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NATIONAL REGULATIONS AFFECTING PRODUCTS IN THE INTERNAL MARKET

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A CAUSE FOR CONCERN

Experience gained in

the application of Directive 83/189/EEC

1992-4

Summary

Despite the completion of the Internal Market at the end of 1992, the Member States are continuing to adopt a great many technically complex national technical regulations concerning products regulating their specification the conditions in which they can be used the tests which they must undergo and the certificates or approvals to which they must be subject In number volume and complexity the national rules far exceed the measures adopted at the level of the Community

Study of these national regulations of which the Commission is kept informed under the provisions of Directive 83/189/EEC leads to concern as regards their impact on the Internal Market Reluctance to see an important extension in the approximation of laws increases the burden placed on mutual recognition as a means to ensure the opening of the Internal Market

The debate on the impact of the regulatory burden on Union industry needs to be extended to include the burden of national technical regulations and the possible advantages where technical regulations are required, of adopting that legislation at the level of the European Union In particular actions to ensure that the views of European industry are more fully taken into account in the examination of draft national measures should be considered

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THE PROBLEM OF NATIONAL TECHNICAL REGULATIONS AFFECTING PRODUCTS IN THE INTERNAL MARKET

The Treaty[1] provides for the Internal Market to include an "area without internal frontiers in which the free movement of goods is ensured" The means which it provides for its achievement and maintenance, following the establishment of the Customs Union are based on two main groups of provisions

The first constitutes a limit on the manner in which Member States may regulate in the field of products Art 30-34/EC provides that Member States shall dispense with quantitative restrictions and all measures having equivalent effect, while Art 36/EC provides for limited exceptions to this rule That is to say, the right of Member States to take measures which affect the free circulation of goods is limited to what is indispensable to enable them to meet the objectives referred to in Art 36/EC and a strictly limited number of other purposes, described by the European Court of Justice as "mandatory requirements" Among these mandatory requirements are the protection of consumers and the protection of environment The freedom of the Member States in this respect is further limited by the provision that such measures shall not "constitute a means of arbitrary discrimination or a disguised restriction on trade " Further they have to be justified and proportionate to the objectives pursued The jurisprudence of the Court has given extensive interpretation to these important provisions and to the determination of their limits

Second the Treaty provides for the approximation of laws and for the recognition of their equivalence Thus its Art 100a/EC provides for the adoption of Community measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishing or functioning of the Internal Market Art 100b/EC provides for decisions in connection with the recognition of equivalence of measures applied by different Member States In this way a mechanism exists to ensure that even if Member States find that they cannot avoid taking measures which would otherwise restrict the free movement of goods, the Internal Market can be preserved

Even where other bases under the EC Treaty permit the adoption of measures which may affect products they do not derogate from the general principles of the Treaty relating to the free movement of goods The freedom of Member States to act therefore remains conditioned by the requirements of Art 30-36/EC

Thus the Treaty provides that the Internal Market is to be achieved by the suppression, as far as possible, of measures which inhibit free movement of goods

Where such measures may, nevertheless be taken by Member States, it is under restrictive provisions and the Community should ensure, either by mutual recognition of equivalence or by approximation of laws that the functioning of the Internal Market is not affected

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[1] EC Treaty Art 7a

It might be supposed that, under the operation of such a regime, national initiative in the regulation of products would wither away, to be replaced by Community measures in those cases where regulation is unavoidable This is not so The provisions of Art 3b/EC, on subsidiarity and proportionality, confirm the reticence of the Union towards Community legislation, as long as any other option remains The alternative to approximation of legislation at Community level, as a means for ensuring that the measures brought forward by the Member States do not undermine the Internal Market, is the recognition of the equivalence of national measures As long as the Member States, concerned with the protection of the public interest regulate extensively and unilaterally in the field of products much depends on the effectiveness of mutual recognition if the Internal Market is to be maintained

It is therefore important for the measures brought forward by the Member States to be carefully monitored and examined for their possible effects on the Internal Market Without this effort, the adoption of national technical rules would overwhelm the Internal Market and the Community would loose the benefits that it brings to the competitivity of its industry and trade

THE INFORMATION PROCEDURE OF DIRECTIVE 83/189

The principle measure through which the Commission seeks to monitor developments in Member State regulation of products and to preserve the Internal Market is the information procedure of Directive 83/189[2] Its importance for the Internal Market is evident

Directive 83/189 aims to ensure the exchange of information between the Member States and the Commission as regards the activities of the Member States in the fields of technical regulation and standardisation, in order to ensure that such activities are undertaken in a manner which is consistent with effective operation of the Internal Market

The Directive requires the Member States to notify the Commission and through it, the other Member States, of their intended national technical rules while these are at the draft stage A standstill period of three months is provided to enable the Commission and the Member States to examine the draft measures and to react to them

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[2]Council Directive 83/189/EEC OJ L 109 of 26 April 1983 providing for an information procedure in the field of standards and technical regulations as modified by Council Directive 88/182/EEC OJ L 81 of 26 March 1988 and European Parliament and Council Directive 94/10 OJ L 100 of 19 April 1994

Three reactions are provided for

- comments as regards the possible consequences of the measures for the Internal Market, if they were to be adopted, and requests for changes to be introduced The Member State concerned is obliged to take these comments into account, as far as is possible, in finalising the measure

