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The New Approach to Technical Harmonization and Standardization

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The elimination of technical barriers to trade in the EC is one of the most important routes to achieve a unified, genuinely free Internal Market in the Community. In the one and a half decades since the comprehensive Commission proposals for technical harmonization were first published, great difficulties have been encountered and progress has been slow. An alteration of this 'traditional' approach and getting Member States to accept other methods was long overdue in the early 1980s.

The 'new approach' to harmonization and standardization, initiated in 1985, is an attempt to accelerate both harmonization processes at the Council level and European standardization processes at industry level while at the same time providing more flexibility for innovation and easier market access. It is potentially of great economic importance.[1] This paper examines the constituent elements of the new approach, evaluates it by means of a systematic comparison with the drawbacks of the old approach and identifies problems that should be dealt with promptly.

BASIC FEATURES OF INTRA-EC LIBERALIZATION

The *central policy question* with respect to technical trade barriers is how the European Community can achieve a fully-fledged common product market, while the Member States retain the ultimate responsibility with respect to societal objectives (such as safety and health). The freedom of movement of products will have to be subject to common judicial review. The national

[1]This paper will concentrate on the institutional and operational details of harmonization in the EC. For a summary of the economics of harmonization and standardization, see Pelkmans, 1986, chapters 1 and 2. See also, for instance, Hemingway, 1975, Nunnenkamp, 1983, and Kindleberger, 1983.

health, safety and environmental policies will have to be harmonized to such a degree that the physical properties and performance, imposed upon products by national regulation, can no longer impede intra-EC trade. Appropriate solutions will hinge on the authority and inventiveness of the case law ex. Art.s 30 and 36, EEC (the legal regime) and on the efficiency and effectiveness of the chosen method of harmonization, ex. Art. 100, EEC (the policy regime).

The '*legal regime*' is based on the prohibition of 'measures having equivalent effect' to quantitative restrictions (in Art. 30, EEC) and the scope of the interpretation of Art. 36, EEC that indicates the exceptions to this prohibition. The details of this case law cannot be discussed here,[2] but a few critical points can be mentioned briefly. In the judicial review process of those national measures which block the importation of products from other Member States, the burden of justification rests on the Member State that actually blocks the import. The burden is not a minor one since the Member State should show that application of the general principle of free movement of goods is not warranted in the particular case at hand. The general principle has been formulated most clearly in the Cassis-de-Dijon case: products having been lawfully produced and marketed in one of the Member States should be given free access throughout the Internal Market. To argue for a justified exception (ex. Art. 36, EEC), one must demonstrate non-conformity to safety or health requirements. In other words, conformity to such requirements in the Member State of origin will have to imply 'incomparably' lower standards of safety or health before impediments can be permitted. Granted this case for an exception, the Court still imposes a 'proportionality' rule: the measure laid down by the importing Member State ought to be proportional to the objectives sought, which might imply, for instance, that an import prohibition is to be replaced by a labelling requirement.

The '*policy regime*' is based on Art. 100, EEC. If considerations of overriding public interest, such as health, safety, consumer or environmental protection, lead to differences in national regulations that hinder intra-EC trade or render it more costly than domestic trade, Art. 100, EEC provides for the possibility to lay down (unanimously) directives 'for the approximation of such provisions'. This is called harmonization (although this term is not mentioned in Art. 100). It is quite obvious that the very purpose of harmonization is to overcome these differences, which must imply that Art. 36, EEC, can no longer be invoked by Member States if a directive on the relevant problem has been drawn up (this point has been confirmed by the EC Court). Harmonization can be linked to standardization, dependent on the quality of the latter.

[2]The literature on the legal regime of the free movement of goods in the EC is large. See, for instance, Timmermans, 1983, Oliver, 1984, Mattera, 1983, and Gormley, 1985.

In theory therefore, the elimination of technical barriers to trade could be achieved when

— Art. 30, EEC (i.e. the general prohibition) would be interpreted broadly
— the exceptions in Art. 36, EEC, would be under strict judicial review
— the harmonization, ex Art. 100, EEC, would efficiently and effectively deal with the differences, arising from the maintained exceptions, ex Art. 36, EEC
— the standardization would precede, or at least move in parallel (where desirable) with, European harmonization.

The first two conditions have gradually become accepted as firm accomplishments of the case law of the EC Court of Justice. The other two conditions remain a matter of considerable concern.

THE 'TRADITIONAL' APPROACH OF THE POLICY REGIME

For more than one and a half decades the European Commission has tried to pursue an ambitious harmonization programme. Following a few ad hoc cases, and a prudent first step towards the harmonization of the national regulations concerning pharmaceutical products, in March 1968, the Commission proposed a General Programme. From that time until the so-called Mutual Information Directive 83/189/EEC, an incredible amount of energy on the part of civil servants and experts had been devoted to the production of an extremely limited number of Council Directives. Many of these directives focus on specific technical *aspects* of products and they therefore fail to solve all the problems of access in product markets. During these fifteen years the EC has adopted on average only a little over ten technical directives a year.

