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* The Political Economy of Regulatory Federalism in the European Union

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1. Market-preserving federalism

Monetary union, under the conditions specified by the Maastricht Treaty, will complete the development of the European Union (or rather of the European Community as the supranational "pillar" of the Union) as a market-preserving multi-level system of governance. According to Weirgast (1995) a market-preserving federal system has three basic characteristics: a) member states have primary responsibility over the economy; b) a common market is ensured, preventing the national governments from using their regulatory authority to erect non-tariff barriers against the persons, goods and services from other member states; c) national governments face a hard budget constraint, that is, they have neither the ability to print money nor access to limited credit.

The third condition is not met if the federal government bails out a member state whenever the latter faces fiscal problems. Precisely this possibility is excluded by Article 104 of the Treaty: "Overdraft facilities or any other type of credit facility with the European Central Bank or with the central banks of the Member States... in favour of Community institutions or bodies, central governments, regional, local or other public authorities...shall be prohibited". Article 104 empowers the Commission to "Monitor the development of the budgetary situation and of the stock of government debt in the Member States with a view to identifying gross errors". The protocol on the excessive deficit procedure specifies the reference values on the ratios of government deficit and public debt to GDP, and requires the member states to report their planned and actual deficits and the levels of their draft "promptly and regularly to the Commission".

The first criterion of market-preserving federalism is also satisfied by the EC. Of the three main functions of government in the socio-economic sphere -- redistribution, macroeconomic management, and regulation -- the first two are still the responsibility of the national governments. The EC has neither the legal competence nor the financial resources to act in these areas in any significant way. Only the regulatory function is highly developed at the European level (Majone 1996), and to emphasise this fact I speak of regulatory federalism, rather than of federalism tout court.

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2. A transaction-cost approach

This paper is mainly concerned with the second characteristic of market-preserving federalism: a common market preventing the member states from using their regulatory powers to impede the free movement of goods, services and capitals. I shall analyse the different strategies adopted over the years by the European institutions in order to restrain the regulatory power of the member states whenever the legitimate use of that power could in practice split the common market.

I compare these different strategies from the perspective of the political economy of institutions. In this perspective, the design of economic and political institutions affects how far transaction costs allow or prevent achieving gains from co-operation. Transaction costs include the resources consumed in gathering information, bargaining, observing performance, obtaining enforcement of an agreement, providing incentives to reduce agency costs. If information was freely available, specialisation and delegation would not produce agency costs. If commitments could be enforced at low cost, ex-post opportunism would not be a concern. However, all these problems exist, and institutions deal with the trade-offs they create, providing opportunities for beneficial transactions that would not take place in the absence of the institutions (Alt and Alesina 1996: 647).

Particularly important in the present context are the costs associated with the delegation of powers. The decision to delegate entails several key institutional choices (Horn 1995):

- The extent to which decisions are delegated, especially the scope of the delegated authority and the extent of ex post direction to the agents.
- The governance structure of the agency, especially the way senior personnel are selected, the degree of statutory independence, and the jurisdiction of the agency.
- The rules that specify the procedures that must be followed in decision making, including the rights different stakeholders have to participate directly in decision making.
- The nature and degree of monitoring of agency decision making, and the ability to use ex post rewards and sanctions.
- The rules governing the allocation and use of resources, in particular the extent to which the agency may be financially self-supporting.

Formally, the problem of the principal(s) is to choose among these institutional arrangements so as to minimise the sum of the transaction costs (decision-making costs and agency costs) they face in a given situation.

3. Harmonisation and its modes

The harmonisation of national rules and regulations is one of the three main legal techniques which the Treaty of Rome has made available for pursuing the objective of creating and maintaining a common market between the member states. The other two techniques are

liberalisation -- the removal of obstacles to the freedom of movement -- and the rules on anti-competitive behaviour (Dashwood 1983).

The aim of harmonisation is to adapt national regulations to Community requirements, not their elimination. It is important to realise the Article 36 of the Treaty of Rome explicitly acknowledges the competence of the member states to regulate in such areas as health, safety and the environment. It is clear, however, that different national regulations may lead, whether intentionally or unintentionally, to a splitting of the common market. Harmonisation is best understood as an attempt to reconcile the integrity of the Single European Market with the protection of important non-commodity values, in a situation where the member states control most of the policy levers. In short, harmonisation under EC law represents a difficult balancing act between conflicting objectives and for this reason has always given rise to serious conflicts concerning such issues as the scope of community competences, preexemption of national regulatory powers, and implementation. Such unresolved conflicts explain why the approach to harmonisation has changed dramatically over the years. It is these changes we try to explain in the following pages.

