are relatively insulated from outside attacks and are therefore at liberty to make decisions in a more flexible, informal manner, US regulatory bodies are surrounded and scrutinised by a number of actors who have the means, motives and dispositions to call into question the legality, legitimacy and acceptability of their actions. In other words, this paper argues that in the United States, more so than in Europe, regulatory authorities are to a large extent dependent on scientific evidence and formal compliance with decision-making procedures to justify (or legitimate) the policy choices they make.

In the following sections, I will examine some of the factors which, in my opinion, shed some light on the apparent greater need for scientific justification experienced by American regulatory authorities.

2.A Prestige and authority

The first explanation hinges on the hypothesis that the less prestige and authority an institution has, the more it needs to resort to outside support (such as the support offered by scientific evidence) to justify its actions. In other words, scientific expertise can be used as an instrument to boost a regulatory body's credibility, thus functioning as a form of legitimation, or a substitute for legitimacy, of its policy decisions (Barker & Peters, 1993). John Kingdon puts it this way: in order to be a successful policy entrepreneur, a person needs to have some claim to a hearing. This claim can be founded on one of three sources: *"[e]xpertise; an ability to speak for others; or an authoritative decision-making position"* (Kingdon, 1984; Obradovic, 1996). Logically, one might infer that the less access a policy-entrepreneur has to one these sources, the more it will need to rely on another. For example, the more controversial and politically sensitive the issues to be decided (and hence the more questionable the policy entrepreneur's authority and ability to speak for others), as in the case of nuclear policy decision-making in Italy which was examined by Angela Liberatore, the greater the need for expert -- and by preference scientific -- justification (Liberatore, 1993; Topf, 1993).

Applying this hypothesis to the case at issue, this would mean that US regulatory agencies are more strongly dependent on scientific data to justify their decisions because they have less authority, less prestige than their European counterparts. There are indeed a number of indications confirming this assumption. Most US regulatory agencies, particularly those dealing with environmental, health and safety policies, are relatively young institutions. Children of the New Deal, they are the representatives of market interventionism in a country with a strong *laissez faire* tradition (Sunstein, 1991). It is therefore not surprising that, particularly during periods of republican administration, regulatory activity may be considered a necessary evil rather than a public good, to be condoned (at best) rather than encouraged (Shapiro, 1988). This disposition of suspicion, sometimes amounting to outright hostility, contrasts sharply against, for example, the almost mythical status of civil servants in the French administration. Instead of a necessary evil, the French bureaucracy was traditionally viewed as the driving force which held the country together and made it prosper during the Third and Fourth Republic, a reliable counterbalance to match the instability and capriciousness of French politicians and political alliances: *"[W]hile the politicians had their fun and played their games in the Third and Fourth Republic, the country was held on an even keel and actually prospered under the guidance of a permanent body of dedicated officials"* (Suleiman, 1974). The French bureaucracy was able to act with a great deal of autonomy

and discretion; its authority and legitimacy was so strong that numerous important social policies could be developed and implemented outside the political arena (Suleiman, 1974, Muller, 1992). Now, even if the reputation of the civil service is no longer as impeccable as it once was, French administration, staffed with highly educated officials trained in one of the most prestigious and competitive schools in the country (the ENA), remains a force to be reckoned with (Muller, 1992; Poirmeur, 1992).

Perhaps US regulatory authorities are not really given a fair chance when the comparison restricts itself to France, a country which, in Europe as well as abroad, stands alone in its regard for administration and public service. However, even when looking at less bureaucracy-oriented European countries such as Britain (Suleiman, 1974; Sunstein, 1991, Vogel, 1986)), the prestige and credibility of US regulatory bodies appear relatively low by comparison. Jean-Jacques Salomon claims that, on the whole, European countries are not bound by market ideologies (*laissez faire*) and do not have a strong tradition of separating the public and private sphere. Consequently, there is a higher tolerance for those institutions the (new) activities of which can be described as interventionist, such as environmental and health regulatory authorities: *"[b]y giving the bodies responsible for science policy an "output-oriented" function in the economic domain, they were only extending into a new field of governmental responsibility a long tradition of interventionism"* (Salomon, 1987).

2.B Who's watching? Different degrees of regulatory scrutiny

Inextricably linked to the prestige and authority of regulatory authorities is the intensity with which other actors -- government, the legislator, the public and the judiciary - scrutinise regulatory decision-making and their ability to question or even attack science-policy choices. In Europe, health and environmental regulatory authorities as a rule have relatively little intrusion to fear from either Parliament, interest groups or the judiciary (Vogel, 1986; Rose-Ackerman, 1995). The activities of US regulatory bodies, on the other hand, are watched more closely by the Presidency, Congress and the public. Additionally, the American system is characterised by a much stronger tradition of judicial review of regulatory decisions. Thus, US regulators find themselves far more frequently in a position where they have to defend their science-policy choices - both in and outside the courtroom - than their European colleagues. It would therefore seem obvious that they would seek to strengthen their positions as much as possible, both by gathering expert opinions and scientific data in support of their evaluations and decisions and by scrupulous compliance with the formal rules of administrative decision-making. The following sections offer a - very preliminary - discussion of those factors which contribute to the higher degree of scrutiny to which American regulatory authorities are subjected. Admittedly, the description is very cursory and does not pretend to do full justice to the intricacies and complexity of current American and European governance regimes. Nonetheless, even a brief sketch of the environment in which regulatory decision-making takes places on both sides of the Atlantic may be helpful in understanding different needs for scientific expertise and varying styles of decision-making.