- a detailed opinion, issued by the Commission or by a Member State, if they consider that adoption of the draft measure would create obstacles to the free movement of goods In practice, Commission detailed opinions have been limited to infringements of Community law They constitute letters of formal notice under the infringement procedure of Art 169/EC The emission of a detailed opinion results in an extension of the standstill period to 6 months[3] The purpose of this standstill is to enable the matter to be reviewed and the infringement to be avoided,

- a declaration that the Commission will propose, or has proposed, Community measures in the field results in a standstill of 12 months in total, prolonged to 18 months if the Council reaches a common position on the proposal in question while the standstill is in progress This is to enable the Community institutions to discuss the matter without their position being prejudiced or complicated by pre-emptive national measures

The Directive makes it clear, as regards the technical rules to be adopted by the Member States, that the aim is to make national intentions transparent to permit better understanding of the reasons behind national measures, and to enable their market consequences to be thoroughly assessed Further, draft measures are to be evaluated in the light of the overall development of national measures and the total burden of requirements imposed for a particular product It is also foreseen that firms should have a chance to make their views known as to the effect of proposed national measures The aim is to maintain an environment favourable to the competitivity of firms and to help them make better use of the advantages of the Internal Market

WHAT THE INFORMATION PROCEDURE HAS REVEALED

The information procedure reveals a cascade of national technical regulations, important as to the number of measures brought forward, their length and their complexity Despite the achivement of the agreed programme of measures covered by the 1985 White Paper on "completing the Internal Market' - which identified the aspects that were essential to be harmonized leaving the others to the application of mutual recognition - the Member States continue to adopt a vast array of national technical regulations concerning products regulating their specification, the conditions in which they can be used the tests which they must undergo and the certificates or approvals to which they must be subject

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[3] Directive 94/10/EC provides for the introduction of a 4 months standstill for voluntary agreements only

The relative scale and significance of this national regulatory activity is not easy to grasp However, its extent and its pervasive nature can be demonstrated if the regular flow of Member State regulation is compared with that generated in the same fields by the Union In number, volume and complexity, the national rules far exceed the measures adopted at the level of the Community

Some 415 Community directives and regulations currently apply to the placing of products on the Internal Market It has taken the Community 35 years to achieve such a stock of measures Indeed there is some tendency for the total of Community measures to decline, with the introduction of new techniques of regulation, such as the Community's New Approach, which are more economical in terms of their requirements than older methods

In contrast, in the years 1992-1994 the 12 Member States together notified proposals for no less than 1136 proposals for technical rules The figures are even higher if the activities of the three new Member States are taken into account, and higher still if draft measures which should have been notified, but were not, are included[4] In 1994, alone, including Sweden, Finland and Austria, there were 442 measures Yet 1994, was not, in this respect, an exceptional year The number of regulatory measures adopted by the 15 Member States in any one year regularly exceeds the whole Community *acquis* Further, the level of Member State regulation has been high in every year of operation of the Directive It is not a once-for-all activity but a continuous flow of detailed regulation which confronts and may well perplex the would-be supplier operating, or considering operating, on the Internal Market

Table 1 shows the number of proposals brought forward by the Member States and the Commission

TABLE 1

Number of regulatory proposals[5]		
	Member States[6]	**European Union**
1992	362	60
1993	385	28
1994	389	28

[4]See page 19

[5]The EU measures have been assessed as far as possible on the basis of the same field of coverage as the Directive

[6]Data are for 12 Member States Including Austria Finland and Sweden the totals would be 466 in 1992 438 in 1993 and 442 in 1994

The number of pages involved is also instructive as it gives some insight into the comparative complexity of the measures involved in each category In 1994, the 15 Member States put forward some 10 000 pages of regulation The Commission proposed some 250 pages

THE THREAT TO THE INTERNAL MARKET FROM TOO MUCH NATIONAL REGULATION

It is impossible to study this mass of national regulations without a feeling of profound concern for their impact on the effectiveness and smooth operation of the Internal Market

The achievement of the Internal Market in the European Union provides scope for competition along with the benefits associated with large scale By ensuring alternative sources of supply and competing technological solutions at competitive prices, it offers the European purchaser the benefits of economic dynamism Further, to the European producer it offers access to large scale demand with scope to grow and develop new outlets and a home market from which European industry can hope to take on the best that the world can offer

For the Union to reap the benefits of the Internal Market is not a once and for all event Its achievement has to be supported and sustained If this is not done, the barriers which once segmented the Union market into "penny packets" and which contributed to a relative economic decline of Europe, will reappear These benefits which accrue to the whole population of the European Union, depend on the integrity of the Internal Market being maintained

In order to be entitled to place his products on the Internal Market, the producer should only have to comply with the simp est, most uniform and most transparent legal and technical obligations that are compatible with the protection of the public interest Simplicity is needed to avoid imposing unnecessary costs on the producer Uniformity is desirable so that producers can introduce variation in product lines in order to exploit market opportunities rather than to satisfy bureaucratic needs Transparency is required so that resources can be devoted to economic development rather than to trying to interpret obscure obligations This means that the requirements concerning the safety of users, the security of the product, the avoidance of environmental damage and the protection of consumers should not be unnecessarily onerous or divergent long or complex and should be framed in such a way as to avoid requiring the producer to face different legal obligations before marketing his product in different Member States

