



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.05.1998
COM(1998) 291 final

REPORT FROM THE COMMISSION TO THE COUNCIL
AND THE EUROPEAN PARLIAMENT

**EFFICIENCY AND ACCOUNTABILITY IN
EUROPEAN STANDARDISATION
UNDER THE NEW APPROACH**

CONTENTS

INTRODUCTION: THE NEED FOR CONSTANT REVIEW	1
I. THE SPECIFIC FEATURES OF THE NEW APPROACH IN RELATION TO STANDARDISATION.....	2
The Relationship Between the New Approach and Standardisation	2
The Need for Accountability	4
The Role of National Standards Bodies	4
The Use of Publicly Available Specifications (PAS)	5
II. THE SEARCH FOR EFFICIENCY	6
The concept of Efficiency	6
Timetable for the Standardisation Procedure.	8
III. PROPOSALS FOR IMPROVING THE EFFICIENCY OF THE EUROPEAN STANDARDISATION SYSTEM	9
Management of the standardisation process.	9
The role of public authorities	11
A Single European Standardisation Body, or More Competition?	12
Improving Awareness	13
Financial Support to European Standardisation	14
IV. CONCLUSIONS	15
 Annex: Progress in standardisation programmes	 16

16
10a

INTRODUCTION: THE NEED FOR CONSTANT REVIEW

1. European standards play a vital role in the proper functioning of the Single Market. At its November 1997 meeting, the Council for the Internal Market asked the Commission to "*prepare a report on the efficiency of European standardisation, in co-operation with the European and national standards organisations, and with the appropriate European-level committees*". During subsequent discussions, and in particular at the occasion of the informal meeting of Ministers for the Internal Market held in Cambridge in February 1998, it was agreed that the Report should focus on the New Approach.

This Report was produced in response to that request. It was prepared in close collaboration with Member States, European and national standards bodies and other interested parties.

2. Efficiency in European standardisation has been brought to political attention at various occasions in the recent past. In its Action Plan for the Single Market¹, the Commission noted that *considerable progress has been made in the area of standardisation, but that there is no room for complacency*. In its Communication on "the impact and effectiveness of the Single Market"², the Commission noted that "some problems have been experienced due to delays in the delivery of standards, but that the standards bodies have made great strides in adapting to the surge in demand put upon them. The onus will be on European industry, if it wants the harmonised standards, to provide sufficient resources to finish the job."
3. A recent report prepared by Denmark³ and presented to the Internal Market Council highlighted the fact that a significant number of standards for the New Approach has still to be delivered and that the average development time for standards remains too long in most cases. The Commission welcomes the initiative taken by Denmark, as it allows for verifying where further progress can be made.
4. This Report describes the relationship between the New Approach and standardisation, and emphasises the need for accountability in standardisation. It then indicates how efficiency can be assessed, and formulates a number of proposals for improving efficiency. Its conclusions are that
 - *the basic concepts of the New Approach and of European standardisation have proved their validity for the development of the Single Market,*

¹ CSE(97)1 final of 4 June 1997.

² COM(96)520 final of 30 October 1996.

³ The European standardisation work: analysis and recommendations for efficiency initiatives. Report prepared for the Danish Agency for Trade and Industry, October 1997.

- *the management of the standardisation process and transparency can be improved, which is a task mainly for the European standards bodies,*
- *standardisation as a voluntary system has its limitations and public authorities have the responsibility to create incentives and a framework in which standards can be developed in an efficient way.*

I. THE SPECIFIC FEATURES OF THE NEW APPROACH IN RELATION TO STANDARDISATION

The Relationship Between the New Approach and Standardisation

5. The principles of the New Approach to technical harmonisation and standards were laid down in 1985 (*OJEC C 136 of 4.6.1985*).

The New Approach deals with large families of products (e.g. machinery, construction products, toys, packaging, etc), or with horizontal risks (e.g. electro-magnetic compatibility). It defines the essential requirements that products must meet when they are put on the market, but it does not indicate the technical

New Approach and New Approach-like directives have been adopted, covering a range of products as diversified as toys, construction products, electro-magnetic compatibility, machinery, telecommunications terminal equipment, satellite earth station equipment, medical devices, packaging, etc.

Products covered represent 17% of intra-Community trade.

A list is attached in Annex.

means by which to meet the requirements. With the exception of the Construction Products Directive, New Approach directives leave manufacturers the choice of technology. The New Approach directives, therefore, allow for a high degree of technological flexibility.

To facilitate the marketing of products, the *New Approach foresees the use of European standards as a fast track to meet essential requirements*. Compliance with such standards remains voluntary, but provides definite advantages to manufacturers who place products on the market.