Parliamentary and governmental control

Different governance structures lead to different incentives and disincentives for both the legislative and executive branches to control policy development and implementation by regulatory bodies. The US presidential system is characterised by its commitment to the principle of checks and balances, which reaches its epitome in the relation between the elected President, as main representative of the executive branch, and the elected members of Congress. As is widely known, the political party to which the President and his Cabinet appertain do not always hold a majority in Congress; in

fact, during the least 17 years there have been only two -- the first two years of the Clinton administration -- in which both the President and the majority of Congress belonged to the same party. In this constellation, where the interests of the majority in Congress certainly do not always overlap with executive priorities, the legislature has a clear incentive to keep a close watch on the President and his administration, including the regulatory authorities and agencies, such as the Environmental Protection Agency, which have been established under the Presidency, and of which the members are directly appointed by the President (Shapiro, 1988; Rose-Ackerman, 1995) According to Joel Aberbach, 25,2 % of all parliamentary committee meetings in 1983 dealt with issues of Congressional oversight (Aberbach, 1990). Moreover, a 1988 study of the National Academy for Public Administration pointed out that, between 1984 and 1986, the EPA had to appear before Congress no less than 198 times (NAPA, 1988). Given this preoccupation with administrative oversight, it is not surprising that US environmental and health statutes (such as the Clean Air Act, the Toxic Substances Control Act) are often drafted in a manner that will enable Congress to exercise its control, namely, by detailing requirements and decision-making standards -- including requirements to rely on scientific evidence -- for the regulatory authorities to comply with in the implementation of health, safety and environmental policies (Rose-Ackerman, 1995). Needless to say, close Congressional scrutiny will also affect the relation between the President and his administration. Since he is as likely to be held accountable for its failures as to share in its successes, he too has an incentive closely to monitor their behaviour.

The situation is markedly different in European parliamentary regimes. Let us take the German Federal Republic, for example. Here, the same political party -- or coalition of parties -- controls both the legislative and the executive branch. Consequently, there are less incentives for both branches to exercise a close oversight, either on each other or on the bureaucracy which implements governmental policies. Apart from adopting broadly formulated framework legislation, the legislature generally abstains from meddling in policy development (this appears also to be the case for Britain; *see* Vogel, 1986), and the likelihood that regulatory policies will be scrutinised and successfully challenged in Parliament is smaller (Rose-Ackerman, 1995). In their analysis of the German federal bureaucracy, Fritz Scharpf and Renate Mayntz recognised the limited role of parliamentary parties in policy-making: *"[T]hey (parliamentary parties) respond to early information about governmental policy proposals, and their criticism will definitely influence and change the content of such proposals, but they will hardly embarrass the government -- as the opposition will often try to do -- by introducing their own legislative initiatives when the government is active in a particular field. But of course, opposition initiatives are rarely successful in a parliamentary system. Thus, the active involvement of the parliamentary parties does not basically detract from the policy-making responsibility of the government in power"* (Mayntz & Scharpf, 1975). Needless to add, where government and administration are left largely on their own to develop and implement public policies and neither body should expect many challenges from Parliament (nor, as will be discussed below, from the judiciary), government itself will not experience strong incentives to set rigorous (scientific) standards for the regulatory decision-making which happens under its authority.

The public eye

Not only do regulatory bodies in Europe have relatively less to fear from parliamentary and governmental scrutiny that US authorities, they also stand in a different relation to the public and, more specifically, industrial interest groups which are the main -- and most vocal -- addressees of environmental and health regulation. Here again, the European regulatory system strikes one as more insulated. Industry certainly is consulted prior to the adoption of a rule or regulation, however this consultation tends to

happen behind closed doors and usually at the exclusion of other, less well-organised or powerful interest group representatives (Rose-Ackerman, 1995). One could almost describe regulatory tactics in European countries such as Britain, Germany and Sweden as following a strategy of "divide and conquer": certain interest groups -- predominantly industry group representatives -- are integrated, incorporated into the decision-making process, and become themselves part of the black box of decision-making (Bulmer, 1993; Barker & Peters, 1993,1.b; Vogel, 1986; Murswieck, 1993). Within this setting, industry is able to affect or even determine policy-outcomes (Rose-Ackerman, 1986); often there is room for informal negotiation and flexible problem-solving (this is predominantly the case in Britain, where voluntary agreements and industrial self-regulation are frequently preferred to strict rule-making. Vogel, 1986). The down-side to this corporatist form of science policy decision-making is that, for outsiders, the decision-making process remains quite intransparent and impenetrable and, consequently, more difficult to control. Thus, potential critics of regulation are either "neutralised" through incorporation or are too removed from the process to affect it.

In the United States, in contrast, science policy decision-making happens more "out in the open": agencies post public notices on their intention to draft a rule, comments -- which may include scientific analysis -- from interest groups are received and, subsequently, draft notices are published. Then follows another round of formal hearings prior to the enactment of the rule (Shapiro, 1988 and comments). Once again, the American approach appears more rule-based and formal than the European. Here, interest groups retain their status of outside commentators or critics rather than becoming integrated into the regulatory machinery, which results in a more adversarial relation between regulatory agencies, industry and other interest groups. On the other hand, the process is more transparent and allows a broader access for smaller groups which, in many European countries, would be left out of decision-making processes altogether.

Judicial review of policy decisions

According to some American scholars, the strong reliance on scientific data to supply an explicit justification for policy decisions can be explained by the exigencies placed on administrative rule-making through the process of judicial review: the Court of Appeals of the District of Columbia, backed by the US Supreme Court, has placed progressively high burdens on regulatory agencies to articulate, and thus formalise the rationale behind their decision-making, and has on several occasions insisted on the use, and even on complete reliance on scientific evidence (Wagner, 1995; Shere, 1995; Shapiro, 1988). Close judicial control in the US, as opposed to a low to very low incidence of litigation in European countries (Gusman et. al., 1980), is perhaps the most crucial factor explaining the differences in science-policy styles between them. After all, Congressional oversight as well as interest group and public pressure might to a large extent lose their sting if the watchdogs of regulation would not have access to a forum where they could vindicate their claims.