The Internal Market is both an economic and a psychological phenomenon It consists not just of economic realities, but also of the perceptions of economic agents If the producer forms the impression that, in order to market his products, different requirements will have to be met in each Member State the benefits of the Internal Market will be attenuated The mere existence of different national regulatory requirements may be enough to convince the producer that the situation is too complicated and too diverse to be worth the investment The expression of similar ideas in different ways may achieve the same result Their very existence beyond

what is strictly necessary is therefore in itself a threat to the Internal Market If in addition, they create objective barriers to trade the damage will be the greater

ANALYSIS OF THE MEASURES NOTIFIED

a) Member States responsible

Although all the Member States notified draft technical measures over the three years 1992-1994, the bulk of the notifications came from 3 countries Germany (21%) the United Kingdom (21%), and France (17%) Further, in relation to their size, the Netherlands (9%) and Denmark (7%) provided more than their share Between them, these five Member States accounted for over 75% of the draft regulations that were notified

This share is perhaps the more remarkable given the expressed concern from these Member States about the burden on industry arising from excessive regulation at the EU level

Table 2 ranks the Member States according to the number of texts notified

TABLE 2

Ranking of Member States according to the number of measures notified

	1992	1993	1994	Total	Share
Deutschland	65	80	98	243	21%
United Kingdom	67	106	62	235	21%
France	73	65	60	198	17%
Italia	40	36	34	110	10%
Nederland	38	24	40	102	9%
Danmark	28	18	34	80	7%
España	12	15	25	52	5%
Belgie/Belgique	11	18	16	45	4%
Ellas	11	12	12	35	3%
Portugal	12	7	7	26	2%
Ireland	2	3	1	6	1%
Luxembourg	3	1	0	4	0%
Total EU	**362**	**385**	**389**	**1136**	**100%**

Further, the drafts notified by these Member States were concentrated in certain sectors of activity, although these were not the same for each Member State Thus Germany notified 181 of its 243 draft technical regulations in the fields of building and construction (73) telecommunications (65) and mechanical engineering (43) The United Kingdom on the other hand notified 168 of its 235 draft measures in the fields of telecommunications (94) transport (45) and building and construction (29) France was less concentrated with 122 out of 198 in the sectors of telecommunications (70) agriculture and food products (28) and mechanical

engineering (26) The Dutch figure of 102 was heavily influenced by regulation of agriculture and food products (46) and telecommunications (23) Italy was heavily concentrated on agriculture and food, with 57 out of 110 notifications in these fields

There can be little doubt that these figures reflect, to some extent, differences of national habit In the telecommunication sector, they also reflect the rhythm of technical evolution There may also be some differences in national structures, as notification of draft measures brought forward by local government is excluded

It should not be assumed that the ranking reflects differences in compliance with the Directive, or the effect of transposition of EU measures The Commission maintains a monitoring activity in order to detect measures which have not been notified Some 121 cases of failure to notify have been identified over the period Although significant, it suggests that the achieved rates of notification are high Measures which transpose EU legislation are not notified under the Directive

b) Sectors involved in national regulation

The main sectors involved in national technical measures are shown in Table 3

85% of the notifications received over the three year period came from five sectors telecommunications equipment agriculture and food products, building and construction, mechanical engineering, and transport[7] Despite some fluctuations the same sectors have been responsible year on year and there has only been a slight change in their ranking transport and mechanical engineering changing places in the last year with a sharp increase in the notification of measures in the field of mechanical engineering and a fall in the notification of measures in the transport field

[7]This is of course a sectoral analysis Notifications might have been classified by the issue addressed for example there was a number of notifications that addressed energy efficiency which were spread over different sectors

TABLE 3

Ranking of sectors according to the number of measures notified					
Sector	**1992**	**1993**	**1994**	**Total**	**Share**
Telecom	89	132	110	331	29%
Agriculture and food products	77	56	65	198	17%
Building and construction	56	35	52	143	13%
Mechanical engineering	29	39	74	142	13%
Transport	47	53	34	134	12%
Chemical products	15	22	17	54	5%
Pharmaceutical products	14	20	14	48	4%
Products for household and leisure use	10	2	7	19	2%
Environment packaging	9	7	2	18	2%
Health medical equipment	9	9	4	22	2%
Energy minerals wood	3	6	5	14	1%
Other products	4	4	5	13	1%
Total	**362**	**385**	**389**	**1136**	**100%**

The experience of these main sectors is reviewed below

i) Telecommunications equipment

The field of telecommunications equipment is in rapid development All Member States have been very active in bringing forward regulatory measures in this field and this activity has continued into 1995 However it is also a field in which there is extensive harmonising legislation, introduced with a view to ensuring that the Internal Market becomes effective in the field

The majority of the measures notified relate to the specifications of terminal equipment and the procedures to which they must be subject in order to be authorised for connection to the public network This field is covered by a harmonising directive

the Telecommunications Terminals Equipment Directive (the TTE Directive)[8] whose expressed aim is to eliminate the diversity of requirements and procedures to which producers of terminal equipment are subject Why, then, is the number of notifications so large and how does this affect the aim of harmonisation?