- Products meeting standards have a *presumption of conformity* with the essential requirements of the directives.
 - In most New Approach directives, standards permit a *wider choice of conformity assessment procedures* for manufacturers. For instance, compliance with European standards can allow a manufacturer to declare conformity with the Directive without third party intervention.
6. *Standardisation is, by its nature, a voluntary process carried out within independent organisations*. Parties will only participate in the process if they

perceive a value in doing so. The incentive to develop standards is mainly an economic one. Standards are adopted on the basis of consensus, defined by standards organizations as the absence of sustained objection from major parties. Compliance with standards remains voluntary.

The New Approach has, however, added a new dimension to standardisation.

- Standards bodies are not entirely free to decide what standards to develop. They are required to meet essential requirements of large legislative programmes, to develop a coherent set of standards that cover aspects of the public interest, such as safety. The standards themselves must remain flexible enough to allow for technological progress while, at the same time, providing a sufficiently precise level of specification to ensure smooth implementation of the directives.
- The New Approach also introduced institutional changes. Responsibility for presenting European standards as "harmonised" standards under the New Approach has been given to the European standards organisations. At the same time, public authorities have committed themselves to not insisting on approving the technical content of such standards; no positive decision is required by which authorities approve the standards, even if previously such technical aspects were subject of regulation.

7. In certain areas, where the market is not sufficiently interested in European standardisation, the approach taken by the European legislator has not itself given rise to a sufficiently strong incentive to develop standards at the European level. *The policy objective of the free movement of goods should not be delegated to the voluntary standardisation level*, as standardisation can only solve technical questions.

- For instance, the *Construction Product Directive (CPD)* does not create a sufficiently strong incentive to elaborate so-called European harmonised standards. As long as no such standards exist, national technical regulation continues to exist, and Member States can even adopt new regulation. Consequently, if the market is not prepared to elaborate standards, the free movement of construction products is not guaranteed by harmonisation and remains governed by the principles of the Treaty.
- Another often-cited example of the "failure" of the European standardisation system is the case of *plugs and sockets*. These are excluded from the scope of the Low Voltage Directive, and no standardisation mandate has ever been given to CENELEC. Given the existence of vested national interests, it is unlikely that on a mere voluntary basis standardisation will take place. If harmonization of plugs and sockets should take place, a political decision is likely to be required.

The Need for Accountability

8. The New Approach charges European standards organisations to elaborate technical specifications the use of which provides a presumption of conformity with legal requirements.

This can only be justified if the standardization system is truly open and transparent, if the standard is supported by all major interested parties, and if the standard is applied in a uniform way throughout the Community.

These requirements are referred to as the accountability of

European standardisation. Principles of accountability have been laid down in the General Guidelines for Co-operation between CEN and CENELEC and the European Commission, adopted in 1984 (currently under revision) and in the Council Resolution of 18 June 1992 on the role of European standardisation in the European economy (C 173 of 9.7.1992).

The General Guidelines for Cooperation and the Council Resolution on the Role of European Standardisation reflect principles of accountability in:

- institutional rules relating to questions such as membership of the standards organisations, access for European-based interest groups to policy setting activities, dialogue with the public authorities, etc.;
- the possibility for all interested parties to participate effectively in standardisation work, under fair conditions;
- the need to verify consensus through national public enquiry, the establishment of consensus through national representation, and, in certain countries, the need to make standards available in the national language;
- the obligation for national standards bodies to transpose European standards in an uniform way, and to withdraw conflicting national standards.

Efficiency and accountability must be balanced. It is essential that all interested parties have the possibility of fully considering the substance of a draft and of expressing their views during the public inquiry, with associated comments taken into consideration, even if this has an impact of efficiency.

Accountability determines to a large extent the role of national standards organisations and of the possible use of Publicly Available Specifications.

The Role of National Standards Bodies

9. Consensus is determined on the basis of national representation. National standards bodies thus play an essential role in expressing the national position and they will continue to play this role. In addition, national bodies are a link between market players, in particular SMEs, and European standardisation, and provide access to and advice on European standards, as well as secretarial support to Technical Committees. The Commission considers that *national bodies are an essential part of the European standardisation system.*

However, national standards bodies should also project themselves as being part of a common European standardization system, serving common interests. This is particular true in their relations with international standardisation.

Nevertheless, the possibility of providing secretariats for technical committees and similar bodies by European-level sectoral associations (such industrial federations) should be considered as an alternative to national standards bodies. This possibility should not affect the approval procedures, which remain with the national standards bodies.