It is doubtful, to say the least, whether such a slow speed can actually bring about a net reduction in the technical barriers to trade in the Community in view of the simultaneous accretion of regulations in Member States. To put it more strongly, given the increase in bureaucratic regulatory capacity in recent decades in all Member States and the greater societal preference for environmental and consumer protection, it can safely be presumed that the tempo of national regulation has, for many years, exceeded by far that of the annual output of 'aspect-directives' at EC level with respect to a rather limited group of products. Apart from being *inefficient* — due to extensive and drawn out consultations on technical specifications — the method was *ineffective* as well: a general improvement of mutual market access was not achieved, at best there was only a slowing down of the rate of increase of technical barriers.

Nor did the wider European standardization processes proceed smoothly. The history of CEN (European Standardization Committee) shows clearly that, without some connection with the EC's own harmonization policy,

progress at the wider European level tends to be exceedingly difficult. A serious drawback of the functioning of CEN is that no long-term programmes are being developed to remove the trade-impeding effects of different national standards (notwithstanding their private and voluntary character).

It is virtually impossible to formulate an adequate judgment about the production, efficiency and effectiveness of CEN standards. Although CEN has issued annual reports for several years, it remains unclear whether, and to what extent, intra-EC trade benefits, or might benefit, from the adopted standards or from those being discussed. The annual reports do not lend themselves to policy assessment: they merely consist of a compilation of the activities over the year of each of the 58 technical committees, presented in an extremely condensed manner. Not only is this method of reporting an insufficient basis for assessing the realization of the objectives of CEN, it also fails to provide adequate information about the accomplishment of greater unification of the industrial Euromarket. Both highly desirable requirements of a CEN report would call for a policy-oriented introduction of the Secretary-General, an analysis of the relevant trade flows and the size of market (current supply) in each of the product markets at issue, a brief survey of the remaining obstacles and a detailed treatment of the priorities in the programme in the framework of a long range perspective. Furthermore, it would be advisable to consider separately the conversion of standards from the worldwide International Standards Organisation (ISO) into (usually more precise) European Standards (wherever appropriate), and the mandates of the EC and EFTA in an accessible fashion. CEN deserves powerful support to enable it to perform these additional tasks effectively.

DRAWBACKS OF THE 'TRADITIONAL' APPROACH

In earlier work[3] I have analysed extensively the considerable disadvantages and shortcomings of the traditional strategy of technical harmonization (and standardization) of the Community. Briefly these consist of:

1. time-consuming and cumbersome procedures
2. excessive uniformity
3. unanimity (ex Art. 100, EEC)
4. the failure, except rarely, to develop a linkage between the harmonization of technical regulations and European standardization, leading to wasteful duplication, useless inconsistencies and time lost
5. the slowness of European harmonization and standardization relative to national regulation and standardization.
6. a neglect of the problems of certification and testing
7. the incapacity to solve the third country problem

[3]See Pelkmans, 1986, and J. Pelkmans & A. Vollebergh, 1986.

8. implementation problems in Member States
9. a lack of political interest by the Ministers.

It is not surprising that by the early 1980s the question of the removal of technical barriers to trade in the EC had led to profound feelings of frustration and disappointment.

The policy climate in which the elimination of technical barriers to trade in the EC had to be realized was such that the individual protectionist was thriving whereas the dynamic exporter, attempting to encroach upon other markets, was hampered. Of course, the opposite climate should characterize European market integration for the benefit of the Community's economy at large.

An evaluation of the 'new approach' at this early stage of implementation can perhaps best be provided by means of a careful checking of the expected improvements on every single one of the nine drawbacks listed above. Before doing this, a summary will be given of the 'new approach' and its broad overall advantages will be set out.

ESSENCE OF THE 'NEW APPROACH'

The new approach consists of three elements:

(a) preventing new technical barriers from arising, on the basis of the so-called 'mutual information directive' 83/189/EEC
(b) recourse to the principle of 'reference to standards' in directives, ex Art. 100, EEC, for certain large product groups; in a narrower perspective one might confine the 'new approach' only to this aspect;
(c) a general promotion of European standardization in various ways, suitable to the problem at issue, as well as specific promotion of the activities of CEN, CENELEC (European Standardization Committee for Electrical Products) and to a lesser extent CEPT (the European Committee of PTTs).

The new vigour in EC policies for the elimination of technical barriers to trade has also led to a 'new approach' in special sectors such as the food sector. Sustained by consistent case law, condemning many protectionist (i.e. disproportionally import-discouraging) clauses in national food laws, without in the least undermining the health objectives sought, the current approach is based on 'horizontal' directives with respect to general aspects of food law such as 'labelling' (etc.) while otherwise imposing free intra-EC trade.