One can think of several reasons why the judiciary is so much more active in the control of regulatory decision-making in the US. First, the presence of a highly active court system as the supervisor of both the regulatory and legislative process is strongly embedded in the tradition of constitutional judicial review, as indicated by Martin Shapiro: *"[T]he Constitution authorised and thus legally legitimated statute-making by Congress. Statutes authorised and thus legally legitimated rule-making by agencies. If the courts had the power to nullify whole statutes on the grounds that they conflicted with the Constitution, then obviously the courts should have the power to invalidate whole rules that conflicted with their authorising statute"*(Shapiro, 1996).The situation in Europe is quite different. Many European countries, such as Belgium, Germany and the Netherlands, do not have a vested tradition of constitutional judicial review. Review of administrative acts was only possible to the extent that the contested act was an

administrative decision, *i.e.*, the application of a legal rule, rather than a rule itself. Although there is a move in most of these countries towards a broader scope for judicial review, it is still a relatively novel phenomenon and the number of actual court challenges of administrative rules is still very modest (Rose-Ackerman, 1995; Gusman et. al., 1980) A second element contributing to the low incidence of litigation in Europe may consist of the fact that countries such as France, Germany, England and Belgium have separate courts for administrative and for constitutional issues. According to Martin Shapiro, this separation of competencies may prove an obstacle for potential critics of regulatory decisions to initiate legal action (Shapiro, in comments). Finally, courts at the national European level have on the whole displayed a greater willingness to allow public policy makers a reasonable range of discretion, and have certainly not exposed policy decisions to the same "hard look" as their American colleagues are prone to do.

2.C Conclusion

When comparing US to European (national) science policy decision-making, it becomes clear that the legality and legitimacy of decisions taken by US regulatory bodies is called into question more frequently than in Europe, both at the political and the judicial level. The weaker authority and prestige of US regulatory bodies, combined with -- and partially caused by -- greater exposure to political and judicial scrutiny form two powerful factors explaining the stronger reliance on scientific data, not only as input but equally as justification of US policy decisions. In contrast, European policy makers, whose decisions are met with a greater willingness to respect a reasonable degree of discretion, generally do not have to be as preoccupied with "covering their tracks," and consequently are able to maintain a more informal, flexible way of decision-making, one in which scientific expertise is less singled out for justificatory purposes, but rather embedded, along with other policy considerations, in the process.

3. The EU-level: a changing landscape?

The following sections address the question whether the comparative analysis of the differences between European and American science policy styles still holds true when the focus is shifted from the national to the European Union (EU) level. During the past decades, EU institutions have become important actors in the development of social and regulatory policies; the increase in the EU's regulatory activities has taken such an impressive flight that some authors refer to the EU as a "regulatory state" (Majone, 1994; Vos, 1997). The control of chemical substances, for example, has been the objective of numerous EU initiatives, ranging from, *inter alia*, the development of rules for the notification, classification, packaging and labelling of dangerous substances to the establishment of criteria for chemicals risk assessment (for an overview of EU chemicals legislation, *see* Haigh, *loose-leaf ed.*). Consequently, when discussing the dynamics between policy and scientific expertise in Europe, it has become indispensable to take a closer look at the role scientific expertise plays in EU policy development.

Based on a preliminary analysis of the distinctive features of the EU as a regulating entity, namely its commitment to the development of internationally applicable rules, its struggle to overcome the democratic deficit, its institutional arrangements and its supervision by the European Court of Justice, I will argue that the maintenance of a flexible, informal and "embedded" approach to scientific expertise may become increasingly difficult. Thus, what we have earmarked as the "European style of science policy decision-making" may gradually be replaced by a more rigorous, formal and justificatory one. In other words, a more "American" one.

3.A Developing international standards

A first argument draws on the observation that, as a regulator, the EU caters to an international audience. Furthermore, EU regulatory decisions not only have to serve the general interest, like domestic decisions, but in addition need to be reconcilable with the furtherance and maintenance of the single market (Oberdorff, 1992). This is an extremely challenging and complex task, particularly in the areas of environmental, health and safety policy, which are politically sensitive (Joerges, 1996). EU member states often have different conceptions of what constitutes environmental protection, health and safety, and which is the most appropriate policy to pursue. The *Woodworking machines* decision is a case in point, illustrating a clash between safety policies where one country relied more on training and information of machine operators (Germany), whereas the other (France) insisted on stricter safety norms in the design of woodworking machines. Given these constraints, and bearing in mind the previously noted phenomenon that, the more controversial (or sensitive) the issue, the greater the need for scientific justification, a search for internationally acceptable, neutral and objective standards as a foundation for policy decisions is to be expected. An increasing reliance on international and, more specifically, scientific standards has indeed been observed in the area of EU health policy. As Ellen Vos points out: *"[S]cientific and technological standards developed within these structures gain an increasing importance in the Community decision-making process on food and standardisation issues where the Commission is confronted with different national traditions and views on these issues. (...) Therefore, it is not surprising that the Commission increasingly tends to rely closely on the scientific standards as developed in these structures"* (Vos, 1997) It would appear that a growing reliance on scientific standards could not only increase the demand for scientific input, going back to the first point of difference between the US and Europe, but that it could equally affect the function of scientific expertise: as scientific standards are pushed to the fore to overcome the hurdles of, *e.g.*, different national safety policies, their justificatory quality gains in emphasis.