The Use of Publicly Available Specifications (PAS)

10. Some Member States have suggested examining whether, in the absence of European standards, PAS adopted by private consortia of companies, or other documents of CEN, CENELEC and ETSI, can be used for the New Approach, even if they do not have the status of standards. *The Commission considers that PAS and similar documents can play a useful role as input to the standardisation process.* Where PAS reflect market practice, it may be useful to verify through the standardisation process whether that practice may meet with overall consensus and thus become a full-fledged standard. The Commission welcomes the procedures developed by CENELEC and ETSI to present PAS for approval as European standards.
11. The advantage associated with the use of such documents is the greater speed with which they can be adopted, compared with standards. The difference in speed is due mainly to the absence of the need to seek a general consensus that is characteristic of the standardisation process. Consensus emerges only from those who consent to the initiative. *For this reason, the direct use of PAS and similar documents under the New Approach has its limitations.*

PAS lack the democratic legitimacy and accountability offered by the standardisation process. Furthermore, the procedural guarantees on the implementation of such documents are less stringent compared with those applicable to standards. A number of practical questions would have to be resolved in order to give greater recognition to PAS under the New Approach, for example: Who could write PAS? Should PAS providers be formally "recognised"? By whom? Should PAS become a new category of specifications under Directive 83/189? Should public authorities approve individual PAS? Could there be conflicting PAS? How should workers, consumers, environmental interests and SMEs be involved in the elaboration of PAS?

In any case, Directives would have to be modified in order to assimilate such documents to European standards.

Thus, although shortcomings in accountability impede the direct use of PAS under the New Approach, the use of PAS as an input to the standardisation process offers interesting perspectives that CEN, CENELEC and ETSI should

exploit.

II. THE SEARCH FOR EFFICIENCY

The Concept of Efficiency

12. An efficient standardisation system should provide *high-quality standards*, deliver them in a *timely fashion*, and the standards themselves should be *effectively used in the market*. Efficient standardisation is, therefore, relevant to public authorities, industry and the social partners.
 - Public authorities are interested because standardisation is carried out within the policy framework of the internal market. Standards need to provide a sufficient degree of precision in order to allow the assessment of compliance with Community law. Conversely, the capacity of standardisation to complete the internal market affects the credibility of the public policy objective. Inevitably, criticisms of shortcomings in the standardisation system will be raised at the political level. A fair balance must, however, be maintained between efficiency and respect for the principles of accountability.
 - The interest of industry in the efficiency of standardisation arises first from the access that standards give to the market-place in regulated technical areas. Secondly, industry itself devotes substantial resources to standardisation and wishes to see the greatest possible return from its investment.
 - Workers, consumers and environment organisations are interested because standards quantify the level of protection that essential requirements are intended to provide. The accountability of the standardisation system and its capacity to deliver standards providing a high level of protection are therefore of prime importance to them.
13. The first objective of European standards under the New Approach is, indeed, to meet the essential requirements of the Directives. Efficiency should, therefore in the first place be assessed on the basis of whether standards are adequate to meet them. It makes no sense to adopt a lot of standards if they are insufficient to give presumption of conformity. Industry is, in any case, primarily interested in the practical results of using standards rather than in the efficiency of the process. However, *a cost-benefit analysis of European standardisation is still missing*. The Commission stands ready to support initiatives to close this methodological gap. *Such an analysis should also encompass benchmarking the impact of standardisation in Europe with standardisation in other regions of the world, including its effect on competitiveness*.
14. An analysis based on the number of standards adopted is simply not sufficient to assess efficiency, as the number does not reflect their impact. As an illustration of this point, the programmes of standards for New Approach

Directives vary widely in size, independently of the economic impact of the Directives to which they refer. For instance, in each of the Machinery and Pressure Equipment areas, there are programmes of over 700 standards, whilst for the economically comparable area of medical devices, only 200 standards are foreseen. For the construction area, where a full programme is still under preparation, some 1500 standards are expected.

15. As a pragmatic approach to improving efficiency, reference can be made to the reduction of delays that occur in the standardisation process. The chart that follows describes the stages of standardisation from elaboration of mandates to the transposition of European standards as national standards. It also shows the actors involved and indicates the average periods needed for each stage⁴. Although the nature of standardization is different in CEN, CENELEC and ETSI⁵, comparing the time taken for different stages of the standardisation process can, at any rate, be used as a benchmark to identify potential weaknesses and to compare methods.
16. It may be concluded from the chart that:
 - *Several actors are involved:* the Commission, national authorities, the European standards organisations and the national standards organisations. Efforts to improve efficiency can be made by each of them.
 - Procedures related to the New Approach (e.g. agreement on the terms of mandates) and to standardisation itself (e.g. acceptance of a mandate, public enquiry, voting by national representation, and transposition of European standards at national level) in themselves take several months. *These procedural periods are inherent in the system, even if improvements are possible.*
 - Substantial differences exist between CEN, CENELEC and ETSI, covering an average standards elaboration period ranging from 24 to 75 months. The differences can be explained in part by *differences in the standardising process*, and may also indicate a potential scope for further reductions; however, determining the scope for such reductions will require a more detailed analysis.