Two explanations can be offered for the large number of notifications In the first place, the liberalisation of the provision of telecommunication services, which has been under way for some time creates a requirement to replace the internal requirements of the former monopoly telecommunications operators by publicly available specifications with the force of law to ensure that the conditions for access to the public network and provisions ensuring interworking between terminal equipment are available to all interested parties and that the safety and integrity of the public network is maintained In this respect, the notifications are a consequence of liberalisation

The second explanation lies in the development of new technology and the characteristics of the TTE Directive The networks of the Member States have historically operated on the basis of national analogue networks These networks used different specifications from Member State to Member State The harmonisation of specifications for the analogue networks has not in general, been considered feasible although some progress has recently been achieved However, the progressive introduction of digital technology creates the opportunity for change The aim is to arrive at a situation in which the digital networks will have common specifications This should progressively unify the requirements for all equipment

It is for this reason that the TTE Directive is special It is, in the first place, a New Approach Directive, that is it sets out essential requirements for the equipment covered, without imposing detailed specifications However, in contradiction with the general principles of the New Approach it provides for the adoption by delegated procedure of Common Technical Regulations (CTRs) for mandatory application to the public telecommunications network across the Union In this way, the Directive aims to establish both a general framework of essential requirements and, where necessary a unique set of specifications much more detailed than the essential requirements, for use in connection with the public network across the European Union

The problem is how to achieve the transition Equipment is being called upon to operate, for the time being, in a mixed environment, using both traditional national analogue technology and new digital technology Specification is required to enable the equipment to operate within the national network as it exists The aim must be to specify what is necessary for operation in connection with the traditional technology, without repeating the errors of the past by creating a *de facto* differentiation of the digital national networks

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[8]Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminals equipment including the mutual recognition of their conformity OJ L 128 1 of 23 May 1991

There are three obstacles in the way of the realisation of Union policy in this matter

- the adoption of CTRs has proceeded very slowly Although harmonised standards can be used in the assessment of conformity, until now they have been of limited effect This is not the place to examine the reasons for such delay[9] Its result has been to provide the occasion for the Member States to adopt their own regulations in the meantime,

- new features for national networks are first implemented on a trial basis, which is extended progressively into a full-scale experiment A notification is not sent at that point, but only when the features have been implemented on a wide scale By that stage it is difficult to achieve any change to a different technical bases,

- the national regulations have often gone beyond the essential requirements of the TTE Directive That is to say, they have not respected the limitations as to the need for specification which were agreed at the time of the adoption of the TTE Directive

The Commission has sought to protect the Internal Market in this field in two ways On the one hand, the difficulties of the TTE Directive have been re-examined with a view to the development of a more flexible instrument that can respond more rapidly to market needs than the existing cumbersome system of CTRs and type approval[10] On the other hand, the Commission has carefully examined the national notifications with a view to ensuring that specifications do not go beyond the limits set by the essential requirements of the TTE Directive Where the draft measures would have led to this result, the Commission has issued detailed opinions, prolonging the period of standstill and creating the opportunity for technical discussion with the Member States in question Should the draft measures be adopted without regard to the Commission's concerns, infringement procedures could follow Elsewhere, the Commission has made comments with a view to simplifying measures from the viewpoint of the Internal Market Further where a mandate has been issued for the preparation of a CTR the Commission interpreted this as equivalent to a Commission proposal Thus the examination of national notifications in this field and the detailed reactions to them have been one of the major fields of Commission activity arising out of the Directive[11]

ii) Agriculture and food products

131 of the 198 measures notified in this field have come from three Member States - France, Italy and the Netherlands Indeed, the 46 measures brought forward by the

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[9]This issue is shortly to be addressed in a Commission Communication covering the review of the Information and Communication Technologies standardisation policy

[10]The Commission has announced its intention to bring forward a proposal for a Directive modifying the TTE Directive in the near future

[11]The Commission is also working on the process of transposing European Standards into harmonised standards in order that these standards can be mad use of under Community directives

Netherlands account for nearly half the notifications of that Member State Given that this is a field which is the subject of extensive Union harmonisation, it is perhaps surprising that Member States should have seen the need for so much additional regulation This has included a number of national draft regulations in fields covered by Union legislation invariably leading to a detailed opinion being sent to the Member State concerned with a view to obtaining modification of the national draft measure However Union legislation in a number of instances leaves details open Certain Member States have been concerned to add further detail to the procedures in these fields

The greater part of the Dutch notifications arose following modification of the national framework law on the control of the quality of products This is essentially an area not covered by Union rules The notifications concern implementing regulations to establish domestic quality criteria for products such as bulbs, drinks cheeses and vitamins The purpose is to establish the quality of Dutch production

40 % of the Italian notifications in 1992 and 1993 concerned designations of origin for meat-based products such as ham and salami and for cheeses This flow of measures came to a halt following the entry into force of a Council regulation[12] on the matter

France has notified a number of regulations in the field of food additives (colourings, aromas, preservatives enzymes) and processing aid, updating national regulations in the light of modification to the Community regulations[13] These measures fill in details which were not harmonised by EU rules

Several Member States notified detailed requirements concerning the presentation and labelling of foodstuffs This subject is covered by a Community Directive[14], but the notifications concerned details which were not harmonised

