

COMMUNITY EXTERNAL TRADE POLICY
IN THE FIELD OF
STANDARDS AND CONFORMITY ASSESSMENT

Communication of the Commission

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EXECUTIVE SUMMARY

This Communication sets out the European Community's trade policy objectives in the field of standards and conformity assessment, and the strategy to achieve these objectives. Its aim is twofold. First, to establish better understanding of the Community's policy and strategy in this area, so that it may be promoted coherently. Secondly, to review and where necessary modify the strategy.

The Communication rests on two assumptions. First, that trade barriers related to product standards and conformance - technical barriers to trade - appear to be increasing, demanding greater attention and action than in the past. Secondly, that the completion of the single market regulatory regime now places the Community in a position to pursue a more outward looking trade policy in this field.

The Community's trade objectives can be summarised simply. First, to reduce technical barriers in overseas markets and prevent the emergence of new ones. Secondly, to encourage our trading partners to adopt standards and regulatory approaches based on, or compatible with international and European practice. Achievement of both objectives will facilitate our trade and market access for regulated products.

These trade objectives are being pursued through a four-fold strategy comprising: reliance on under the WTO, notably the Agreement on Technical Barriers To Trade, in the multilateral framework, and on agreements in the bilateral framework to reduce barriers and open markets; negotiation of mutual recognition agreements to reduce the costs of testing and certification in other markets; technical assistance to a large number of countries to ensure that regulatory regimes are transparent and trade friendly, and regulatory cooperation aimed at harmonising standards and regulations with other trading partners.

Concerning the **WTO**, we need to carry out a comprehensive review of the operation and implementation of the Agreement on Technical Barriers To Trade, as a means to ensure full adherence by all WTO members, and where necessary improve its operation. This implies also more systematic use of the WTO Trade Policy Review mechanism, and greater attention to technical trade barriers in the context of WTO accessions. Bilateral negotiations can also secure adherence to WTO rules, as part of the Community's Market Access Strategy.

On **Mutual Recognition Agreements** a clear line needs to be drawn between the benefits of mutual recognition on the one hand and harmonisation of standards and regulations, since each can be pursued on its own merits. We should however place greater emphasis on using mutual recognition as a vehicle for greater harmonisation. In the longer term, we should be open to plurilateralising MRAs and consider the case for MRAs on a regional basis.

Technical Assistance programmes to developing countries already promote the adoption by partner countries of international and European standards and practices. But there are ways in which technical assistance can better serve external trade objectives in future, and provide a basis for future mutual recognition agreements. We can also improve coordination of programmes and achieve better coherence between Community and Member States' programmes, so as to maximise economies of scale.

As concerns **Regulatory Cooperation**, the principal Community initiatives in this field, whether multilateral, plurilateral, or bilateral, cover key industrial sectors such as vehicles, pharmaceuticals, medical equipment, foodstuffs and chemicals. These different forms of cooperation promote international harmonisation or acceptance of the Community's regulatory approach, and in many cases provide a basis for mutual recognition.

In all these areas, cooperation and coordination between the Commission, Member States, European industry, and the European standards and certification community, is essential. We consider it possible to improve this cooperation.

The Communication ends with a summary of conclusions, and asks the Council to endorse both the broad strategy set out in this document, and the specific proposals made.

COMMUNITY EXTERNAL TRADE POLICY IN THE FIELD OF STANDARDS AND CONFORMITY ASSESSMENT

INTRODUCTION

1. In recent years, standards and certification issues have become a significant factor in the Community's external trade relations. With industrial tariffs at historically low levels, the relative importance of non-tariff, technical barriers, has increased. In parallel, more and more countries, responding to a legitimate demand for increased health, safety and environmental protection, have progressively introduced new product standards and regulatory requirements. Despite the efforts of international bodies to develop globally applicable standards and requirements, different countries and regions have frequently, without justification, adopted differing standards for the same product, unnecessarily increasing costs, and preventing manufacturers from enjoying the economies of scale that flow from being able to produce against one common standard.

2. This proliferation of different standards and requirements has been accompanied by the growing demand that compliance be demonstrated through independent inspection, testing or certification, by the country of import. Today, an ever-growing range of industrial products, from electrical equipment, toys and machinery to chemicals, drugs and medical devices must to be tested and certified to differing national requirements before sale. These conformity assessment procedures, while often unavoidable, imply additional costs to companies seeking to sell in multiple markets. Even in cases where countries rely on harmonised rules or accept as equivalent other countries' regulations, reliance on the exporting country's tests and certificates of conformity is the exception.