⁴ The periods indicated do not necessarily add up. Activities take place in parallel and in many cases standardisation mandates cover ongoing standardisation activities

⁵ As an example, the making of technology-neutral specifications (the usual practice in CEN) is more difficult and time-consuming than selecting among available technologies (the usual practice in ETSI). Standardization in CENELEC is characterised by the high share of international standards adopted as European standards.

Timetable for the Standardisation Procedure.

Commission draws up a mandate, in consultation with 83/189, and in construction CPD, Committee.	6 – 12 months
Commission transmits mandate to European standards organisations (ESO)	2 months
ESO accept the mandate	CEN: 2.5 months CLC: 6 months ETSI: 1–3 months
ESO elaborate a (joint) programme	CEN: 6–18 months CLC: 1–9 months ETSI: 6–12 months
Only in the case of the CPD: Commission accepts programme	2 months
Technical Committee (TC) elaborates draft standard	CEN: 35 months CLC: 12–24 months ETSI: 15 months
ESO and national standards bodies (NSO) organise Public enquiry ⁶	CEN: 6 months CLC: 6 months ETSI: 4 months
TC considers comments	CEN: 19 months CLC: 4 months ETSI: 5 months
NSO vote/ESO ratify ⁶	CEN: 4 months CLC: 7.5 months ETSI: 2 months
ESO transmit references to the Commission, Including translation titles	CEN: 5 months CLC: 3 months ETSI: insufficient experience
Commission publishes the reference ⁷	4 months CTR ⁷ : up to 18 months
NSO transpose European standard.	CEN: 12 months CLC: 12 months ETSI: 9–12 months

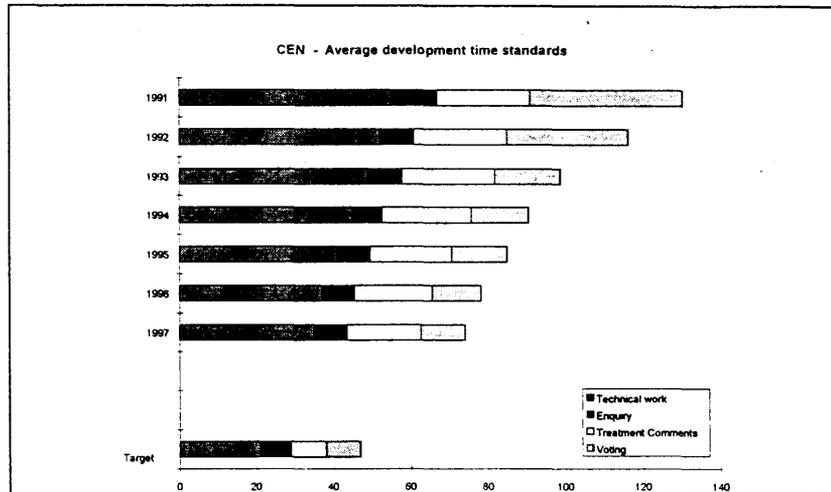
⁶ Excluding secretarial handling in CEN, CENELEC and ETSI.

⁷ Common Technical Regulation, adopted on the basis of ETSI European Standards.

III. PROPOSALS FOR IMPROVING THE EFFICIENCY OF THE EUROPEAN STANDARDISATION SYSTEM

Management of the standardisation process.

17. The management of the standardisation process is, in the first place, the responsibility of the European standards organisations and their members. CEN, CENELEC and ETSI have for a number of years been implementing a policy of increasing efficiency. As an illustration, since 1993, the average development time for standards in ETSI has been reduced from 45 to 28 months. CENELEC has a development time of between 24 and 48 months. CEN has itself set a target of 47 months (in 1991 it needed 135 months); at present it requires 75 months (see chart). *What matters more than the average standards elaboration time is the definition of realistic time schedules in standardisation programmes, the capacity to respect them and the transparency in their implementation.*



24 and 48 months. CEN has itself set a target of 47 months (in 1991 it needed 135 months); at present it requires 75 months (see chart). *What matters more than the average standards elaboration time is the definition of realistic time schedules in standardisation programmes, the capacity to respect them and the transparency in their implementation.*

Detailed reports prepared by CEN, CENELEC and ETSI, explaining the measures taken or intended to improve efficiency, and their position on the suggestions made by Ministers during their meeting in Cambridge in February 1998, will be presented to Member States. *Annual reviews should take place, in co-operation with the European standards organisations.*

18. Some Member States have suggested that CEN, CENELEC and ETSI should consider a more systematic use of voting by qualified majority to speed up the adoption of European standards. Under the rules of standardisation, standards are based on consensus, i.e. the absence of sustained objection from major parties. Consensus is the guiding principle leading up to the vote on a final proposal, based on national representation. A standard is adopted if a qualified majority of national votes is reached.