The Commission has had some success in reducing the flow of national regulations which seek to guarantee the quality of certain products by prescribing a detailed recipe This was achieved by insistence that the matter be addressed through non binding specifications rather than regulation

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[12]Regulation EEC/2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs OJ L 208 of 24 July 1992

[13]Council Directives 94/34/EC and 94/36/EC on the approximation of laws concerning food additives authorised for use in foodstuffs intended for human consumption (colouring sweeteners) OJ L 237 of 10 September 1994

[14]Council Directive 79/112/EEC concerning labelling and presentation of foodstuffs and publicity regarding them OJ L 33 of 8 February 1979

iii) Building and construction

Although nearly all the Member States have had some activity in this field it is from the United Kingdom (29 notifications) and, above all Germany (73 notifications), that the great majority of measures has come

As in the field of telecommunications, this is a domain in which there is harmonising Union legislation The Construction Products Directive (CPD)[15] aims to bring to an end the existing fragmentation of the Internal Market in this enormously valuable sector, worth 672 billion ECU in 1994 However, like the TTE Directive the CPD is unusual It has the appearance of a New Approach Directive, with essential requirements However, the essential requirements relate, not to the products themselves, but to the constructions in which the products are incorporated The implications of these essential requirements for the products themselves are developed through Interpretative Documents[16] In their turn, these are to be used as the basis for the development of Harmonised Standards whose use across the Union would be mandatory Thus, because of the special characteristics of the sector, it is envisaged that there should be harmonised mandatory requirements across the Union

Standardisation work under the Directive has proceeded slowly Although a number of mandates for standards preparation have been issued, the opening of the market by the general availability of European Standards for construction products is still a long way off The practical problems of applying the Directive will be covered in the review at present in hand by the Commission services It is hard to see how the proliferation of differing national rules can do other than make the work of adoption of European Standards yet more difficult

A further characteristic of the construction field is that, by the adoption of the Public Works Directive[17] and the Utilities Directive[18], the Member States have committed themselves to certain procedural obligations as regards the transparency of the specifications which they use in the award of works contracts by public authorities and utilities In summary, they are required, as far as possible, to specify their works contracts with reference to publicly available standards, with a clear preference being given to European Standards There is an underlying presumption that the CPD will lead to the adoption of European Standards and that such specification will help achieve the opening of the Internal Market both in works contracts and in construction

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[15]Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws regulations and administrative provisions of the Member States relating to construction products OJ L 40 of 11 February 1989

[16]Commission communication with regard to the interpretative documents of Council Directive 89/106/EEC OJ C 62 of 28 February 1994

[17]Council Directive 93/37/EEC of 14 June 1993 concerning the co ordination of procedures for the award of public works contracts OJ L 199 of 9 August 1993

[18]Council Directive 93/38/EEC of 14 June 1993 co ordinating the procurement procedures of entities operating in the water energy transport and telecommunications sectors OJ L 199 of 9 August 1993

products Nevertheless the Directives provide in two ways for alternative procedures by the implicit preference for specifications that permit variants (so enabling bids which use alternative specifications to be accepted), and by the provision that the rules regarding specifications are "without prejudice to the legally binding national technical rules insofar as these are compatible with Community law"

It has sometimes been claimed that the adoption of national technical regulations as regards the specification of works and construction products has been a necessary consequence of the adoption of the public procurement Directives This is not so Transposition of the Directives only requires that public authorities and utilities be obliged to follow the rules of the Directives Rather, the adoption of legally binding national technical rules vitiates the public procurement Directives of part of their content and undermines the intention of opening up the market for works contracts and for the construction products used in them

For these reasons the Commission has examined the notifications received in the construction sector with great care, taking account of the essential requirements of the CPD, the Interpretative Documents, and the obligations under the public procurement Directives Where a notified measure has been seen to go beyond the scope of these requirements, a detailed opinion has been sent to the Member State, prolonging the period of standstill and creating the opportunity to find a solution If the measures are nonetheless, adopted in such a way as to infringe Community law infringement procedures may be opened The Commission has also made comments intended to reduce the difficulties for the Internal Market

iv) Mechanical engineering

Germany (43), France (26) and the United Kingdom (17) are the main authors of the notifications in this field, which are however spread across practically all the Member States

Mechanical engineering is the subject of harmonising legislation at the Union level The great majority of products concerned are covered by one or other of the New Approach Directives of which the Machinery Directive is a leading example [19] These Directives cover very large categories of products They lay down the essential requirements regarding health and safety which are of general application and provide more detailed requirements, notably as regards test procedures, for particular categories of product The Directives provide for the adoption of European Harmonised Standards by CEN and CENELEC, under mandates to be provided by the Commission These will make it easier for suppliers to demonstrate the conformity of their products with the requirements of the Directives

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[19]Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery OJ L 183 of 29 June 1989 modified by Council Directive 91/368/EEC of 20 June 1991 OJ L 198 of 22 July 1991 and Council Directive 93/44/EEC of 14 June 1993 OJ L 175 of 19 July 1993

Despite this extensive Union harmonisation, national regulation continues to be brought forward and its volume has even tended to increase in 1994