3. This creates a number of potential barriers to trade. It necessitates the costly and largely redundant repetition of testing and certification for different national markets, raising costs for manufacturers in a global market place, without commensurate public welfare benefits. The need to submit products for approval in often distant markets means delays which, particularly for innovative technologies or products with a short life-cycle can hamper their marketability. Difficulties in understanding the regulatory regime in a foreign market, whether because of distance, language, or cultural differences, can also operate as a de facto discriminatory barrier against imports. Last but not least, the imposition of burdensome standards, testing and certification requirements can be used effectively to frustrate imports and shelter domestic companies from competition.

4. Discussions with Member States and European industry reveal growing concern over the propensity of standards and conformity requirements to present trade obstacles, and one that shows no sign of receding. A number of solutions have been proposed, whose appropriateness may vary with circumstances, but which include: encouraging third countries to reduce obligatory technical requirements and conformance procedures to what is necessary to meet legitimate policy objectives; promoting, where feasible, greater harmonisation of standards and regulatory approaches in other markets; encouraging our trading partners to adopt or accept the equivalence of the standards and technical requirements applicable in the Community; and establishing mutual recognition of conformity assessment results, as a means to reduce conformity barriers.

5. If standards and conformity obstacles demand greater attention than in the past, recent developments within the Community now enable us to address these obstacles more coherently. The introduction of harmonised European product directives through the Single Market exercise is now all but complete and the implementation of the directives is well underway, allowing more attention to be channelled to seeking improvements in the regulatory regimes of our trading partners. At the same time, the regulatory solutions developed by Europe, particularly under the Single Market programme offer, by virtue of their flexibility, trade-friendliness and consistency with international practice, an appropriate reference point for other countries or regions as they establish or reform their own regulatory systems.

6. Against this background, the Community has set itself two basic objectives. First, to reduce or prevent the emergence of new standards and conformity assessment barriers for industrial products in other markets. Secondly, to promote where possible, the adoption overseas of standards and regulatory approaches based on, or compatible with, international and European practices, in order to improve the market access and competitiveness of European products.

7. These trade objectives are being pursued through a four fold strategy comprising: reliance on the WTO, notably the Agreement on Technical Barriers To Trade, in the multilateral framework, and on agreements in the bilateral framework to reduce barriers and open markets; negotiation of mutual recognition agreements to reduce the costs of testing and certifying products in other markets; technical assistance to developing countries to ensure that nascent regulatory regimes are transparent, and trade friendly ; and regulatory cooperation aimed at harmonising standards and regulations with our trading partners.

8. Section I below describes the role of the WTO - in particular the **Agreement on Technical Barriers To Trade** - in containing and reducing technical barriers, and suggests ways to use multilateral instruments more effectively in future. The role of bilateral initiatives in securing adherence to WTO rules is also highlighted.

9. Section II of the document describes the key objectives of **Mutual Recognition Agreements (MRAs)**, and the relationship between mutual recognition, technical assistance and regulatory cooperation. It suggests some adjustments to the current MRA strategy.

10. Section III describes the objectives of the various **Technical Assistance** programmes offered by the Community to developing country partners, and suggests a number of improvements to enable them better to meet our external trade objectives.

11. Section IV identifies the principal Community initiatives in the field of **regulatory cooperation**. The term is interpreted broadly to include both bilateral and plurilateral exercises, and describes initiatives to internationally harmonise standards and regulations, to simplify conformity requirements, and to promote regulatory reform.

SECTION I: STANDARDS AND CONFORMITY ASSESSMENT ISSUES IN THE WORLD TRADE ORGANISATION.

12. Since the late 1970's the multilateral trading system has attempted to limit the impact of standards and conformance barriers. The GATT Tokyo Round led to the conclusion in 1979 of a TBT code, adherence to which was voluntary, and which established basic disciplines such as transparency and non-discrimination in the use of product standards and regulations. This code was strengthened and made binding on all members of the now World Trade Organisation (WTO) following the Uruguay Round in 1994.