From the early 1960s to about 1973, the date of the first enlargement of the EC, the Commission approach to harmonisation was characterised by a distinct preference for detailed measures designed to regulate exhaustively the problems in question, to the exclusion of previously existing national regulations -- the approach known as "total harmonisation". In this period, harmonisation tended to be pursued not so much to resolve concrete regulatory problems as to drive forward the general process of European integration (Dashwood 1983: 194). However, this political use of harmonisation ran into increasing opposition from the member states, especially after the UK joined the Community.

Since the 1973 enlargement the Commission has stressed a less ideological, more pragmatic approach, accepting that the powers granted by Article 100, EEC had to be used so as to interfere as little as possible with the regulatory autonomy of the member states. The emphasis shifted from "total" to "optional" harmonisation. The latter aims to guarantee the right of free movement while permitting the member states to retain their traditional forms of regulation. Thus, a food speciality not conforming to the European standards may still be produced for the domestic market. Uniform regulations are insisted upon only when some overriding interest, such as the protection of consumers or of the environment, demands it.

4. Costs and benefits of traditional harmonisation

Recall that the Community has been given the power to act only if, and to the extent that, national regulations create obstacles to the functioning of the common market. Directives, which are the main instrument of harmonisation, leave to national authorities "the choice of form and methods" for achieving the regulatory objectives. Thus, one important advantage for the member states is that national administrations remain in control of the implementation process. In fact, the expansion of Community competences has generally entailed parallel

expansion of the powers of national regulators (Majone 1996). However, this advantage is outweighed by high transaction costs. First, the unanimity required by Article 100 EEC forces the Commission and the Council to engage in lengthy and sometimes fruitless bargaining. Second, harmonisation is a highly complex type of policy making, forcing policy makers to pay careful attention to technical details which, at the national level, would normally be delegated to specialised agencies. Old-style directives would typically include detailed engineering standards and testing methods. Not surprisingly, one of the problems the Commission had was how to overcome the lack of political interest at the level of the Council of Ministers.

On the other, the large discretion granted to the national administrations in the implementation of harmonising directives and the absence of ex post rewards and sanctions, led to high agency costs. In particular, uneven implementation across the Community generated a sense of legal insecurity for consumers, producers and traders. As a result, by the late 1970s the Commission as well as independent experts and a number of member states had come to the conclusion that harmonisation, as then practised, had been a failure. Ironically, the only exception seemed to be the success of total harmonisation in the common agricultural policy -- the most expensive, wasteful, politically divisive and ultimately unsustainable European policy. The epitaph on traditional harmonisation can be read in the 1985 White Paper on the completion of the internal market: "Experience has shown that the alternative of relying on a strategy based totally on harmonisation would be over-regulatory, would take a long time to implement and could stifle innovation".

5. The new approach

Two important developments opened a new chapter in the theory and practice of harmonisation. The first was the case law of the European Court of Justice, notably the celebrated Cassis de Dijon decision, which introduced the principle of mutual recognition and revealed the possibility of "negative harmonisation" by court action where "positive harmonisation" by legislative action had failed (Sauter and Vos 1996).

The second development was the new strategy proposed by the Commission in the 1985 White Paper. The strategy had the following key elements: mutual recognition of national regulations and standards; total harmonisation to be restricted to lay down essential health and safety requirements; gradual replacement of national product specifications by voluntary standards set by autonomous European standardisation bodies.

In essence, the White Paper proposed a conceptual distinction between matters where harmonisation is essential and those where it is sufficient that there be mutual recognition of the equivalence of the various requirements laid down under national law. The new approach was codified by Article 100A, added by the 1987 Single European Act. The article allows the Council to adopt harmonising measures needed for the completion of the internal market by qualified majority voting instead of the unanimity requirement of Article 100 EEC. Moreover, in its proposal concerning health, safety, and environmental and consumer protection, the

Commission "will take as a base a high level of protection". However, as part of a political compromise, Articles 110A(4) and 100B(2) have given a permanent character, even after harmonisation, to the Article 36 EEC exceptions (to the general prohibition of restrictions on free movement) that Article 100 was intended to phase out (Sauter and Vos 1996).