(a) Preventing New Technical Barriers

The 'mutual information directive'[4] attempts to create better conditions to reduce, if not eliminate, the retardation of EC-wide harmonization and standardization compared to national regulation and standardization. Hence it deals with drawback no. 5 directly. By preventing the trade-impeding effect of new national regulations, it also obviates the heavy harmonization road later and thus several other drawbacks as well. The directive improves and legally underpins the 'gentlemen's agreement' of 1969 (among the 'representatives of the Member States') with respect to timely notification of new national technical *regulations* before their enactment.[5] The significance of the directive reaches further, however, since, in contrast to the gentlemen's agreement, (new) industrial *standards* are also covered. With respect to national draft regulations, three possibilities exist. The most far-reaching is a standstill of one year, at the request of the Commission, in order to prepare a proposal for an EC directive so as to prevent the trade-impeding effect of the intended national regulation. A more modest step is a standstill of half a year, at the request of the Commission or a Member State, in order to discuss formal amendments. Finally, notifications frequently lead to discussions and consultations in the Permanent Committee (set up to check notifications), in turn engendering alterations in the national draft regulation, without any formal standstill.

(b) Reference to Standards in the New Approach

The new approach to harmonization proper is based on the method of reference-to-standards. But its elaboration is so detailed that the approach has to be described carefully.[6]

The aim of the new approach is twofold:

1. *abolition of technical trade barriers* in the EC
2. development of *a European doctrine in the field of safety*, health, protection of consumers, workers and environment (etc.) by means of harmonization on the basis of Art. 100, EEC.

The formal distribution of competences between EC level and Member State level remains under the EEC Treaty (that is, Member States retain

[4]*Council Directive* 83/189/EEC of 28 March 1983 concerning an information procedure in the field of standards and technical regulations, *Official Journal EC* of 26 April 1983 no L 109.

[5]Published as part V of the General Programme resolution of 28 May 1969, under the title of 'Accord' (etc.) concerning the status quo and the notification to the Commission, *Official Journal EC* C 76 of 17 June 1969. This text is only available in the French, German, Italian and Dutch versions.

[6]Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, and two Annexes of which especially Annex II is very detailed. It provides for a 'model directive', article by article that cannot be commented on in every detail in this paper. See *Official Journal EC* of 4 June 1985, no. C 136. For a more detailed treatment see Pelkmans, 1986.

their ultimate responsibility for health, safety, etc.), but the trade barriers arising from this are avoided by harmonizing health and safety objectives. In practical terms this means that:

— interference in trade will be a rare exception
— in that rare event, the burden of justification lies with the Member State and leads to immediate negotiation at EC level.

Since the adoption of the 'new approach' (in May 1985) the Single European Act has specified this further (see below, page 258).

These considerations lead to the following four principles:

— harmonization of legislation is limited to the adoption, by means of the directives based on Art. 100 of the EEC Treaty, of the essential safety requirements (the Court's words for 'objectives', in this case) with which the products brought on the market must comply in order to qualify for free movement in the Community;
— it is the task of the competent (private) standardization organs, given technical progress, to formulate the technical specifications, on the basis of which industry needs to manufacture and market products complying with the fundamental requirements of the directives;
— these technical specifications are not binding and retain their character of voluntary (European) standards;
— but, at the same time, the governments are *obliged to presume* that the products manufactured in accordance with the European standards[7] comply with the 'fundamental requirements' stipulated in the directive. It is this presumption that guarantees business free market access.

Since (European) standards are voluntary,[8] it is possible that producers do not manufacture according to the technical specifications in the standards. In that case, the producer must supply the proof that the product complies with the fundamental (safety or health) requirements. Given this proof there is again free trade.

The 'presumption of conformity' with the relevant requirements that standards confer on products, creates, with the Member States, the strong desire for a *quality policy* in the framework of European standardization. This policy has two elements:

[7]Or, temporarily with national standards when no European ones are available yet.

[8]Observe that

— European standards provide a 'presumption of conformity' and, for that reason, lead to unhampered access, but they cannot be mandatory because the *national* authorities remain ultimately responsible for the protection of health, etc.
— national standards cannot be mandatory either, because there have to be *various* ways through which the 'presumption of conformity' can be obtained (for instance, manufacturers' declarations, backed by a designated certification organ), securing in turn the free movement.

— standardization mandates of the Commission to CEN and CENELEC.
— consultation of a Standing Committee 'Reference to Standards' which will consist of representatives of the Member States chaired by an official from the Commission.

On the basis of this quality policy it is reasonable for Member States (given their ultimate responsibility) to leave intra-EC movement free for all products falling under directives enacted by way of the new approach. Safeguards can only be invoked in very special cases.[9]

(c) Promotion of European Standardization

The third element of the new approach is the general and at times specific promotion of European standardization. The specific promotion is channeled via the successive mandates of the EC Commission to CEN, CENELEC and possibly other sectoral standardizing bodies, in order to ensure that standardization processes take place in parallel with harmonization at Council level and are based on the same 'essential requirements'. The incentive that renders this promotion effective is at the same time the central objective of the 'new approach', namely intra-EC market access. Henceforth, mandates to CEN (etc.) carry an almost definitive prospect of security of market access, if only standardization is pursued appropriately and in line with the 'essential requirements' of the directive. In order to avoid possible delaying tactics, so well known from the traditional Council approach to unanimity on technical details, CEN has had to reorganize its voting rules from unanimity to qualified majority voting. This was also agreed by the EFTA members of CEN. In so doing, the incentive to join standardization efforts is further increased since one or two member delegations can no longer block the outcome of a substantive investment in a joint standard. In addition, the mutual information directive has led to the creation of a 'central unit' of CEN and CENELEC, processing quarterly information on all intended new (or altered) standards and distributing this to members and subscribers to the service. It is to be hoped that CEN/CENELEC will actually reorganize themselves to utilize this rich flow of information in such a way as to prevent new de facto barriers arising. It is no secret that there is hidden resistance to this badly needed shift of emphasis from national to European standardization.