Voting at an earlier stage will not necessarily speed up standardisation, but can do so in certain cases. Much will depend on the skills of the Chairman of a Technical Committee. Proceeding at an early stage to voting might hamper the standardisation process by making it more political. Diverging opinions might be made more visible, and arbitration between different interests may become

more complicated. Furthermore, those who fear to be defeated may organise opposition to a standard. On the other hand, voting or indicative voting can speed up the process, for instance where vested interests block progress and show no willingness to compromise, or where hidden commercial interests block progress. In such cases, voting can create transparency and unlock situations. *The European standards bodies should carefully consider the possibility of speeding up the standardization process by having recourse to voting at an earlier stage.*

19. *CEN and CENELEC should consider further opening their structures to representative European-based interested parties, such as workers, consumers, environmental interests and industry, allowing them to participate in strategic discussions and the elaboration of policy. In contrast to ETSI, in CEN and CENELEC policy decisions and strategic discussion remain limited to their Boards and national standards bodies. Especially in CEN, which covers a very broad number of industrial domains, there is no visible forum for the consultation of stakeholders on strategic aspects of standardisation.*

According to the organisations representing European consumers and European workers, *improvements can be made in a number of national organisations, mainly as regards representation and clear procedures for establishing a national consensus. Environment organisations feel that they are not sufficiently represented in the standardisation process, which is considered to be mainly industry driven and market led. Their fear is increased in the light of the shift from national to European, international and informal standardisation levels. The Commission considers that the participation of all interested parties is important for consensus building and accountability. Possibilities for collective interests to participate in European standardisation in a balanced way should be the subject of further discussion and monitoring in the enlarged 83/189 Committee.*

20. *Use of electronic means of communication is an important contributor to efficiency. In 1997, the Commission gave a contribution of 1.6 MECU, covering 50% of costs of participating national CEN members, to the INES (CEN Internet Network for European Standardisation) project. INES intends to promote the use of modern tools of communication. INES covers four areas: Electronic Committee processes, Document Management Service, WEB Information Service, and Standards Deliveries Service. Electronic standardisation and such means of information dissemination already exist in ETSI and are being implemented in CENELEC. In this effort, no Community support was requested. However, co-operation should be enhanced between CEN, CENELEC and ETSI.*
21. *New Approach Directives state that presumption of conformity is linked to the use of "national standards transposing European standards". National standards bodies should be aware of the importance of European standards being presented to the market, and should therefore handle transposition with all necessary urgency. Transposition periods for European standards should be set as short as is reasonably possible and time limits should be better*

respected. Delays in transposition by national standards bodies should not diminish the benefits of the New Approach for manufacturers. If such delays occur, and since European standards have to be transposed in a uniform way, a manufacturer can rely on any national standard transposing a European standard or directly on the European standard.

22. The quality of standards and the efficiency of the process can be improved if the work in the European standards organisations is preceded or complemented with well-targeted pre-normative research actions. On the one hand, pre-normative research promotes the development of new standards while on the other hand the standards can better disseminate the results of research. As announced in its document "Research and standardisation"⁸, the Commission will continue promoting pre-normative research in close co-operation with the European standards organizations and the economic operators involved in standardisation.

The role of the public authorities

23. Some Member States have suggested that mandates should be made more precise. Mandates have been agreed with Member States through the 83/189 Committee. The only area where the work of mandating and programming is not yet completed is in construction, although all final mandates are expected by mid-1998. The elaboration of final mandates for the Construction Products Directive was in itself a difficult exercise, mainly due to the need to identify national technical specifications that should become subject of European standardisation. Therefore, the average time for their elaboration was much longer than for other areas. Similarly, the elaboration of standardization programmes by CEN is a long process. Where mandates are given, it is important to integrate essential issues, such as the protection of safety, health and environment.

If in the course of standardisation work a need arises for more precise indications regarding the terms of the related mandates, the European standards organisations should raise that question with the Commission, who, in co-operation with the relevant Committees, will address such questions and clarify the mandate. Questions can also be raised directly in the various Committees and groups in which the European standards organisations are invited to participate. However, when interested parties cannot agree on technical specifications, the Commission should not be considered as a "court of appeal" to make technological choices.