The new approach makes possible a dramatic reduction in transaction costs. Thus, in the area of technical standardisation, a multitude of specification standards contained in the old-style directives are replaced by a few performance standards which a product must satisfy in order to secure the right of free movement throughout the common market. Moreover, the performance standards are specified by the European standardisation bodies rather than by the Community policy makers. Member state are required to presume that products manufactured in accordance with the relevant European standards satisfy the essential requirements stipulated in the directive. If, on the other hand, producers choose not to follow European standards, all they need is a certificate of conformity from designated bodies. Such certificates have to be mutually recognised by the member states. Again, under the old "vertical" approach, each product had to be dealt with separately. The new "horizontal" approach groups together thousands of products that are similar in terms of their health, safety, or environmental properties.

In sum, qualified majority voting, concentration on a few essential requirements, and delegation to autonomous standardisation bodies, all contribute to a significant reduction of decision-making costs for the European institutions. Moreover, the contractual arrangements between the Commission and the European standardisation bodies are likely to keep agency costs at a tolerable level. The terms of the contract specify that the Commission's proposals for technical harmonisation shall explicitly refer to standards to be set at the European level. The Commission is also expected to actively support the use of European standards at national and international levels. For their part, the standardisation bodies take responsibility for ensuring that their standards conform to the essential requirements of EC directives. In case of doubts concerning conformity, the matter is referred to a Standing Committee, which is an advisory board to the Commission. In addition, the European standard-setters guarantee the right of all interested parties to participate in the standard-setting process, and, in particular, the right of the Commission to be invited to all meetings of the technical committees. Thus, under the new approach the Commission has shed the operating side of technical harmonisation and has, instead, assumed responsibility for monitoring the quality and fairness of the standard-setting process at European level.

6. Some open problems

In spite of its considerable advantages, the new approach to harmonisation cannot be assumed to be an institutional equilibrium since a number of problems remain open. First, the principle of mutual recognition rests on the empirical assumption that "the objectives of national legislation, such as the protection of human health and life and of the environment, are more often than not identical" (Commission of the European Communities 1985: 17). Only if this

assumption is correct does it follow that "the rules and controls developed to achieve those objectives, although they may take different forms, essentially come down to the same thing, and so should normally be accorded recognition in all the Member States" (ib.).

The problem is that this essential equivalence of national regulations cannot be taken for granted. This is shown, for example, by the judgement of the European Court of Justice in the "wood-working machines" case (Case No. 188/84 ECR, 1986, p.419). In this case the Court was confronted with two different national approaches to safety: German regulation was less strict and relied more on an adequate training of the users of this type of machinery, while French regulation required additional protective devices on the machines. The Court ruled against the Commission which had argued that both regulations were essentially equivalent, and found that in the absence of harmonisation at Community level, a member state could insist on the full respect of its national safety rules, and thus restrict the importation of certain goods.

Second, in the case of certain products like food, which are particularly sensitive from the point of view of public health and safety, mutual recognition is often possible only if the essential requirements are spelled out by detailed specifications contained in the directive itself. In this area it is not sufficient to set a few general requirements for the member states to fulfil their responsibility of protecting the health of their citizens. As a consequence, the distinction between traditional, ex ante harmonisation and mutual recognition (which is a sort of ex post, market driven harmonisation) becomes blurred.

A third problem is that the success of mutual recognition depends crucially on a high degree of mutual trust among national regulators. That the requisite level of mutual trust may not always be available is shown by the EC experience with the mutual recognition of new medical drugs. The old procedure for EC-wide approval included a set of harmonised criteria for testing new products and the mutual recognition of toxicological and clinical trials, provided they were conducted according to EC rules. In order to speed up the process of mutual recognition a "multi-state drug application procedure" (MSDP) was introduced in 1975. Under the MSDP, a company that had received a market authorisation from the regulatory agency of one member state could ask for mutual recognition of that approval by at least five other countries. The agencies of the countries nominated by the company had to approve or raise objections within 120 days. In case of objections, the Committee for Proprietary Medicinal Products (CPMP) -- a group which includes experts from the member states and Commission representatives -- had to be notified. The CPMP would express its opinion within 60 days, and could be overruled by the national agency that had raised objections.

The procedure did not work well. Actual decision times were much longer than those prescribed by the 1975 directive, and national regulators did not appear to be bound either by decisions of other regulatory bodies or by the opinions of the CPMP. Because of these disappointing results the procedure was revised in 1983. Now only two countries have to be nominated in order to be able to apply for a multi-state approval. But even the new procedure

did not succeed in streamlining the approval process since national regulators continued to raise objections against each other almost routinely (Kaufer 1990). These difficulties finally induced the Commission, with the full support of the European pharmaceutical industry, to propose the establishment of a European Agency for the Evaluation of Medicinal Products (EMEA), and a new centralised procedure, compulsory for biotechnology products and certain types of veterinary medicines, and available on an optional basis for other products, leading to an EU-wide authorisation. Both the agency and the centralised procedure have been established by Council Regulation No 2309/93 of 22 July 1993. There are reasons to believe that the creation of EMEA marks the beginning of a new phase in the practice of regulatory federalism in the EU.