Finally, standardization is promoted in radically new ways in sectors where the product market cannot really emerge if *ex ante* standardization has not been satisfactorily dealt with. This applies to standards for communications between computers, for telecom equipment standards and possibly for bio-technology. Such processes of standardization may imply advanced

[9] Namely, if standards contain imperfections; if manufacturers' declarations are false; if standards are not applied correctly.

research and co-ordinated product development or adaptation of prototypes. In other words, they need not necessarily be comparable with processes whereby the prospect of adjustment costs in well-known product and process technology generates resistances and delays in standardization. At the same time, promoting ex-ante standardization may also enhance the worldwide competitiveness of all firms involved.

ADVANTAGES OF THE 'NEW APPROACH'

The most important potential advantages of the 'new approach' are (i) greater coherence between the policy regime and the legal regime to eliminate technical barriers, and (ii) the better conveyance between European harmonization of technical regulations and European standardization. As stated earlier, the Council will have to assume the task of reaching a 'European doctrine' in the fields of safety, health, etc., so that the technical barriers to intra-EC free movement can disappear. The new approach is a serious attempt to achieve this coherence by combining *total harmonization* of the objectives at issue (safety, etc.) with a *flexible approach* of the means (standardization). It also improves the scope for a timely interchange of information so that national draft-standards and technical draft-regulations can be altered or converted into European ones before formally taking effect.

These advantages are commendable and may explain the willingness in Member States and in various circles to view the new approach with a 'prejugé favorable'. They are however *potential* advantages because a great deal depends on the actual results, both in the Council, with respect to the total harmonization of objectives of health, safety, etc., and also from the standardization processes in the CEN/CENELEC framework.

The advantages can be formulated in a less abstract way by examining which *dis*advantages of the traditional approach, as mentioned before, will be reduced or eliminated by the new approach. The effects on these nine disadvantages and deficiencies are summed up below. The reader is warned that for the time being a speculative evaluation concerning the 'quality policy' is needed in some cases. The author considers the model directive[10] to be a sufficient basis to develop an adequate quality policy from the co-ordinated work of the Commission, the Standing Committee 'Reference to Standards' and CEN/CENELEC. Given this presumption, the effects on the 'old' approach disadvantages are summarized as follows:

1. *Time-consuming and laborious procedures.*
Both the Commission and the Council (and the Coreper bodies) could save a considerable amount of time, not only because technical specifications do not need to be approved twice, but also because technical aspects — within the quality policy — are in fact delegated. Whether this time-saving can be

[10]See note 6.

transformed into acceleration depends on the speed of standardization. Standardization speed can be increased by pressure originating from the procedures under the Mutual Information Directive and by apportioning Commission payments for the implementation of mandates to CEN and CENELEC. It is not precluded (indeed, it is implicit in the new approach) that, should the safety objectives, etc., be agreed, legislation can also lead to greater pressure being exerted to speed up standardization.

2. *Uniformity.*

The advantage here has already been reported: the combination of uniform safety objectives (etc.) with the desired variability in the means for industry or for the consumers. Moreover, the fact that no mandatory reference takes place leaves room for original solutions in existing products and for product innovation.

3. *Unanimity.*

The central question remains whether unanimity with respect to the objectives, including the demands on the quality policy, will always be achieved so easily. This question is even more pressing because the new approach is applied to relatively comprehensive product groups. The way out in the Council that is apparently used with the first 'new approach' proposals of the Commission is to negotiate 'mixed forms' of the old and the new approach, with some technical specification in the directive itself but not as detailed as before. The 'traditional' approach will not completely disappear: the White Paper contains some 90 industrial and 60 agricultural proposals of the traditional type. Recent experience with lead-free petrol and with the reduction of exhaust gases of motor vehicles has shown that even unanimity *can* lead to decisions if the pressure of time arising from the Mutual Information Directive together with economic (export) interests increase the willingness to reach compromises.

The newly agreed Art. 100–A, included in the Single European Act and providing for qualified majority voting, could constitute a significant boost in overcoming the resistance of a single country. It is expected to enhance the room for manoeuvre of the Commission, which was almost non-existent under unanimity. Nevertheless, the usage of products for workers and the possibility of safeguards (subject to Court review) may continue to cause occasional problems in case of majority voting (given paragraphs 3, 4 and 5 of this new Article).

4. *Harmonization not related to standardization.*

For every case in which the 'new approach' is applied, this problem is by definition solved.

5. *EC standardization slower than national standardization.*

Because standards are included in the Mutual Information Directive, and because 'reference to standards' will be used in directives, an increase in the tempo and in the volume of European standardization can reasonably be expected.