24. Standardisation programmes, containing priorities and timetables, have been examined by the 83/189 Committee and sectoral committees or expert groups
-

in place for all the New Approach directives⁸. *The Commission and national authorities should reinforce the monitoring of progress in the implementation of programmes. Progress in standardisation under the New Approach will also be covered in the Internal Market Scoreboard.*

25. A recent survey by the Commission services has revealed that the operation of Community Committees and expert groups in several cases could be improved. *The Commission intends to address the efficiency of Committees and expert groups in a Report to be further examined in collaboration with Member States.* In the management of committees, sufficient periods should be left to Member States to adopt a national position, and national administrations should ensure that co-ordination amongst all interested national services takes place in due time. More electronic transmission of documents, as well as electronic consultations between the Commission and Member States, should take place, the more given the continual budgetary constraint on the operation of such Committees and expert groups.
26. The participation of public authorities in the standardisation process raises the question of the balance between their different roles: on the one hand, they participate in the standards making process at the same level as industry, workers, consumers, SMEs, environment interests; on the other hand, they act as an authority with a duty to protect the public interest. Once public authorities have agreed on a mandate, *the search for technical solutions should in principle be left to the interested parties. In certain areas such as environment, health and safety, the participation of public authorities on a technical level is important in the standardisation process.* Efficiency can be improved if the technical expertise of public authorities is present at the level of working groups. Furthermore, when a mandate is given, public authorities should examine draft standards, particularly when submitted to public enquiry, in order to ensure that the draft standards meet the requested safety, health and environmental levels.
27. *The Commission will take practical measures to improve the publication of references of European standards in the Official Journal,* a condition for such standards to become effective under the New Approach. The electronic sending of titles and references for publication of references of European standards in the Official Journal is an important instrument to make further progress. In particular, CEN should accelerate the translation of titles of the standards into the Community languages.

A Single European Standardisation Body, or More Competition?

28. There have been suggestions that CEN and CENELEC should be merged. The Commission considers that CEN and CENELEC are independent

⁸ Reports prepared by CEN, CENELEC and ETSI on the state of progress of European standardisation under New Approach directives are made available to Member States.

organizations and that a decision on a merger belongs to the CEN and CENELEC constituencies. *In the Commission's opinion, it is unlikely that a merger at European level would improve efficiency unless it was matched by corresponding structural reorganisations at the national level.* In many cases, the structure of CEN and CENELEC reflects corresponding national structure, and each organisation has its own constituency, its own fields of competence and own links to the international and national standardisation levels. Modern management tools, such as benchmarking, should be promoted amongst the European and the national standards organisations.

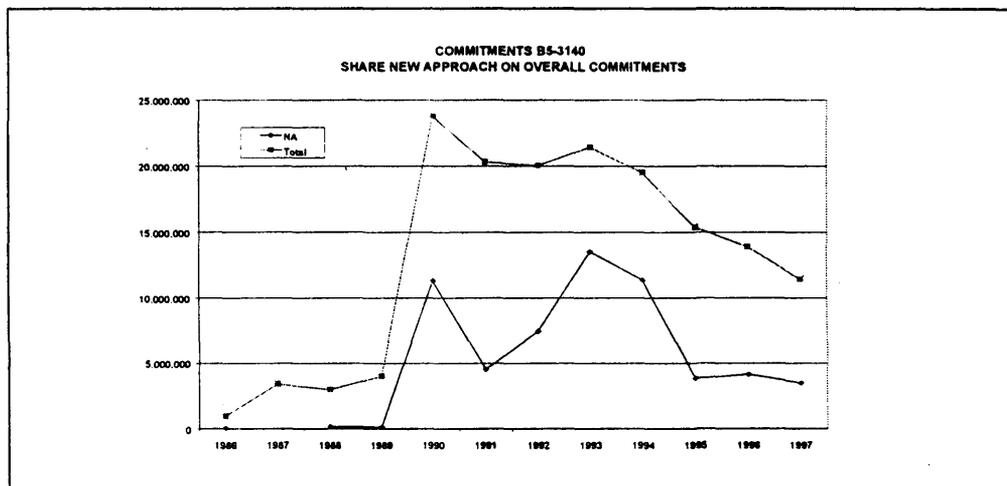
29. *Efficiency is not likely to be enhanced by the recognition of new standards bodies.* New organisations would have to cope with the same tension between efficiency and accountability as CEN, CENELEC and ETSI. As they would not be members of the international standards organisations ISO/IEC/ITU, they would not be in a position to represent Europe's interest at the international level, which is becoming increasingly important.

Improving Awareness.

30. *It is necessary to bring standardisation and standards to the attention of market participants, in particular SMEs.* This is mainly a task of the national standards organisations, national authorities and national federations representing industry. In order to give impetus to a European policy in this area, a Memorandum of Understanding was agreed in 1995 between the Commission and the European standards organisations. It aimed to improve policy on awareness. NORMAPME, who represents SMEs and craft interests in European standardisation, takes part in the implementation of this MoU.
31. *Progress reports on New Approach areas should be made available on the Internet by the European standards organisations.* Links should be foreseen with information on directives, mandates, lists of references of European standards published for individual New Approach directives, lists of notified bodies and related information at the national level.
32. In order to give a high visibility to the efficiency issue, *the Commission envisages to organise a conference with all interested parties.* Other questions that might be dealt with in such a conference are the relations with international standardisation and the relations with Central and Eastern European countries.