7. Between comitology and the agency model

According to Article 145 EEC (third indent, added by Article 10 of the Single European Act) the Council shall "confer on the Commission, in the acts which the Council adopts, powers for the implementation of the rules which the Council lays down. The Council may impose certain requirements in respect of the exercise of these powers...". The requirements intended to limit the discretion of the Commission in implementing the regulations, directives and decisions of the Council are spelled out in the so-called Comitology Decision of 13 July 1987. This Council Decision distinguishes three kinds of committees ("comitology committees"), to one of which the Commission is to submit the draft of a proposed implementation measure: "advisory committees" "management committees", and "regulatory committees". All such committees are made up of representatives of the member states and are chaired by a representative of the Commission, who has no voting power but some agenda-setting power.

The Commission is not bound by the opinion of an advisory committee, but must take it into account as far as possible. It is interesting to note that when adopting the Single European Act, the Intergovernmental Conference requested the Council "to give the Advisory Committee procedure in particular a predominant place in the interest of speed and efficiency in the decision-making process, for the exercise of the powers of implementation conferred on the Commission within the field of Article 100A of the EEC Treaty". However, the Council has chosen not to follow this request: of all the proposals made for the completion of the internal market, by the end of 1992 the Council had chosen the advisory-committee procedure in only 17 cases, whereas the Commission had proposed this procedure in 77 cases (Falke and Winter 1996).

Under the management committee procedure (already introduced in 1962 and used mainly for measures implementing the Common Agricultural Policy), the committee, acting by qualified majority, gives its opinion on a Commission's proposal. A negative opinion is communicated to the Council, and the Commission must postpone implementation of the proposed measure for a period of one month (or three months, under another variant of the same management-committee procedure). Within this period the Council can adopt a different decision. If, however, it does not decide before the deadline expires, the Commission's proposal is adopted.

The regulatory committee procedure (introduced in 1968 and used mostly for Commission's proposals concerning the adaptation of directives and regulations to technical progress) is broadly similar, but tends to give more power to the committee and the Council, and thus, indirectly, to strengthen the monitoring capacity of the member states.

There is a good deal of inter-institutional controversy concerning the choice of appropriate committee procedure, with the Commission and the European Parliament favouring advisory committees, and the Council favouring the regulatory committees. It should be pointed out that controlling the discretion of the Commission, is only one function of the comitology committees. Another important function is to provide technical and scientific imputs into the EC regulatory process. Thus, important meetings of a management or regulatory committee are usually preceded by an "expert meeting" in which the same civil servants who act as representatives of their governments in the actual committee meetings express themselves as independent experts, in their own name, on the problems under discussion.

In their turn, committees can set up informal working groups. While a committee votes on a Commission's proposal, the working groups normally do the bulk of the actual work. Membership is different in committees and working groups. Committees are usually made up of officials coming from the national ministries, while working groups include specialists coming from national regulatory agencies or autonomous research institutions (Falke and Winter 1996: 556). When a solution has been found and agreed to by the working group (which is the general case)the committee does not discuss the point any further but immediately votes on the matter (ib.).

Today there are at least 400 comitology committees, without counting working groups and numerous ad hoc committees set up to investigate particular issues. Such a proliferation poses obvious problems of administrative co-ordination, policy consistency, and public accountability. Yet the system has not performed too badly, at least so far. It has increased the monitoring capacity of the member states but, as already noted, it has also provided the Commission with much needed scientific expertise. In addition, the system establishes links between national administrations, builds up trans-national networks of experts, keeps political leaders informed about politically sensitive regulatory issues. It even provide opportunities for the representation of various interests through the consultative committees whose members are appointed by the Commission. Some comitology committees, such as the Scientific Committee for Food and the Committee on Proprietary Medicinal Products, enjoy a high and well deserved reputation.

Why, then, the increasing support for the agency model? In October 1993, the member states established not only the European Agency for the Evaluation of Medicinal Products (EMEA) but also the European Trademark Office ("Office for Harmonisation in the Internal Market"), the Community Plant Variety Office, the European Environment Agency the European Agency for Health and Safety at Work, and the European Monitoring Centre for

Drugs and Drug Addiction -- not to mention the European Monetary Institute, forerunner of the independent European Central Bank. Moreover, there is a good deal of support -- especially from industry, but also within some services of the Commission -- for the creation of a European Telecommunications Office and even, more controversially, for an Independent European Cartel Office modelled on the German Bundeskartellamt.