With regard to the short-term, it is doubtful whether this acceleration and volume increase is sufficient to bring about a net reduction in the barriers; in the long run this is certainly possible. It should be ensured that the volume increase does not merely consist of CEN approval of all sorts of sectoral standards which in certain sectors have already been agreed at European level for a long time. Indeed, to the extent that this is a 'cosmetic' operation, little value can be attached to it. To the extent that the standards were not actually followed, it does have significance. Moreover, where government contracts are at stake, the European Commission can possibly extend the significance further. Ultimately a strong tempo and volume increase by CEN and CENELEC depends on capacity limitations and the rapidity with which these can be overcome.

6. *Limited attention to tests and certification.*

Except for a vague promise nothing can be found on this in the new approach. This serious weakness of the new approach must be dealt with soon (see below, page 265).

7. *The third country problem.*

Here also the effect of the new approach is still not clear.

8. *Application and implementation.*

It seems reasonable to accept that the combination of total harmonization of health/safety objectives, European standards linked to an adequate quality policy of the Council and the already existing legislation, will have a favourable effect on the actual application of the directives in the Member States. Of course, it is the details of application that will be decisive for the economic agents in the market. Proper implementation is, however, a slow process and substantial improvement is not to be expected before the 1990s. It can be speeded up by the greater potential which careful total harmonization of objectives offers for the national judicial process. However the real problems are sometimes deep seated, for instance, reference to national standards in insurance contracts, in the conditions for connection imposed by public utilities or in local delivery conditions.

9. *Lack of political interest.*

Total harmonization of the objectives as well as the comprehensiveness of the product groups form the arguments which give rise to the presumption that *more* political interest in the Internal Market Council and in the Commission will be mustered.

Taking everything together, improvements can be perceived with respect to seven of the nine disadvantages of the 'traditional' approach. The extent of these advantages, however, is at the moment far from obvious and the length of time before they will be felt by industry and consumers could be considerable. Nevertheless this does not detract from the fact that the 'new approach' looks as though it will be *qualitatively an enormous improvement* over the traditional approach.

Finally, two advantages must be pointed out which are directly connected with the nine points just mentioned, but are of such potential importance that they deserve to be mentioned separately and emphatically.

In the first place the new approach is linked to the issue of *improvement in the competitiveness of European industry*. Harmonization and standardization are still viewed in many branches of industry or in individual companies as a potential threat to the market position or a cause of unwanted adaptation costs. Except for extremely specific conditions in a large market, however, protectionism leads in due course to a worsening international competitiveness.

If, on the other hand, *standard quality* is such that penetration into many foreign markets is possible, then standardization can be seen in quite another light. Because specialization is becoming ever more refined, and scale effects in many cases form an important determinant of the export position, the quality approach offers a much better perspective, not only for industry and the consumer but also for the economy as a whole. Seen in this way, emphasis will come to lie on quality and international acceptance of the standard, two matters which — except in the case of far-fetched protectionism — are closely connected. The new approach stimulates this because it aims at making market penetration easier and at the same time at pursuing a quality policy. This is further stimulated by Art. 100–A, sub 3 of the Single European Act. Considering the weaknesses widely observed in the competitiveness of European industry, this advantage can be described as carrying some weight.

In some branches of industry the positive impact of European standardization on competitiveness will weigh even more heavily. Standards can have a market-creating effect or, in other words, the lack of a standard between adjoining countries can make the Euromarket (i.e. trade between Member States) impossible, as is for instance the case with car telephones. Standards can also have an anticipatory effect. For instance, sufficient investment in product development, process technology and further innovations takes place in some products only when compatibility is secured first. Interesting examples of this are the recently proposed Council directives concerning standardization in the field of information technologies and telecom and concerning the mutual recognition of type approval of terminal equipment for telecommunication, the latter now having been adopted.[11] Given the very close relationship between telecom and information technologies, the key to promoting European product development and greater intra-EC trade is a system of European standards which provides specifications in much more detail than the CCITT world standards.[12] When (different)

[11]See Council Directive 86/361/EEC of 24 July 1986 on the initial stage of the mutual recognition of type approval for telecommunications terminal equipment, in: *Official Journal EC* L 217 of 5 August 1986, also COM(85)230 of 1 July 1985 and the essay of E. de Robien in Beuter & Pelkmans, 1986.

[12]The CCITT is the Consultative Committee of the (UN) International Telecommunications Union that recommends standards for telecommunications equipment and information technology.

computers or word processors communicate at a distance, compatibility standards require precise conventions (on the basis of which information exchange takes place) while safeguarding the inter-operability of the systems for processing and communicating the information. European industry lacks these standards and, thereby, a necessary condition for maintaining and improving its world competitive position.

Secondly, it can be expected that the workload on some Commission services will be considerably reduced by the new approach and that the excessively detailed regulations will gradually become of lesser importance. The Commission has already withdrawn various draft directives which were laid before the Council in the context of the traditional approach. *The reduction in the Commission's workload* is welcome because attention can then be given to more urgent problems in the field of technical trade barriers which have a more direct and greater effect on the free intra-EC movement of goods. A couple of urgent problems ask for that attention: the whole set of problems concerning testing, inspections and certification marks; and the consultation procedures in the framework of the Mutual Information Directive which are labour intensive but prevent many potential bottlenecks in the national draft regulations at an early stage.