3.B Legitimacy and institutional structure

It is well-established that the EU's institutional set-up differs significantly from the classical governance structures existing in the member states. EU institutions defy traditional categorisations in terms of the legislative, the executive and judicial branches of government. The originality of the EU institutional structure is perhaps most evident in the European Commission, which functions as the EU's bureaucracy but at the same time fulfils executive tasks and is the only institution at the EU level having the legal initiative (Smith, 1996). Furthermore, although its competencies are gradually being expanded, the European Parliament still performs a supervisory rather than legislative role, and the EU's main law-making body, the Council of Ministers of the European Union, consists of members who, in their own countries, are part of the executive branch. In the following sections, I will argue that the institutional characteristics of the European Union, including the problems and controversies which are at least partially attributed to institutional shortcomings, are conducive to the development of a regulatory regime which is strongly dependent on scientific evidence and expertise, and adheres to formal, proceduralised rules of decision-making.

Coping with the democratic deficit: the need for legitimacy-building

The first argument is linked to the previously established hypothesis that there is an inverse relation between the authority and democratic legitimacy (or the ability to speak for others) of policy decision-makers and their dependence on scientific expertise. There are indeed indications that EU institutions may lack the necessary authority and, even more so, democratic legitimacy to develop science policy and take policy decisions without recurrence to outside support, mainly in the form of concurring scientific expert

opinions.

Obviously, the introduction of a new, supranational level of governance, even one with limited competencies, can hardly occur without giving rise to problems and controversies. It is widely known that, in its quest for credibility, acceptability and legitimacy as a supranational source of authority and binding decisions, the European Union struggles with what has become known as the "democratic deficit." The EU, initially constructed as an elitist project which intentionally steered clear from the dangers of over-democratisation -- a major concern in the aftermath of the war -- is characterised by a relative absence of rules and procedures guaranteeing participation, representation and accountability (Golub, 1996). Hence, the EU has but a weak democratic legitimacy (Lodge, 1994). As the EU's competencies expand into areas which are politically sensitive, such as social regulation, its shaky democratic foundations become more and more problematic (Joerges, 1996). It remains to be seen whether the recent attempts to make the EU a more democratic and, by consequence, legitimate source of authority, such as the broadening of the European Parliament's powers in the Maastricht Treaty, will in the long run prove sufficient to rescue the EU from democratic bankruptcy (Obradovic, 1996). Finally, recalling Jean-Jacques Salomon's argument, one may wonder whether Europeans will remain equally disposed to market interventionism when they do not recognise the intervening party as forming part of their constituency (Weiler, 1993).

The non-majoritarian nature of EU institutions is particularly visible in the European Commission, the foremost initiative-taker in the field of science policy development. Similar to the US regulatory agencies, the Commission is a relatively young institution, and its members are appointed, not elected (Smith, 1996). Not surprisingly, one of its trump cards to justify its involvement in science policy decision-making consists precisely of an affirmation of its own expertise, or of the scientific validity of the opinions and advice on which the decisions are founded (Majone, 1994). Emile Noël's words coin the message: *"[O]n a daily basis, the officials who work in the institutions , in the Commission, the Parliament, the Council, are tied to the development of the legislative process. It is therefore of the utmost importance that their interventions do not obstruct the democratic goings-on of the institutions and that they contribute the maximum of expertise"* (translation from French original). Furthermore, in their attempt to accumulate legitimacy, both the Commission and the European Parliament have paid a great deal of attention to the need for transparency of decision-making (Héritier, 1996; Smith, 1996). As decision-making processes become more exposed to outside scrutiny, one might expect that a greater emphasis will gradually be placed on the validity of the (scientific) arguments underlying regulatory decisions, and compliance with the procedures for decision-making.

Summarising, when it comes to legitimating its decision-making authority, democratic foundations are not the EU's strongest point. Consequently, efforts are undertaken, both to strengthen the Union's claims to democratic decision-making (for instance, by broadening the European Parliament's powers) and to compensate for the lack in participation and accountability with a high level of expertise and increased transparency of the decision-making process.

A Europe of checks and balances

A further consequence of the institutional set-up of the European Union is that the political glue, which connects national governments and parliamentary majorities in the member states, comes unstuck at the EU-level. None of the three "primary" institutions -- the Council, the Parliament and the Commission -- can safely assume that the other two have roughly the same agenda and priorities, and therefore each has a strong incentive closely to monitor the decision-making process, to maximise its involvement and see to it that its prerogatives are not violated. In this respect, and bearing in mind the absence of a rigid, clear-cut separation of powers (*see* above), the EU governance structure appears to

function as a system of checks and balances (Joerges & Neyer, 1996). As discussed in my brief analysis of US Congressional oversight, where institutional actors have clear incentives to scrutinise each other's decisions, this may result in a greater need for justification and, hence, recurrence to scientific expertise. Adrienne Héritier observed this phenomenon within the EU: *"[T]he Commission also uses the strategy of insulating decision-making in expert circles, so that policy cannot subsequently be challenged due to a lack of proper expertise"* (Héritier, 1996). In this framework, Articles 190 and 130R of the EC Treaty are particularly revealing. Article 190 stipulates that Community acts should be reasoned (*see* below). Article 130R, in turn, covers environmental policy, and includes the following requirement: *"[I]n preparing its policy on the environment, the Community shall take account of available scientific and technical data."* Thus, the Treaty has lays down the basic foundations and standards for science policy decision-making against which the performance of EU institutions can be measured.