The reasons for this activity at national level are associated with a desire to make more precise specifications available to producers, as regards safety and similar requirements Thus some Member States have taken the view that safety requires the adoption of detailed rules making the implementation of the essential requirements more precise, at least until such time as European Standards become available Other Member States have sought to update existing legislation in these fields to take account of technical progress In the field of the Machinery Directive, Germany has been the only Member State to bring forward national technical regulations in the period 1992-4 This reflects the German system of adaptation of its legislation to technical progress, using expert committees whose conclusions are implemented by ministerial decision, without the underlying legislation being affected

In many cases, measures are intended to provide details of a means of ensuring conformity with the essential requirements of the basic regulation without excluding alternative, equivalent means This highlights a problem with national measures The essential requirements of the Directives are supposed to be sufficient to ensure safety and similar public concerns are met European Standards are a help to industry in meeting these, but are not intended to be compulsory Does the adoption of national specifications not tend to undermine this principle, even if they are accompanied by a specific statement that equivalent measures will be accepted? National measures have a way of becoming *de facto* exclusive requirements The New Approach offers producers freedom to find the technical solutions that suite them best It is hard to see how national measures can do other than undermine this flexibility

The Commission takes the view that the adoption of further requirements by the Member States is not compatible with the existence of Union legislation under Art 100a/EC which provides for total harmonisation Draft national measures which impose additional requirements are met with a detailed opinion If the national measures are adopted without appropriate changes, the Commission may initiate infringement procedures

The best solution to the problems identified in this sector is for interested parties to achieve the adoption of the European Harmonised Standards that they consider to be necessary The adoption of such Standards under mandates provided by the Commission, is now advancing more rapidly In the presence of such Standards, it would be contradictory for the Member States to continue to impose additional requirements or to bring forward detailed specifications

v) Transport

The United Kingdom alone has notified 45 of the 130 notifications in this field No other Member State has made a disproportionate number of notifications There are three main fields which have been the subject of notifications

In the first place, 48 notifications relate to the motor vehicle sector This is a field of extensive Union legislation covering vehicle functioning and construction

requirements and where major progress has been achieved towards replacing the separate national systems of type approval by a single Union system This is largely achieved for motor vehicles and their trailers and is far advanced for two and three-wheeled road vehicles There has also been Union harmonisation as regards tractors and agricultural vehicles Further, the Union legislation is closely aligned with the regulations of the UN-ECE The Commission made observations in 28 cases and sent detailed opinions in 17 cases The European type-approval procedure has become mandatory from January 1996 for passengers cars and notifications for these vehicles should cease As far as other categories of vehicles are concerned, it is important that serious efforts are sustained by Member States to prevent the fragmentation of the Union position, which brings enormous benefits in this important sector

Road traffic rules and road traffic signs are not harmonised at EU level, although 6 (out of 12) Member States are contracting parties to the relevant UN-ECE conventions and three further Member States maintain de facto application The 14 notifications in this field came principally from the United Kingdom It is hard to understand why extensive national specification is needed in the presence of a widely acceptable common point of reference It may be asked whether variation in technical regulations could not be reduced by achieving uniform application of UN-ECE requirements across the Union and by restraint in the Member States in adding detail to them However, it would appear that there is resistance to such a development among the Member States

Maritime safety and pollution prevention, the subject of International Maritime Organisation (IMO) conventions has given rise to 40 notifications 10 of these were the subject of detailed opinions and on 24 occasions comments were sent to the Member State concerned with a view to obtaining modification of the measures Member State sensitivities regarding competence have made it difficult to obtain a consistent posit on and uniform application of IMO requirements across the Union This has led the Commission to make proposals with a view to uniform application under Union law[20]

THE COMMISSION'S REACTION TO THE NOTIFIED MEASURES

The Commission reacts to all the notifications it receives Even where there is no comment to be made, the Commission takes a formal decision to that effect

In 526 cases, the Commission presented comments with a view to the measure being adapted to make it less onerous for the Internal Market In 357 cases, the Commission presented a detailed opinion to the initiating Member State, warning it that adoption of the measure in its existing draft form would lead to an infringement of Community law (Sometimes a notification was the subject of both observations and a detailed opinion)

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[20]Proposal for a Council Directive on marine equipment COM(95)269 Final of 21 June 1995

Commission proposals for Union legislation gave rise to the initiating of extended standstill periods in 62 cases However the number of extended standstills has fallen rapidly with the completion of the Internal Market programme

In the vast majority of cases, the Member States took the Commissions' reactions into account Nevertheless in some cases adoption of the measures may have failed to take full account of Union obligations Where this comes to the attention of the Commission, infringement proceedings under Art 169/EC may be initiated

Further, as a result of its monitoring activities, the Commission identified 121 cases where the Member State had failed to notify measures at the draft stage Infringement proceedings were initiated for these cases under Art 169/EC and 9 were submitted to the Court of Justice

TABLE 4

Infringement procedures initiated because of non-notification of draft technical measures												
B	**D**	**DK**	**EL**	**ES**	**F**	**IRL**	**I**	**L**	**NL**	**P**	**UK**	**TOTAL**
8	19	-	15	7	13	-	30	1	16	9	3	121

As appears from the above comments, in many cases there were good reasons for the measures that were being proposed Nevertheless, the accumulation of measures is still a cause for concern because of their implications for the operation of the Internal Market