Reduction in the Commission's workload can also lead to more attention being given to implementation and enforcement questions in the Member States. For many years responses have only been made to complaints and the question is whether even these have been pursued adequately.

PROBLEMS EXPECTED

The ultimate success of the 'new approach' depends largely on the political and entrepreneurial climate in the Community. The swift adoption of the 'reference-to-standards' approach, right after the acceptance of the Mutual Information Directive' 83/189/EEC, contributed in itself to a psychological improvement of the climate. Favourable, too, is the increasing readiness to recognize the problems of the Internal Market and to try to arrive at a solution, not least because manufacturers consider the competitiveness of European industry a priority objective. The consumer however vies with the manufacturers for quality standards as a means, as a two-edged sword, to achieve safety (etc.) and a better market position. Unfortunately, neither government officials nor neutral observers should infer from that observation that in such a climate the present political will can set harmonization quickly on its course once again. The interests of some are too specific for this and the exceptions which require detailed regulations too numerous.

The following list of problems should not put the reader into too sombre a mood. Many of these questions are solvable if politicians, followed by civil servants and standards institutions, continuing to work within the predominant perspective of the unification of the Internal Market, wish to

invest in the search for solutions. Politicians, and certainly government officials, have difficulty in perceiving useful *politics* in this technical material. Therefore the European Commission and CEN or CENELEC should explain in detail, with each important directive, the economic significance (production; intra-EC trade; world market positions; supplies to other sectors; technological aspects, etc.), to make it easier for ministers to propagate the political fruit of their paying attention to these matters.

In brief the expected specific problems are as follows:

(a) *Problems in the acceptance of directives*

— Art. 100 EEC will only be applied to objectives and criteria but will naturally continue to require unanimity. The key is therefore the newly agreed but not yet ratified Art. 100–A of the Single European Act.

— The hitherto national requirements of 'usage' of products can lead to difficult decision-making in Brussels; this problem is (has been made) terrifically complicated and yet insufficiently recognized. In an article such as this the question cannot be addressed further but certain observations can possibly lead to reflection or further action. For instance, it might be asked whether the restrictive 'Gerätesicherheitsgesetz', referring to German standards on machines and machine-tools (and possibly similar legislation in other Member States) conforms to Community Law. To the author's best knowledge, neither the Commission nor a Member State has ever lodged or followed up a formal complaint for infringement.

It might even be asked whether infringement procedures are the best way of dealing with the matter. For instance, the Mutual Information Directive does indeed offer scope to limit the effective result of this type of legislation. Another interesting point is how the directive concerning legal liability for defective products,[13] which has just been accepted, relates to these (national) usage regulations. Obviously inspection marks and certificates are also at issue here (see further).

(b) *Problems with exceptions*

The 'new' approach replaces the 'traditional' one only when the selection criteria for the choice of product groups are applicable.[14] This,

[13] Council Directive 85/374/EEC of 25 July 1985, in *Official Journal EC*, L 210 of 7 August 1985.

[14] The selection criteria for product groups to be suitable for the new approach are five (source: see note 6):

— should be possible to distinguish sufficiently the identification of the factors of the health or safety objectives, from the technical specifications in the standards referred to
— primacy of standardization (rather than regulation as in food and medicines) in the sector
— precedence for product groups in which, at present, Community action is lacking
— sufficiently large number of products in the product group (inspired by the Low Voltage Directive)
— regulation, also by directives, should really be necessary in order to avoid technical barriers.

In the Netherlands a sixth criterion has been emphasized strongly: harmonization is especially desirable in product sectors undergoing rapid technological progress. See Pelkmans, 1986, pp. 96/7.

however, creates the remarkable, and extremely unsatisfactory, picture of large variations (possibly) arising in the extent of effective integration of product markets which rely heavily on 'traditional' procedures. Here special attention should be given to the possibly increasing backlog in food and pharmaceutical products that suffer from 'traditional' procedures.

(c) *Problems with standardization*

— Fears are widespread that CENELEC and, especially, CEN are insufficiently equipped to support the new approach adequately. This is an extremely serious point. In standardization institutes and in industry and commerce many experts dismiss the idea of a European standardization institute (something the USA has at federal level). Resistance is understandably strongest in three of the larger Member States with big standardization institutes and large stocks of national standards: Germany, France and Great Britain. Unfortunately the arguments on which this dismissal rests are one-sided. They concern primarily the fear of too much centralization and bureaucracy from such a federal bureau. However one cannot dismiss a proposed solution on such grounds if the problems giving rise to proposals of a federal kind are not tackled. With respect to output limitations, it should be noted that plans beyond the modest capacity extension of CEN recently decided are not foreseen. CENELEC has just received an increase in budget allocation of 40 per cent but the Central Unit is included in that. The financing of the Central Unit approved by the Commission and EFTA has resulted in more secretariat capacity for both standardization organs. Nevertheless, the central secretariat is tiny and the extremely decentralized activities are not really co-ordinated by priority setting, programmes and effective deadlines. If the new approach were in full swing, this would be bound to create recurrent problems.