Before turning to the following section, some attention should be paid to the phenomenon of comitology. Some might argue that, rather than strengthening the "giving reasons requirement" and focusing on scientific evidence, the EU -- and specifically the Council of Ministers -- has opted for an institutional solution in order to control science policy decision-making by the European Commission. Instead of monitoring and assessing the process from the outside, institutional checks and balances have been internalised into Commission decision-making through the committee procedure, with the committees representing the interests of the member states (Joerges & Neyer, 1996; Wessels, 1996; Edwards & Spence, 1994). Undeniably, each governance structure has its idiosyncrasies, and over the last ten years comitology has certainly become one of most distinguishing characteristics of delegated and implementing decision-making in the European Union. However, in my opinion this institutionalisation of checks and balances at the EU level is not incompatible with the argument I am trying to make. First, one should not forget that the Comitology decision and ensuing decisions entailed the formulation of rules for decision-making. Thus, the rules of the game, and the relationships between the different actors involved or interested in decision-making (Commission, member states, Parliament, scientific experts and interest groups), have acquired a relatively more formal, fixed character than before. Furthermore, several authors have commented on the importance attached to expertise and scientific evidence within the framework of comitology (Joerges & Neyer, 1996; Wessel, 1996). Alongside committees consisting of member states representatives, comitology procedures include the consultation by the Commission of scientific committees, particularly in areas of high technical and scientific complexity such as environmental and health and safety policies. According to Joerges and Neyer, the Commission actively seeks the support of these scientific committees (their study focuses on the Scientific Committee for Foodstuffs) in order to boost the credibility and acceptability of its proposals: *"[A]s far as scientific evidence in comitology is accepted to be the most valid currency for making convincing arguments, this is an important bargaining chip which the Commission uses deliberately to support those arguments which fit its general interests."* In other words, the Commission relies on scientific expertise in other to justify its policy choices vis-à-vis other institutional actors, irrespective of whether these actors are integrated into (committees) or outside observers of the Commission decision-making process. Finally, these same authors observed that, even within committees consisting of member state representatives, positions taken by the members -- whether really based scientific evidence, or rather on economic, political or social considerations -- usually have to be "translated" into scientific arguments in order to count as valid, legitimate arguments upon which the other committee members can agree (Joerges & Neyer, 1996).

3.C The Role of the European Court of Justice

An analysis of science policy-making at the European Union level would not be

complete without reference to the European Court of Justice (the "Court"). Owing to its competencies to check the compatibility both of national legislation and Community decisions with European law -- directly by means of court decisions and indirectly through preliminary rulings -- the Court is gradually emerging as an active and potentially crucial player in the shaping of EU regulatory policies (Joerges, 1996). Furthermore, like American courts and unlike the courts of the member states, the ECJ has both constitutional and administrative law jurisdiction.

As a rule, Court opinions relating to the use of scientific expertise stem from one of two different sources: jurisprudence on the permissibility of national trade barriers examined under Articles 30 and 36 of the EC Treaty, or case law dealing with the legality, the interpretation or the national implementation of secondary EC harmonising legislation. Additionally, mention should be made of Article 190 of the EC Treaty, which lays down the requirement for Community institutions to motivate their decisions (see, for example, Case C-41/93 on the PCP ban discussed below). Through this Article, the Court is enabled to examine whether Community acts are sufficiently reasoned -- in other words whether decisions have been justified -- and to invalidate them if they fall short of the "giving reasons requirement." Martin Shapiro predicts that, in the future, the Court will increasingly rely on Article 190 to check whether Community acts state reasons and to investigate the soundness of the motivation itself (Shapiro, 1996). In the area of environment, health and safety, such an investigation will inevitably trickle down to an examination of the technical and scientific evidence underlying Community regulatory decisions.

A first overview of the body of Court decisions dealing with scientific expertise reveals an increasing reference on the part of the Court to the use of "objective" standards in the development of national and Community rules, embodied in scientific research, statistics, expert opinions and sampling methods. For example, in the 1982 *Commission v. Ireland* case, the Commission strengthened its argument that the Irish ban on the import of poultry meat from member states which permit vaccination against the Newcastle disease was an unpermissible barrier to trade on the basis of statistics indicating a low and further decreasing incidence of the Newcastle disease in the Community. Ireland retorted by submitting veterinary studies which showed that, in countries where vaccination was permitted, the virus still subsisted, although masked by the effects of vaccination. In its reply, the Court decided in favour of the Commission, referring back to the offered statistics and their trustworthiness. A different kind of reference to scientific expertise can be found in the *Van Bennekom* case, which addressed the question whether vitamins should be classified as medicinal products. Here, the Court stated that this classification must be decided on a case-by-case basis, *"[h]aving regard for the pharmacological properties of each vitamin to the extent to which they have been established in the present state of scientific knowledge"* (emphasis added). A third illustration of the Court's reference to scientific expertise is offered in the *Delattre* case, where the Court was confronted with the more general question whether there existed a European Community definition of illness or disease. The Court reasoned that there was no such definition, but added that the only possible definitions for these terms are those most commonly accepted on the basis of scientific knowledge.

This handful of cases already provides some indication of the important value the Court attaches to scientific expertise in the formulation of policy decisions. The following chapter explores this issue in greater detail.

4. European Court decisions: three channels for influence

Going deeper into the existing case law relating to scientific expertise, it becomes possible to identify different ways in which the Court directly or indirectly affects the use of expertise. Here again, the emergence of an EU-level of decision-making -- *in casu*, judicial decision-making -- appears to have the potential to affect science policy styles

and, more particularly, the integration of scientific evidence in decision-making, both at the national and the EU level.

In this paper, I distinguish three channels for influence, namely Court rulings relating to areas marked by scientific uncertainty, rulings on domestic use of scientific expertise (effects at the national level), and Court decisions on scientifically related requirements for valid EU decision-making (effects at the EU level).