PREVENTING DAMAGE TO THE INTERNAL MARKET THE LIMITS OF MUTUAL RECOGNITION

The first instrument foreseen by the Treaty for the preservation of the Internal Market is the suppression of barriers to trade contained in national technical requirements However, where these persist, the Treaty provides for approximation of laws and mutual recognition In view of the current reticence towards further extensive approximation of laws the Internal Market is bound to rely heavily on mutual recognition for its preservation

In the operation of Directive 83/189, the principle of mutual recognition is recalled by the inclusion of a provision in notified draft technical regulations This provision indicates, in substance that the technical requirements do not apply to products originating in other Member States[21] which are in conformity with a standard a code

[21] The reasoning here applies equally to products originating in EFTA countries which are parties to the EEA

of conduct, a technical regulation or a legally imposed procedure in another Member State which enables the aim of the technical regulation in question, in so far as it is a legitimate objective under Community law, to be achieved in an appropriate and satisfactory manner (Legitimate objectives include the protection of health, safety, protection of the environment and so on, as described above)

The inclusion of such a provision is a useful reminder of the mutual recognition requirements which flow from the Court's jurisprudence relating to Arts 30ff of the EC Treaty, according to which in particular a Member State cannot properly forbid the placing on its domestic market of a product that has been legally manufactured and marketed in another Member State Indeed, where a product "suitably and satisfactorily" meets the legitimate objectives of its destination Member State's rules (safety consummer protection, environment, etc), this Member State cannot justify prohibiting the free movement of this product by claiming that the way it meets these objectives is different from that imposed on domestic products In other words, a product legally manufactured and marketed in another Member State which is not in conformity with the regulations of its destination Member State may only be denied free movement if it really puts at risk the public interest protected by the destination Member State regulations

However, it can be questioned whether the inclusion of a simple provision of mutual recognition in texts with an average length of 20 pages, in the midst of detailed and otherwise apparently exclusive requirements, can guarantee the integrity of the Internal Market The practical difficulties encountered by operators are essentially due to the fact that, according to the case some Member States consider the application of voluntary standards by the operators to offer sufficient protection of the public interest, while others consider it necessary to set binding rules The application of national rules, which are numerous, different, complex and binding, undeniably increases the risk of obstacles to free circulation of products which, without being formally or strictly in conformity with these rules, can nevertheless meet, in an appropriate and satisfactory manner, the legitimate objective sought

This risk could be offset this by proposing Community measures to ensure both the protection of the public interest and free circulation However for the Community to launch a programme of harmonisation, to compensate for the regulations of Member States, would hardly be compatible with the aim of keeping regulation to a minimum Further, the principles of subsidiarity and proportionality would doubtless be invoked, making it difficult or impossible to obtain the support of sufficient Member States to adopt such a programme

Even where national requirements do exist in different Member States it is extremely difficult to know how well mutual recognition is applied in practice The concern cannot only be the compatibility of national measures with Community law The underlying economic concern has also to be addressed as to whether economic agents have sufficient confidence that mutual recognition will be applied in practice for the national measures to be compatible with an open and dynamic Internal Market In practice there is a permanent temptation for national market surveillance authorities to apply the letter of national provisions with which they are familiar to the detriment of Community operators whose products suitably and satisfactorily" meet the

legitimate objectives of these national provisions (that is, they do not put at risk the public interest protected by these provisions)[22] Faced with this situation the Commission has been very active In the first place, it has pursued complaints about failure of the Member States to respect their obligations under mutual recognition Indeed many of these complaints are solved without the need to open formal infringement proceedings Nevertheless, it is also aware that businesses are often reluctant to complain They are seeking economic outlets, not involvement in legal battles

Second, in order to identify cases in which a Member State has refused free movement to goods, despite the fact that they were legally produced and marketed in another Member State the Commission has proposed - and the Council and Parliament subsequently adopted - the setting up of an information procedure[23] under which the Commission and the Member States will exchange information, from January 1997, on national measures which derogate from the principle of the free movement of goods

Third, in the context of its 1996 review of the Internal Market, the Commission is seeking to study practical experiences with the way mutual recognition is applied by national market surveillance authorities Nevertheless, it is aware of the difficulties of finding out from such a global review specific informations from economic operators such as those which will be collected through the procedure described above

ISSUES TO BE ADDRESSED

The need to ensure the competitivity of European industry has provoked a wide debate about the burdens imposed by regulation on industry[24] This debate has been carried on at both the national level and at the Community level[25], although its intensity has varied from Member State to Member State

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[22]France and the United Kingdom have in a number of their notified drafts invited the other Member States to inform them of their equivalent measure with a view to their being specifically mentioned in the national measure This is an interesting development which the Commission will follow up

[23]Proposal for a decision of the European Paliament and the Council establishing a mutual information procedure on national measures derogating from the principle of free movement of goods within the Community COM(93)670Final of 15 December 1993 (OJ C18 of 21 January 1994) modified by COM(94)250Final of 15 June 1994 (OJ C 200 of 22 July 1994)

[24]The issue was addressed by the Commission in the White Paper Growth competitiveness and employment (the Delors White Paper) Bulletin of the European Communities Supplement 6/93