13. The 1994 Agreement on Technical Barriers To Trade carries several innovations. It draws a clear distinction between standards, which are voluntary, and technical regulations, which are mandatory. It brings regulations and standards on product - related process and production methods within its scope. It strengthens the test of proportionality in the adoption of technical regulations, requiring members to regulate products in the least-trade-restrictive way possible. It makes members responsible for standards and rules applied at sub-federal level, and establishes a Code of Good Practice for non-governmental standards bodies. It imposes disciplines on the way in conformity assessment of products may be carried out, and encourages WTO members to recognise tests and certificates of other members where they can be relied upon, noting that this may be secured through mutual recognition negotiations. Finally, as part of the Uruguay Round package, the Agreement is subject to the integrated WTO Dispute Settlement system.

Operation and Implementation of the TBT Agreement

14. At this stage it is too early to draw firm conclusions as to whether the new TBT Agreement has fully met its objectives. On one hand, there is arguably a limited awareness of the Agreement amongst those WTO members adhering to it for the first time, and of the domestic reforms they may have to make to bring their regimes into compliance. An educational effort is therefore needed. It may be questioned whether some of our trading partners are making sufficient effort to accept and use international standards, to comply with notification procedures, to encourage adherence to the Code of Good Practice, or ensure that technical regulations are proportionate.

15. On the other hand, the introduction of several new disciplines in the 1994 Agreement, their binding nature, and the availability of dispute settlement procedures in the event of non-compliance, should over time lead to improvements. Already, the number of WTO dispute settlement consultations related to the new Agreement shows the determination of some WTO members to ensure proper implementation and to take action where its provisions are not respected.

16. A major review of the operation and implementation of the Agreement will take place not later than the end of 1997 (Article 15.4 of the Agreement), and this will be the appropriate time to review the Agreement's success, to identify if it has been adequately implemented, and to consider whether its operation is adequate.

17. The WTO Ministerial meeting in Singapore in December this year will be an opportunity for Members to reaffirm the importance of full implementation of the TBT Agreement, and to obtain a commitment to make the 1997 review a comprehensive one. Further to that we should then consider elements appropriate for this review. One such element is to consider how to reinforce the role of international standards, concern having been expressed that international standardisation fails to reflect the real needs of international trade. To achieve this objective, the coordination between national, regional and international standards bodies is an area for improvement. A procedure to measure the extent of members' adoption and use of international standards should be developed. Other issues which have been raised include the possibility of developing guidelines to assist WTO

members in complying with the agreement, for example concerning the "least trade restrictive" test in the use of technical regulations and conformity assessment procedures. It could also include clarifying the scope of existing rules relating in particular to non-product related process and production methods (PPMs), and, if need be, whether a more structured relationship between the WTO and international standards-making bodies may be useful

18. The Commission therefore concludes that if both the implementation *and* the operation of the Agreement are to be properly examined, the WTO Ministerial must both underline the importance of proper implementation of the TBT Agreement, and commit to a thorough 1997 review. The Community should therefore seek, at the Singapore Ministerial meeting :

a) reaffirmation by all WTO Members of their commitment to thorough implementation of the TBT Agreement; and

b) commitments to undertake a comprehensive and in-depth review of the implementation and operation of that Agreement in 1997.

19. A closely related issue is the relationship between the Community and international rule-making/standards setting bodies. The TBT Agreement and other WTO Agreements have given great weight to the activities of international bodies and in several fields it has become difficult to deviate from internationally developed rules and standards even where there may be technical reasons for doing so. Because of this it would be desirable to consider whether, and in which circumstances, the Community should be involved more closely in the work of such international bodies, so as to ensure continued consistency between internationally established rules and standards, Community rule-making and our WTO obligations. These questions will also need to be considered.

Complementary Actions in the WTO

20. The WTO offers several additional avenues to secure full implementation of the Agreement, and which can in future be used more fully.

a) The Trade Policy Review Mechanism (TPRM).

21. The TPRM was established in 1988 as a mechanism to study at fixed intervals the trade policies of each WTO member, and to enable other WTO members to evaluate their WTO-compatibility. So far TPRM treatment of standards, conformity assessment and technical barriers to trade has been cursory. It is clear however that the growing importance of these issues merits closer TPRM scrutiny.