4.A Scientific uncertainty and national discretion

In areas characterised by scientific uncertainty, in other words where there is insufficient scientific evidence to decide on the harmfulness of certain products (or substances or procedures), and consequently on the necessity and justifiability of policy decisions relating to these, the Court has generally upheld that member states retain a large degree of discretion to develop their respective policies. Thus, a national rule banning the import of a product because it represents a potential threat to health and safety will usually be deemed permissible if the scientific evidence is either absent or inconclusive, even though the same product may be lawfully marketed in other member states (Hankin, 1996; Joerges, 1996).

A seminal case in point is the *Eyssen* decision. The facts to the case are the following: the Dutch government prohibited the presence of a food additive called nisin in cheese. However, this prohibition only applied to cheese sold on the domestic market. Although the nisin prohibition clearly constituted a trade barrier, and even one discriminating between domestic trade and export, the Court decided that the Dutch rule was justifiable on the basis of Article 36 of the EC Treaty. In its judgement, the Court acknowledged the difficulties international organisations were facing in assessing the risks relating to the use of nisin, and reasoned that this scientific uncertainty might explain different national views on the harmfulness of the substance. It further referred to different dietary habits in the various member states, indicating that in a country where cheese is consumed in great quantities, such as the Netherlands, concerns about food additives in cheese might assume a more pressing character, justifying the difference in treatment between cheese destined for the Dutch market and cheese for export.

The rule which links scientific uncertainty to national discretion in policy decision-making was reconfirmed in later Court decisions, such as the *Sandoz* and *Van Bennekom* cases. The *Sandoz* decision furthermore made clear that member states' discretion to take protective measures restricting the free movement of goods would also be respected in cases where scientific research was being undertaken, but insufficiently advanced to be conclusive: *"[A]ccording to the observations submitted to the Court, however, scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects ""*(of vitamins consumed in large quantities).

One might question how these cases relate to the argument that the European Court directs national and EU policy-makers towards a greater reliance on scientific expertise and, if there is such a relation, whether the above-mentioned cases do not point in the opposite direction: less scientific research and greater uncertainty could be deployed as a tool by national governments to retain discretion over market-related science policy areas. The first part of the answer lies in the reverse side on this medal: if other member states or the European Commission seek to challenge the legality of trade barriers which are justified as averting potential threats to health, safety and/or the environment and concerning which scientific evidence is lacking or inconclusive, their success will largely be dependent on their ability to demonstrate that, contrary to what the defending member state claims, there is in fact sufficient scientific evidence to make a reliable assessment of the risks relating to, *e.g.*, the marketing or use of a substance, and that scientific research has conclusively established the harmlessness of the substance. This is precisely what happened in the *Commission v Greece* case, where the Commission

was able to dispel doubts concerning the wholesomeness of pasteurised butter brought forward by the Hellenic Republic in defence of its import restriction pertaining to the product. The Commission was able to convince the Court on the basis of scientific evidence and inquiries conducted in all the other member states that these fears were unwarranted. Hence, the Court declared the import restriction unpermissible.

The second part of the answer lies in the observation that, although allowing the member states a large degree of discretion, the Court did not offer a "blank check" in cases of scientific uncertainty. The following section examines how member states' exercise of discretionary decision-making power in science policy areas is gradually becoming conditionalised on the use of scientific expertise.

4.B Effects at the national level : domestic science policy decision-making

On numerous occasions, the Court has confirmed that, in making science policy related decisions, member states have to take into account scientific expertise. For example, in another *Commission v Greece* decision, the Court repeated its rule that, in the case of uncertainty, member states may apply measures which restrict the free movement of goods (here, a restriction on the marketing of beer containing additives and manufactured enzymes). However, it limited the member state's freedom to a significant extent by adding that these restrictions must be proportionate to the goal of, *in casu*, health protection. Obviously, this begged the question how one should go about assessing whether a measure is proportionate to the goal it aims to achieve. The Court answered as follows: in order to be proportionate, the restricting measure must limit itself to what is actually necessary to secure the protection of public health. Necessity, in turn, must be determined taking into account the findings of international scientific research, national eating habits and technological need (for additives or enzymes). Assessments of technological need must, again, take account of scientific research. Thus, by means of the proportionality principle, the Court introduced a qualitative requirement for national policy decisions, namely that they are supported by (or at the very least not in contradiction with) scientific research. The Court requirement to take account of scientific research has been confirmed repeatedly during the last ten years. Furthermore, in, *inter alia*, the *Muller* and *Bellon* cases, the Court strengthened this requirement by placing the burden of proof squarely on the national regulatory authority's shoulders: *"[i]t is for the competent authorities to show in each case, in the light of national eating habits and with due regard to the results of international scientific research, that their rules are necessary (...)"* (Bellon case summary).

Finally, the *Van der Veldt* and *Mirepoix* decisions give an illustration of how the Court is able to, step by step (or, more accurately, case by case), tighten up standards relating to domestic use of scientific expertise. Discussing these cases in inverse chronological order, the *Van der Veldt* case addresses the permissibility of market restrictions on salted bread. The Belgian Ministry of Health justified its import ban on Dutch bread by stating that its salt level was too high. Consumption of Dutch bread would result in a significant increase in the average daily intake of salt (+ 0.6 g), which, according to the Ministry, was unpermissible. Even though it is widely accepted that an overly salty diet may lead to health problems, the Court was not impressed by Belgium's scant substantiation of its claim. It stated that: *"[G]eneral conjecture of that nature does not prove that increasing salt intake by such an amount poses a risk for public health. (...) the risk must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research"* (emphasis added). Never before had the Court indicated in such unambiguous terms that the requirement to rely on the findings of scientific expertise was to be much more than mere "window dressing," and that perfunctory justifications would not be deemed sufficient.