Financial Support to European Standardisation

33. Financial support has been one of the main means by which the Community has promoted European standardisation. Since 1986, a total of 60 MECU has been committed to New Approach standardisation work at European level; amongst the most substantial beneficiaries are construction (21 MECU), machinery (17.8 MECU) and medical devices (10.3 MECU). For work under a large area such as the low-voltage directive, no financial support was requested. The average contribution requested for standards was gradually reduced from 50,000 to 30,000 ECU. As a consequence of the progress of the work, the financial contribution to standardisation from the Commission has been continuously reduced over recent years.



Review meetings between the Commission and the European standards organisations concerning the implementation of contracts and the financial consequences to be drawn from delays will be intensified. *Alternative ways of providing financial support will be developed if this would increase efficiency.*

34. Following a review of standardisation policy carried out in 1996 and 1997, policy for *financial support has been adapted in order to emphasise the market-driven nature of standardisation:*
- Support is now provided mainly to contribute to maintaining a strong infrastructure for European standardisation. Consequently the Central Secretariats of CEN, CENELEC and ETSI are financially supported to ensure respectively 45%, 17% and 15% of their operational costs.
 - Particularly important is support for the current 17 New Approach Consultants, appointed by common agreement between the Commission and the European standards organisations. Their task is to verify as independent experts whether standards respect the essential requirements and the terms of the mandate.
 - Translation into the so-called "minority" languages absorbs a large amount of funds. Such funds are used mainly to support national standards

bodies in the translation of European standards for transposition as national standards.

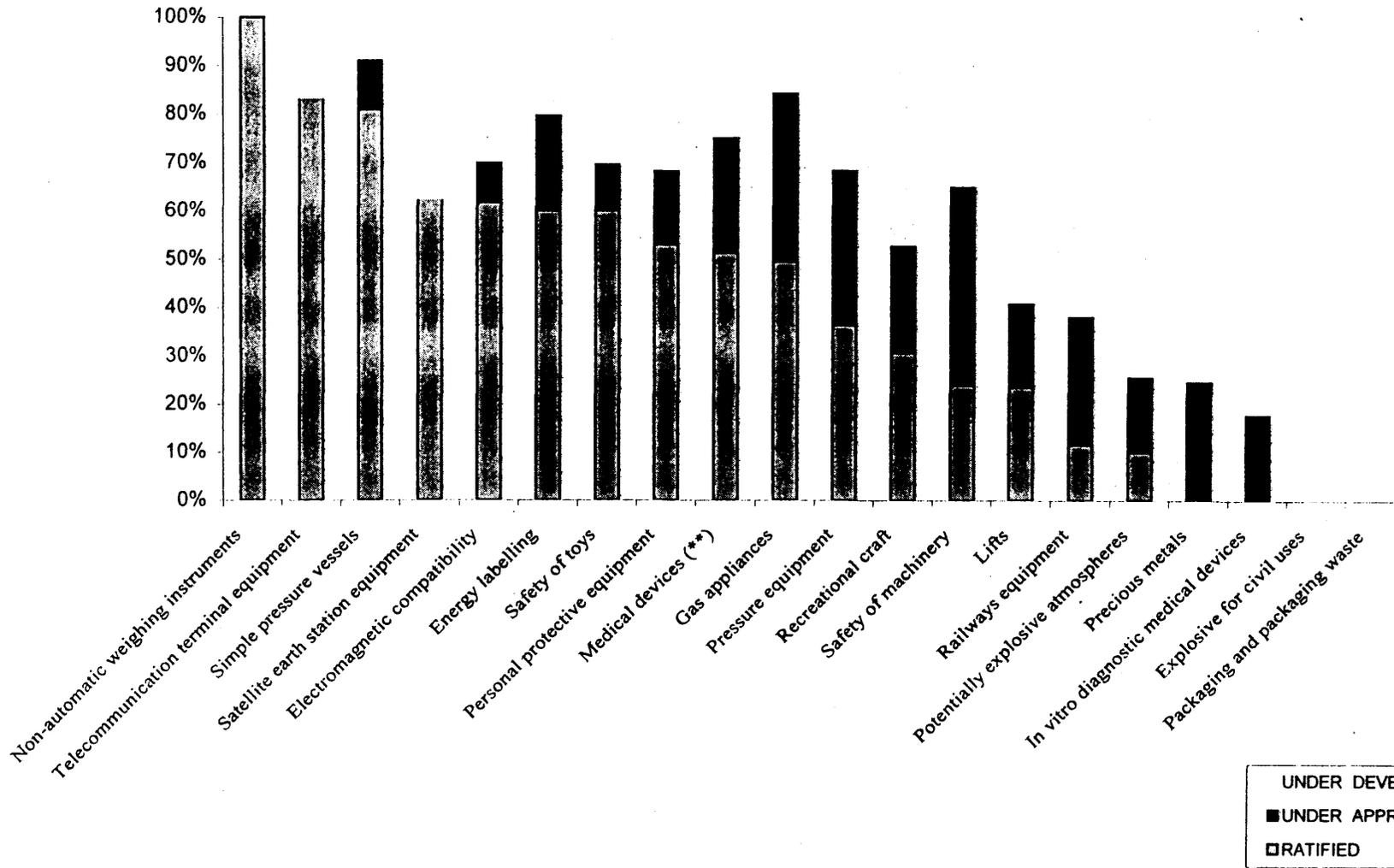
- Priority will be given, within the limits of budgets available, to standardisation work in new areas, such as protection of consumers and of the environment.
- In order to assess the achievements of the past and to identify the future financial needs for the maintenance of an effective European standardisation system, the Commission invites CEN, CENELEC and ETSI to launch an independent evaluation of the financing of European standardisation. The results of the evaluation should be examined in collaboration with the Commission and Member States.