National standardization institutes complain about shortage of money, industry and commerce have undertaken few initiatives for expansion in CEN (as far as the author knows), and the Commission has only promised to finance per mandate.

If the preference for a division of labour between regulators and standardizers, as foreseen in the 'new approach', is accepted in earnest, *the financial and organizational consequences ought to be faced.* If neglect is allowed to drag on, the new approach will be seriously hampered.

— A link should be made between the European standards of CEN/CENELEC/CEPT and government procurement policy. On the one hand this would imply a change in the so-called supply directive of 1977 and the directive for procedures for the tendering of public works.[15] On

[15] The so-called supply directive 77/62/EEC as published in *Official Journal EC* L 13 of 15 January 1977, and the public works directive 71/305/ EEC as published in *Official Journal EC* L 185 of 16 August 1971.

the other hand it should already play a role in the standardization process (e.g. in building materials, telecom and electro-medical products for hospitals), as has indeed been accepted for telecom terminal equipment recently.

(d) *Problems with implementation*

— As already stated, infringements of Community law in the implementation of directives into national law are quite an issue. This problem will, it is hoped diminish in the new approach. This expectation is based on the limited stress on, or absence of, product specifications in the directives. Experience with the Low Voltage Directive of 1973 (where reference to standards was used for the first time at EC level, albeit in a much looser way than in the new approach) has shown that illegal national deviations can be tackled by a combination of consultations with CENELEC and judicial review. The Commission should therefore prevent 'new' deviations from occurring and, should this ever happen, act fast. In view of Article III of the model directive this can be immediate.[16]

— Infringements of the mutual information directive, up to 1986 the only practical result of the new approach, continue to take place but are in most cases settled amicably by an attentive Commission. This in itself shows how important the directive is! Nevertheless, the Commission recently issued a stern warning to the Member States with a view to preventing infringements.[17]

(e) *Problems with the implementation deadlines*

The new approach has been presented without calendars or deadlines. In addition it is partially complementary to the traditional approach. The effects on the product markets will therefore not be directly noticeable. It is realistic to think in terms of ten to fifteen years if the aim is full freedom in all the larger product markets.

The Dekker Plan and the White Paper of the Commission have, however, created the impression that this can be crammed into six or seven years.[18] This seems heroic. Nevertheless in six to seven years the trust of industry and commerce can be won back. Because of the strong fixation on informatics and telecom it tends to be forgotten that there are other sectors which are of the same or even greater economic importance. While attention to these questions is undoubtedly necessary, it would be unfortunate if this were to generate too great expectations. If one wants to go significantly faster, then the new approach is not sufficient. Above all, it would need stronger political

[16]After ratification of the Single European Act, Art. 100–A, sub 4 may give rise to problems, however, although Commission surveillance and Court review will mitigate their effects. For a treatment of this question, see Lauwaars, 1986.

[17]Commission communication concerning the non-respect of Council Directive 83/189/EEC (etc.), *Official Journal EC*, C 245 of 1 October 1986. The Commission warns, inter alia, that (unnotified) national regulations thus adopted are 'unenforceable against third parties'.

[18]See Dekker, 1985, and EC, 1985.

and financial backing. This does not mean, however, that in certain sectors rapid progress will not take place.

(f) *Problems with certification*

The gravest omission in the new approach is that it causes certification to become more prevalent, without offering any concrete proposal or initiative to deal with it at European level. This failure to tackle certification is bound to lead to more temporary or even permanent barriers, and in any event to cost increases.

Certification is, in this connection, the last line of defence against a genuinely free Internal Market. Occasionally, certification is even complemented by connection conditions relying on specific testmarks or certification reports. Until 1986, the Commission never went further than repeated but vague promises about future action. The promises go back to the General Programme of 1968 and the Colonna report on Industrial Policy of 1970. They are firmly made in a Communication to the European Parliament in 1980 and appear again in the White Paper.[19] The Promolog reports (1985) have clarified that it is difficult, even for a reputable institute such as AFNOR (the French Standards Institute), to get a comprehensive picture of the national certification marks in usage, let alone to understand fully the national systems for the various sectors and the trade impeding effects caused by all this.

The Commission should prepare

— a comprehensive list of national certification bodies, and summaries of their procedures
— a comprehensive list of laboratories relevant for certification
— meetings at European level about mutual recognition procedures
— initiatives for a reduction of these potential and real barriers.

One possibility would be to apply the example of the CENELEC Certification Agreement (second edition, of July 1984) to other sectors. A more ambitious alternative would be a system of national Certification Councils, as now exist in the UK and the Netherlands. Such Councils aim to secure a high quality level of certification, not merely in a technical sense but also in terms of transparency of procedures, legal form (a foundation!), means of legal redress, objectivity, etc. An EC-wide system of Certification Councils would firmly establish the mutual confidence that is lacking at present.