A comparison of the comitology system and the agency model is complicated by the fact that the institutional design of the new institutions embodies important elements of the old system. Thus, the Committee for Proprietary Medicinal Products forms the core of the EMEA since it evaluates the authorisation requests and drafts the opinions of the agency. Nor should one forget the rather ad hoc character of the recent developments. Keeping these and other difficulties in mind, one can tentatively explain the current popularity of the agency model in the light of two main factors, one specific to the EC, the other more general.

The specific factor is the growing realisation that the harmonisation approach has probably reached its limit and is no longer adequate to the main task of the EC: the smooth functioning of the common market. A clear example of the limits of the approach is provided by the failure to establish a common market for pharmaceuticals on the basis of harmonised testing procedures and mutual recognition of national approvals. As we saw above, this failure led to the establishment of the EMEA and of a centralised testing procedure.

The underlying problem is that harmonisation has traditionally focused on rule-making, supported by a proliferating system of committees of national experts and administrators. However, regulation is not achieved simply by passing a law or a harmonising directive, but requires detailed knowledge of, and intimate involvement with, the regulated activity. The experience of the United States and other countries shows that this requirement will necessitate, sooner or later, the creation of specialised agencies entrusted not only with rule-making, but also with fact finding and enforcement. The rise of the European agencies, I would argue, is a necessary stage in the development of a European regulatory state.

A second factor behind the rise of independent agencies, both at national and European levels, is the issue of policy credibility. In an increasingly interdependent world, credibility is an essential resource of governments but it is also quite problematic for elected politicians. In part this is because in a democracy political executives have shorter time horizons than their counterparts in the private sector, so the efficacy of reputational mechanisms is more limited in the political sphere. Also, in any situation of collective choice there are many possible majorities, and their respective preferences need not be consistent. Because a legislature cannot bind a subsequent legislature and a majority coalition cannot bind another, public policies are always vulnerable to reneging and thus lack credibility. Hence, as Gatsios and Seabright (1989: 46) write: "The delegation of regulatory powers to some agency distinct from the government itself is....best understood as a means whereby governments can commit themselves to regulatory strategies that would not be credible in the absence of such delegation. And it is an open question in any particular case whether the commitment is most effectively achieved by delegation to national rather than supra-national agencies".

It is true that in Europe the advantages of agency independence are acknowledged in theory, but old habits of ministerial interference continue to persist in practice. The relative ease with which agency autonomy may be disregarded in the name of political expediency shows how precarious the position of national regulators still is. As a consequence, their national and international credibility remains open to doubt. However, regulators can build resolve by forming trans-national networks. A regulatory agency that sees itself as part of a network of national and super-national institutions pursuing similar objectives and facing analogous problems, rather than as a new and often marginal addition to a huge national bureaucracy, is more motivated to resist political pressures. This is because the regulator has an incentive to maintain his or her reputation in the eyes of fellow regulators in other countries. A politically motivated decision would compromise his/her international credibility and make co-operation more difficult to achieve in the future (Majone 1996).

European agencies would naturally play a key role in facilitating and co-ordinating the work of European regulatory networks, and in ensuring that their activities are consistent with European objectives. The trans-national network model is perhaps easiest to visualise in the field of competition. An over-worked and under-staffed DG IV has already advocated a move towards a decentralised system of enforcement via proceedings before national courts. Actually, it would make more sense to transfer responsibility for enforcement to the national competition authorities which perform a role analogous to that of DG IV, and possess the kind of experience and expertise that courts of ordinary jurisdictions often lack.

There is no reason why the network model could not be extended to all areas of economic and social regulation, and indeed to all parts of public administration where trust and reputation are the key to greater effectiveness. It could be objected that also the comitology committees form a trans-national network of national and European experts. This is true, but there are significant differences between such committees and the model of a network of national regulators co-ordinated by a European agency. The differences concern governance structures, decision-making procedures, the nature of monitoring, and the rules governing the allocation and use of resources (see section 2 above).

In particular, it will be recalled that in the comitology system experts from national regulatory agencies play a role in the working groups rather than in the committees themselves. The latter tend to be dominated by representatives of the national ministries and hence are under more direct political control. Thus, the rise of European agencies and regulatory networks, like the emerging network of independent central banks, is another manifestation of the growing de-politicisation of policy making in Europe. The separation of politics and economics raises serious problems of democratic legitimacy, but it is, I am afraid, the price we have to pay for choosing to integrate our national economies while preserving national sovereignty essentially intact.

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