22. A benefit of the TPRM is obviously to focus attention on the regimes of our trading partners. Problems in other members regimes can be identified and solutions proposed. Transparency is required, and the country under review has to justify the maintenance of particular rules or standards, which in many cases could be a challenge. The process itself can be used by the reform-minded as an external pressure to encourage regulatory reform.

23. In addition, the Community should be open to detailed review of its standards and regulatory policy under the TPRM. Our regime offers a good model of compliance with the TBT Agreement. Harmonised Directives satisfy its key requirements. Standards - largely based on international ones - are mostly voluntary, and regulatory requirements set only where necessary on health, safety or other legitimate grounds. Producers thus have flexibility in how to meet requirements, in line with the obligation to make technical regulations the least restrictive possible. Conformity assessment procedures are transparent, while the modular system under the New Approach, which provides different approval procedures related to degree of risk, offers an example of how to meet the least-trade restrictive test. Acceptance of third country test data is possible through sub-contracting by European certification bodies, while the Community can also point to its efforts to secure mutual recognition agreements with other partners.

24. The Commission therefore recommends that standards and certification issues be more thoroughly addressed in future TPRM reviews, notably those of our major trading partners and those countries where barriers are particularly acute. We would also be open to similar study of the Community's standards and conformance system at its next review. To do this will require improved coordination within the Commission and with Member States in the run-up to TPRM reviews, while we will need also to request the WTO Secretariat, to focus on the issue more fully when compiling future TPRM reports.

b) WTO Accessions

25. In the past technical barriers to trade were rarely an issue for GATT accessions due to the voluntary nature of the Tokyo Round TBT Code. And in those cases where a GATT member voluntarily subscribed to the Code, this was quasi-automatic. With the integration of the Uruguay Round TBT Agreement into the body of WTO obligations, compliance has naturally become an issue for new accessions, and one to which European industry attaches priority. Considerable attention has been given to standards and certification issues in the accessions of Russia and Saudi Arabia, and similar attention should be given to these issues in other Working Parties, so as to secure concrete commitments to align systems to TBT Agreement rules.

26. The Commission will therefore ensure, in coordination with Member States, that these issues are given high priority in current and forthcoming accession negotiations.

Bilateral Initiatives to Secure Compliance with WTO Rules and Reduce TBTs

27. The Council recently approved a new Community Market Access Strategy by which the Commission will address trade barriers in third countries both through the multilateral framework and where appropriate bilaterally. Trade barriers relating to standards and certification clearly figure among the non-tariff barriers the market access strategy must overcome. In conformity with the approach underlined there, the Community will continue to use WTO dispute settlement proceedings to address the most egregious and clear breaches of the TBT Agreement.

28. For those barriers which will continue to be more amenable to bilateral resolution without recourse to the full WTO machinery, the Community has a range of resources at its disposal, including its trade and cooperation agreements with many trading partners, formal consultative mechanisms such as Ministerial and high level meetings, and the possibility to address problems in a sector specific or ad hoc way as they arise. The Trade Barriers Regulation, while primarily multilateral in purpose, can also be a useful instrument to resolve bilateral disputes.

29. In view of the apparently growing number and importance of technical barriers to trade, more systematic use of these mechanisms may be necessary in future. It follows from this that the Community's limited resources will need to be used effectively, and priorities set rigorously. Decisions will need to be made, for example, on whether in a particular case to use the WTO route or bilateral means; whether to seek solutions through market access negotiations or via longer term regulatory dialogue; whether to concentrate efforts on resolving problems in one or two major markets or cast the net more widely; and whether to seek to address all TBTs in a particular market or focus only on the most serious ones.

30. It is not easy to give a categorical answer on how such priorities should be fixed. But experience to date suggests that the Community has emphasised problems in the USA at the expense of other countries where problems clearly exist and are growing. At the same time the relative priority to be accorded to different problems has not always been established. A refocussing to encompass other trading partners, as well as to assess the relative importance of different barriers - and hence the resources to devote to them - is warranted.

31. This refocussing will be carried out in the following ways. First, within the framework of the Market Access Strategy a data base of third country barriers is being established and will be operational next year. This will carry information on technical trade barriers of our trading partners, and be verified, updated and published regularly. This information will provide a basis for consultations with Member States and industry so that collectively our priorities, both geographical and sectoral, can be firmly established, regularly updated, and agreement reached on the appropriate actions to take.