IV. CONCLUSIONS

1. European standardisation has had a difficult start, but has improved considerably. Nevertheless, the management of processes needs to be improved, notably by adopting better management techniques. More openness in strategic standardisation policy-making, (particularly in CEN, given its horizontal competence), will contribute to an increase in efficiency and accountability.
2. CEN, CENELEC and ETSI are independent organisations. It is therefore their responsibility to ensure efficiency and respect for time schedules.
3. Standardisation is a voluntary, consensus-driven process; standards cannot be imposed. In some cases, apparent failures of standardisation must be explained by the nature of standardisation itself. There are limits to the capacity of market participants to self-regulate. In the case where public interest is at stake, public authorities should create a sufficiently strong incentive for standardisation, or take other measures as appropriate.
4. The Commission intends to hold regular reviews, together with Member States and European Standards Organisations, to examine measures for efficiency on the basis of reports prepared by CEN, CENELEC and ETSI.
5. Transparency on progress should be improved. The standards organisations are invited to make reports on the progress of standardisation in New Approach areas available on the Internet, and to continually update them.
6. A number of aspects, such as the an analysis of the impact of standards on the market, the working of sectoral committees and expert groups, the visibility of European standardisation, and the financing of European standardisation requires continuous follow-up, involving the co-operation of standards bodies, national authorities and the Commission.

ANNEXE

PROGRESS STANDARDISATION ACTIVITIES IN THE FRAMEWORK OF THE NEW APPROACH (*)



(*) excluding construction products, for which a standardisation programme is still under development.

(**) including active implantable medical devices.

**STANDARDISATION ACTIVITIES RELATED TO THE
NEW APPROACH**

DIRECTIVE REFERENCES	AREAS	MANDATED	RATIFIED	UNDER APPROVAL	UNDER DEVELOPPME NT
90/384/EEC<	Non-automatic weighing instruments	1	1		
87/404/EEC	Simple pressure vessels	47	38	5	4
88/378/EEC	Safety of toys	10	6	1	3
89/392/EEC	Safety of machinery	894	214	370	310
89/686/EEC	Personal protective equipment	300	159	47	94
90/385/EEC	Medical devices, including				
93/42/EEC	active implantable medical devices	248	127	60	61
90/396/EEC	Gas appliances	91	45	32	14

18
17

93/15/EEC	Explosive for civil uses	51	0	0	51
94/9/EEC	Potentially explosive atmospheres	50	5	8	37
94/25/EEC	Recreational craft	49	15	11	23
95/16/EEC	Lifts	17	4	3	10
94/62/EC	Packaging and packaging waste	21	0	0	21
89/336/EEC	Electromagnetic compatibility	128	79	11	38
92/75/EEC	Energy labelling	5	3	1	1
91/263/EEC	Telecommunication terminal equipment	30	25		5
93/97/EEC	Satellite earth station equipment	8	5		3
89/106/EEC	Construction products :		Overall programme under development		
97/23/EC	Pressure equipment	771	280	250	241
COM/96/0643 final	In vitro diagnostic medical devices	22	0	4	18
COM/97/0034 final	Railways equipment	104	12	28	64
COM/93/322 final	Precious metals	8	0	2	6

ISSN 0254-1475

COM(98) 291 final

DOCUMENTS

EN

10 01 02

Catalogue number : CB-CO-98-320-EN-C

ISBN 92-78-36153-4

Office for Official Publications of the European Communities

L-2985 Luxembourg