The *Mirepoix* decision adds yet another requirement to domestic use of scientific expertise, namely the obligation to keep abreast of new scientific developments, and

review existing policy decisions in light of these developments. The case is all the more significant because it deals with pesticides, which are considered by the Court as *"per se"* dangerous products. Prohibitions relating to pesticides are therefore exempt from the requirement to establish a "danger," but may form part of a more general policy to limit their use (Joerges, 1996). Nevertheless, member states are obliged to reassess their policy decisions *"[i]f it appears to them that the reasons which led to the adoption of such measure(s) have changed, for example, as a result of the discovery of a new use for a particular pesticide, or as a result of further information becoming available through scientific research"*. Thus, even in areas where policy-makers are granted wide discretion, scientific expertise is pushed to the fore as a decisive element is decision-making.

4.C Effects on science policy decision-making at the EU level

The previous sections predominantly concentrated on the potential influence of European Court decisions on domestic science policy development. However, in a handful of recent cases the Court has also taken a stand on the relation between science and policy developed at the level of EU institutions. Three of these cases and their significance are examined below.

In *Fedesa*, the Court confirmed the discretionary powers of the Council to develop a Common Agricultural Policy in cases of scientifically conflicting evidence. The history to the case is the following: Fedesa and others had initiated court proceedings in the United Kingdom against the Ministry of Agriculture. They contested the validity of national regulations which prohibited the use of five different hormones. Since these regulations formed the implementation of an EC directive, the issue ultimately trickled down to the question whether the directive itself was valid. Consequently, the case was referred to the European Court for a preliminary ruling. The applicants in the main proceeding (Fedesa) based their allegation on the incompatibility of the directive with the principle of legal certainty. According to them, the directive lacked any scientific basis to justify the public health considerations and consumer anxieties which the directive aimed to address, and therefore had frustrated the legitimate expectations of traders, who were entitled to expect that the hormones in question would not be prohibited without any objective (*i.e.*, scientific) justification. The Court did not follow this reasoning. It argued that, even if it were to accept the premise that the principle of legal certainty should be interpreted to mean that Community institutions have to found their adopted measures on a rational and objective basis, *"[j]udicial review must, having regard to the discretionary power conferred on the Council (...), be limited to examining whether the measure in question is vitiated by a manifest error or misuse of powers, or whether the authorities in question had manifestly exceeded the limits of their discretion."* The Court furthermore hinted that Fedesa's claim concerning the absence of any scientifically based doubt relating to the safety of the five hormones was questionable, considering the divergent appraisals of the substances by the different national authorities, and the differences between member states' legislation on the issue. In this respect, the *Fedesa* decision echoes a previously discussed court rule, namely that in the case of scientific uncertainty, national policy-makers, in this instance acting jointly at the level of the European Council, retain a high degree of discretion.

The *Angelopharm* decision equally started with the contestation of a national rule implementing a Community directive, but the results were quite different. In compliance with the EC directive on cosmetics (76/768/EEC), and more in particular with the twelfth Commission amendment adapting the directive to technical process, a German regulation had banned the use of the substance 11 alpha OHP. This substance was used in Sedaterm, a product manufactured and marketed by Angelopharm. Seeing itself forced to cease production, Angelopharm challenged the 11 alpha OHP prohibition before the national German court. An expert was appointed to assess the scientific validity of the

prohibition, and his findings were that the substance in question was not dangerous. The German court was persuaded by the expert's opinion. However, since the regulation was an implementation of a Commission directive, the court turned to the European Court and asked whether (1) national law could be invalidated when is was the transposition of a directive; (2) the directive had direct effect; and (3) the directive was valid. Addressing the last question first, the European Court examined Angelopharm's allegation that the directive was invalid because the Commission had not consulted the Scientific Committee on Cosmetology in the decision-making process. The Commission replied that such consultation was only necessary if a member state so requested, an event which had not produced itself during the drawing up of the contested directive. Since a close reading of the basic cosmetics directive (76/768/EEC) did not supply a definitive answer, the Court resolved the issue in the following way: it asked whether the consultation of the Scientific Committee was necessary to ensure the legal validity of the Commission amendments. The Court continued that this legal validity was determined by the fact that the amendments were founded on scientific and technical assessments, based on the results of the latest international research. Subsequently, the Court checked which of the bodies involved in the decision-making process was competent to carry out such assessments. Both the Commission and the Committee on the Adaptations to Technical Process of the cosmetics directives were disqualified, which left the Scientific Committee as solely competent to make scientific assessments. Bringing its reasoning to a logical conclusion, the Court decided that the non-consultation of the Scientific Committee had indeed invalidated the directive. The circumstances of the *Angelopharm* decision have been discussed in some detail because of the case's important ramifications on EU science policy decision-making. First, it settled the procedure for the adoption of Commission directives pursuant to the cosmetics directive. Furthermore, it confirmed the link between scientific expertise and legal validity of Commission decisions. Finally, by upholding that the Scientific Committee is the only party involved in the policy-making process which is competent to make those scientific and technical assessments on which the legal validity of the measures depends, the Court effectively transferred policy-making authority to a body of scientific experts.