(g) *A problem of interpretation*

In or just before the Council meeting of 7 May 1985, two sentences were added in item III of the model directive of the new approach.[20] Item III is about the 'essential (safety) requirements'. After a call for enough

[19] See Pelkmans, 1986, for the various quotations.
[20] See note 6, pp. 4/5.

precision 'in order to create, on transposition into national law, legally binding obligations which can be enforced' — a sentence originally proposed by the Commission — the following was added:

'They [the essential requirements] should be so formulated as to enable the certification bodies straight away to certify products as being in conformity, having regard to those requirements in the absence of standards. The degree of detail of the wording will depend on the subject matter.'

These two sentences can lead to great confusion. In the light of the frustrating experience with the traditional approach of Art. 100, EEC and given the manifold problems of certification (Pelkmans, 1986), there is every risk that these two sentences will be exploited to the full by covert lobbies resisting the new approach. Parts of the sentence, such as 'enable the certification bodies straight away to certify products' appear equally open to abuse to anyone who knows even a small amount about certification. Certification requires sufficient detail about the technical properties of the product and exact definitions of the testing methods to be employed. If the latter were not present, mutual recognition would be out of the question since the test would not be repeatable, hence not comparable.

Thus, extensive technical annexes may once again appear if the protectionists get their way. One major precedent for this effect and the new approach would, in fact, be aborted. Even more worrying is point 2 of Item III of the model directive: 'Amendments to these requirements can be made only by means of a new Council Directive under Article 100 of the Treaty'. Imagine, for a moment, the effects of the need for unanimity merely for tiny points of technical progress. The easier method of delegated Commission Directives, used hitherto for such amendments, would not even apply!

However, it is crucial to see that the confusion originates from bad formulation, perhaps last minute drafting, since a careful reading shows unmistakably that a protectionist interpretation of the addition must be inconsistent with the new approach. This can be deduced as follows.

We know the Council's pronouncement about the *essence* of the approach: the Council 'emphasizes the importance and desirability of the new approach which provides for reference to standards . . . for the purposes of defining the technical characteristics of products . . .'[21] On the other hand the model directive speaks about the ability to 'straight away . . . certify products' on the basis of the essential requirements. These two statements are inconsistent, and clearly the former takes precedence. The reason for the confusion is that the central point of the latter sentence is tucked away at the end: 'in the absence of standards'.

[21]Council Resolution, as in note 6; Annex 1.

The correct interpretation, in line with the logic and objectives of the new approach, is as follows:

— 'in the absence of standards and where the manufacturer does not observe standards', Item VIII, point 3, sub 1, establishes the obligation that the certification bodies designated by the Member States will have to intervene.
— this is consistent with the part 'in the absence of standards' in the added sentence in III, 1.
— since technical annexes are excluded, by virtue of the above and for good reason, the solution must be that, *as long as* standards do not exist, certification has to occur on a private contractual basis between the manufacturer and a designated certification body. The latter will have to interpret the essential requirements and specify the technical consequences and the used test methods in the contract and the test report. This does not pose any great risk since designated bodies are trustworthy and will certainly wish to remain designated. The basis of the 'presumption of conformity' will thus be the certificate of the designated body chosen. It is far-fetched to expect more than marginal differences in actual testing results. Even if this were a real fear, it is far superior to back initiatives on certification (see (f) above) and accelerate standardization (so that the 'absence of standards' no longer applies) than to persist in pressing for extensive technical appendices as if still working with the 'traditional' approach.

A FINAL WORD

The new approach deserves to be embraced much more firmly than has been the case hitherto. The extreme prudence of Member States in the gentlemen's agreement of 1969 has proved to be inimical to the proper functioning of the Internal Market. The experience of the first one and a half years of the Mutual Information Directive (up to 1 September 1985) is, on the other hand, extremely positive. Notifications of intended technical regulations have increased *fivefold* on an annual basis; silent consultations have been effective at an early stage of legislative processes; five standstills for one year have proved to be necessary.

For the first group of products subjected to the new approach, the Commission has chosen 'simple pressure vessels'. Before the draft directive was published,[22] problems emerged on how (technically) specific the 'essential requirements' of safety ought to be. Since, in the absence of European standards (which is the case in this product market), the essential

[22]Draft directive of the Council on simple pressure vessels, COM(86)112 of 14 March 1986, as published in *Official Journal EC*, C 89 of 15 April 1986.

requirements ought to be sufficiently precise to serve as the basis for certification, the borderline between the safety objectives, on the one hand, and the technical specifications, on the other hand, will be blurred. The Commission finally came up with eight pages of requirements, some of which are quite detailed. However, the pressure to insert still more specifications will inevitably return in the Coreper groups preparing the Council's decision, either because the experts are the same or because civil servants get their briefs from those national experts. All this is regrettable because the new approach deserves a good start with a directive that will reduce mistrust and reservations. A swift adoption of the directive, even though it is somewhat heavy on technical specifications, would be of symbolic importance in creating confidence in the further elimination of technical barriers to trade in the EC.

Finally, the Commission should do its utmost to come up with its long-awaited proposals on certification, tests and certification-marks. In and by itself this would probably greatly increase the confidence of industrial exporters that the new approach will become effective.

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