[25]Studies on the regulatory burden include this Opening of Markets and Competition a report prepared for the German Federal Government by the Deregulation Commission March 1991 Deregulation Now a report by the Anglo German Deregulation Group 1995 and the Report of the Group of Independent Experts on Legislative and Administrative Simplification (the Molitor Group) presented to the European Commission June 1995

Analysis of the reports of the various studies and enquiries undertaken suggest that, as concerns the regulation of products, it is not the objective of the measures - safety health, protection of the environment and the consumer or even promotion of energy efficiency - that is at issue, so much as the means employed Rules have been attacked in some cases rightly, for being obscure ambiguous, disproportionate or ill-conceived But the majority of these studies have failed to develop an analysis of the detrimental effects of national regulation on the functioning of the Internal Market and so, directly, on the competitivity of industry Nor has there been a debate on the relative merits of national and Union regulation in ensuring that the public interest is protected while the competitivity of industry is promoted[26]

It is high time that the debate on these issues is joined Without questioning the right of the Member States within Union law, to initiate the measures they consider necessary for the protection of their citizens, a debate on these issues could open the way for action improving the operation of the Internal Market and through it benefiting European industry and the European economy

A number of questions could be addressed These include the following

- Are regulations really required in all the cases where they are proposed? In a number of cases the national rules do not owe their existence to the coverage of a risk so much as to the preservation of a particular way of doing things or even to a desire for order in the domestic structure Given the negative consequences of national regulation for the Internal Market, is this a sufficient reason for a measure to be adopted especially when other Member States seem able to survive without it? Many good steps can be achieved without regulation

- National rules may be proposed because there are no specific Union rules A recent example concerned the safety and stability of children's cots Concern had arisen out of a number of accidents to children falling from their cots Two Member States notified rules on different aspects of the problem But children are no more or less likely to fall out of bed in Italy than they are in Sweden, nor are Greeks less concerned with the safety of children than the Irish Union law already provides the General Product Safety Directive One solution which would not involve a risk to the Internal Market could be to encourage the development of voluntary standards

- What further measures can the Member States take in order to make sure that mutual recognition is properly applied? Member States cannot refuse free circulation of goods produced using technical procedures, standards or practices which enable the product to meet the objectives of national regulation (such as the protection of health or of the environment) What have they done in practice to educate enforcement authorities about their obligations under Community law?

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[26]Nevertheless a number of studies undertaken by national employers organisations for example in Belgium Danemark Spain the Netherlands and the UK have drawn attention to the difficulties which are frequently met by business when they try to take advantage in one Member State that their products have been legitimately produced or marketed in another Member State

- A Union regime which is not working or is not working fully, may become the target for national notifications Two fields have been discussed above in which the defects of the Community regime could account for the mass of national measures Or perhaps it is the determination of the Member States to regulate for themselves that gave rise to the defects of the Union regime Such regulatory problems will not be resolved without courageous action at the Union level and industrial competitiveness suffers in the meantime Would it not be better to work for implementation (and, if necessary revision) of the Union regime than to multiply national measures ?

- Some notifications, without being in infringement of Union law, undermine existing Union policy For example, national regulation in the field of construction undermines the opening of the market in public works Others undermine the development of European voluntary measures Directive 83/189 provides measures to discourage national standards from being developed in areas where a European standard is being prepared, and it blocks national regulation where Union legislation is under discussion But there is no way to stop regulatory measures in areas where European Standards are in preparation What measures could be envisaged, either in the internal co-ordination of the Member States, or at Union level, to maintain the coherence of national and Community initiatives?

- The subsidiarity debate has focused attention on the need to justify action at European level in particular as concerns need and efficiency As regards product regulation, the efficiency of European level action is often not at all difficult to demonstrate A single Union regime is likely to be more efficient and less restrictive than 15 national regimes Further the Union, through its New Approach, has developed a technique of legislation that is confined to what is essential and which makes a virtue out of leaving space for business to find its own solutions The New Approach also offers stability over time which is a great advantage to economic operators Use of this approach has become widespread at Union level, but is not in evidence at national level Where there are real risks to be protected against, there is a strong *a priori* case for considering that European regulation may will be more efficient than national regulation If rules are really needed and unless the Member States can implement their measures in a way which creates more confidence for the integrity of the Internal Market would it not in general, be better to adopt them at Union level, so combining protection of the public interest with an effective Internal Market ?

CONCLUSIONS

The volume and complexity of national regulatory activity in the field of products as revealed by the Directive, is a matter for serious concern in view of the risks it creates for the Internal Market

With a view to promoting the vigorous examination of the consequences of regulatory proposals, the Commission services will take steps to involve Union industry in consultations concerning national draft measures Member States usually take good account of the concerns of their own industry in the preparation of draft measures However, in the context of the impact of those measures on the Internal Market, it is the views of industry in other Member States that really need to be considered The Commission will develop the means for such consultation

As a practical measure to assist industry in understanding the national technical rules, the Commission is looking into commercially viable means of developing a data base of national technical rules in some or all Union languages Translations are already prepared in the context of the examination of notifications The Commission services are looking into the ways in which this information could be made accessible to industry

The best way of ensuring that national technical regulation does not prejudice the operation of the Internal Market is to limit it to what is absolutely indispensable The means to this end are in the hands of the Member States Debate on the issues set out in this report could be a contribution to their development