The last Court decision to be reviewed is the famous *PCP* case. The background to the case is well-known: Germany's legislation relating to maximum concentrations of pentachlorophenol (PCP) was more stringent than the provisions on PCP contained in a Council directive (directive 91/173/EEC, amending for the ninth time directive 76/769 on market restrictions for dangerous substances). Seeking to retain its own, tougher standards, Germany resorted to the procedure provided in Article 100A(4) of the EC Treaty, which stipulates that a member state wishing to apply national provisions instead of Community harmonising measures (adopted by qualified majority) on the grounds of, *inter alia,* health and safety concerns, has to notify the Commission of this intention. The Commission will then examine the national provisions and, on the condition that they do not constitute a means of arbitrary discrimination or a hidden trade barrier, confirm the provisions (the "opt up clause"). In accordance with this procedure, the Commission confirmed the German ban on PCP. The Court, however, annulled the Commission decision because it was insufficiently reasoned. In its judgement, the Court states that *"[t]he Commission confined itself to describing in general terms the content and aim of the German rules and to stating that those rules were compatible with Article 100A(4), without explaining the reasons of fact and law on account of which the Commission considered that all the conditions contained in Article 100A(4) were to be regarded as fulfilled in the case in point".* The reference to "reasons of fact and law" apparently creates a duty on the part of the Commission to substantiate its decisions both on a legal and a factual level. In the area of science policy, such facts will in the first place consist of scientific data.

Summarising, the *Angelopharm* and *PCP* decisions have imposed extensive duties on the European Commission to justify its decisions, to refer and even defer to scientific

expertise. The high level of judicial scrutiny to which its decisions are exposed stands in stark contrast to the degree of discretion granted to the European Council in the *Fedesa* case. Indeed, how could one explain this "odd man out"? In an attempt to answer this question, it is useful to recall the previously developed hypothesis concerning the inverse relation between legitimacy and scientific expertise. Following this hypothesis, the Council, composed of national Ministers, may be perceived as having a greater political and democratic legitimacy than the Commission, and is therefore less dependent on outside sources of justification (Joerges, 1996). However, different (and bolder) arguments could be developed. For example, considering that four years lapsed between the *Fedesa* and *Angelopharm* judgements, the possibility that the Court had in the intervening time ratcheted up its standards for legal validity, must be taken into account. It remains to be seen whether future case law will confirm this assumption. Alternatively, it is possible that the European Court simply does not like hormones, and was therefore willing to review a Council directive introducing a ban on hormones with a certain indulgence. However, it should be noted that none of the three offered explanations refute the main observation relating to science policy decision-making at the European Union level, namely, that the European Court of Justice has introduced stringent requirements for the Commission to substantiate its decisions, and that scientific expertise is to play a prevalent role in this process.

4.D Conclusions

The analysis of EU case law has borne out that the European Court of Justice displays a growing tendency towards stressing the importance of scientific evidence as a basis for policy decision-making. On various occasions, the Court has referred to "the findings of international scientific research" as one of the touchstones to assess the validity of regulatory decisions, both at the national and the EU level.

Admittedly, the European Court's scrutiny still falls short of the "hard look" to which US regulatory decisions are exposed. There can be little doubt that a requirement to take into account scientific research still allows regulators a reasonable degree of discretion and flexibility, particularly when compared to some notorious US court decisions which did not only insist on the use of scientific data, but even prescribed the risk assessment methods US regulators should embrace in order to make valid decisions.

Nevertheless, the trend towards closer judicial scrutiny of the scientific validity of regulatory decisions cannot be ignored. So far, the heaviest burden to justify its decisions and defer to scientific expertise has been placed on the European Commission. Considering the ever-growing workload of EU institutions in the areas of health, safety and environmental policy, and the corresponding move to delegate tasks and authorities to institutions such as the Commission, following comitology procedures, and newly established agencies, particularly for those issues which are deemed of a technical rather than political nature, this development is extremely significant.

Thus, EU case law analysis reinforces the expectation that scientific expertise is to play an increasingly important and visible role in European science policy decision-making.

5. Final remarks

This paper has argued that the emergence of an EU level of science policy decision-making, in combination with the judicial supervision of both national and Community regulatory decisions by the European Court of Justice, may significantly affect European regulators' approaches to and dependence on scientific expertise, both at the national and the EU-level. The relatively informal and "embedded" style of integrating scientific expertise into decision-making may gradually be replaced by a more rigorous and formal one. Additionally, the function of scientific expertise as a

justification and validation of policy decisions appears to increase in importance.

It is furthermore significant that the anticipated changes in European decision-making structures relate to precisely these characteristics which have been used to set the European approach apart from the American approach to science policy. Consequently, the paper claimed that an approximation of styles may be expected.

The relevance of this conclusion lies in the potential it opens for comparative studies, and for Europe to learn from American experiences with rigorous procedures and "hard look" reviews. On the positive side, more extensive use of scientific expertise coupled with heavier burdens to substantiate and provide reasons for policy decision-making may lead to a greater openness and transparency of regulatory procedures in Europe (Krämer, 1992). However, the US system has also been confronted with the down sides of "scientification." During the past few years, US regulatory authorities' extreme reliance on scientific expertise and quantitative methods to calculate risks -- allegedly to the virtual exclusion of all other factors -- has been subjected to harsh criticism (Shere, 1995; Wagner, 1995; Hornstein, 1992). Objections have been raised against the portrayal of science in regulatory decisions as a neutral, objective and inherently positive value, against the neglect of considerations relating to equity, fairness and social distribution of the effects of regulatory decisions due to an excessive focus on scientific validity, against the over-rationalisation of policy decisions, against the paralysing effect of overly stringent standards for scientific proof, etc. (Finkle, 1994; Hornstein, 1992; Schrader-Frechette, 1991; Green, 1989; Jasanoff, 1987; Alexander, 1985). Without going into a discussion of the merits of each of these objections, they clearly indicate that reliance on scientific methods and evidence alone does not guarantee acceptance of science policy decisions. If European policy-makers do indeed march further down the path of "scientification," it becomes imperative to study these criticisms, assess their relevance in a European framework, and work towards solutions.

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