32. Secondly, and separately, we can improve coordination by pooling the resources of all interested parties in Europe: the Commission and the Member States (with their respective overseas delegations), European industry including European Business Councils in third countries, and European standards, certification and accreditation bodies, to understand more fully regulatory issues and barriers in key markets - for example the USA, Japan, Korea, China and Russia, and to follow and influence the course of regulatory change. Information (for example translations of regulations made by different parties) needs to be shared, a continuous dialogue established with regulatory agencies in the third countries in question, an ongoing assessment of problems made, and systematic pressure applied to reduce technical barriers on the basis of the priorities identified.

33. This is an exercise which demands time and expertise, and involves not only thorough coordination within the Community, but also in the third countries concerned. In respect of the key markets noted above, and potentially others, the Commission will ensure that its delegations are charged with making standards and regulatory issues a priority. In this way, coordination between the Commission and the Member States (and their respective overseas delegations), European business and the third country authorities can be enhanced, developments in the third country regimes followed systematically, and more coherent action taken. Such coordination will of course be of benefit not only in cases involving technical barriers to trade, but also to support the Community's activities in the fields of mutual recognition, technical assistance and regulatory cooperation, each of which is considered below.

SECTION II: MUTUAL RECOGNITION AGREEMENTS

34. Two years ago, on the basis of negotiating directives from the Council, the Commission opened negotiations for mutual recognition agreements (MRAs) with a number of third countries. Negotiations are currently underway with the USA, Canada, Australia, New Zealand, Japan and Switzerland, some of which should be concluded this year. Further negotiations with additional priority countries will subsequently be opened¹.

Nature of MRAs

35. Mutual Recognition Agreements are agreements on the mutual recognition of conformity assessment of regulated products. Through an MRA, each party is given the authority to test and certify products against the regulatory requirements of the other party, in its own territory and prior to export. Each party recognises the tests, certificates and approvals issued by agreed conformity assessment bodies of the other party, and the products can be exported and placed on the other party's market without undergoing additional procedures. Such delegation of procedures can be envisaged, for obvious reasons, only in those cases where countries require mandatory third-party certification of products. This is normally required for products which present risks and which governments must submit to stringent controls.

MRAs seek to facilitate trade while safeguarding the health, safety and environmental objectives of each party. They do not require or presuppose harmonisation of each Party's substantive requirements or recognition of their equivalence (as is the case in the EC internal market). Each party to an MRA is free to set its health, consumer protection, environmental standards or other regulations at whatever level it deems necessary as long as they comply with international obligations. MRAs do not interfere with that freedom at all. However, they do require that each side has full confidence that the certification process of the other side can wholly satisfy its requirements. Such confidence is most easily established at a bilateral level and between partners with broadly comparable concepts of product testing and approval, and once established requires mechanisms for its maintenance.

Benefits of MRAs

36. MRAs can bring several benefits : some immediate and others long term, some tangible in terms of savings to industry, some less quantifiable but nonetheless useful in promoting efficient, transparent, and increasingly compatible regulatory systems in different countries. All of these factors should be borne in mind when considering the benefits of mutual recognition in the future.

a) the expense, time and above all the unpredictability incurred in obtaining approvals can be reduced by having the product evaluated in the country of production, or a quality system evaluated by local inspectors. These savings can be particularly important: where the market is distant, and where rejection of products by agencies in the country of destination can create delays and necessitate additional shipping or other costs; where the sector is very heavily regulated; where testing is carried out both prior and post export, or where early marketing may be crucial to competitiveness of a product.

b) for small and medium sized enterprises, who may lack the resources to understand and access the regulatory systems of a distant third country market. MRAs can bring benefits by enabling all testing and certification steps to be carried out locally.

37. In addition, MRAs can create longer term regulatory benefits, including the following:

¹ The Council indicated the following priorities : USA, Canada, Japan, Australia, New Zealand, Hong Kong, Israel, Korea, Singapore, Philippines and, upon membership of the GATT (now WTO) TBT Agreement : China, South Africa, Malaysia, Indonesia, Thailand and Turkey. Among the latter six countries, all but China are now members of the WTO TBT Agreement. Mutual recognition arrangements with Turkey form part of the EC-Turkey Customs Union. A separate negotiating mandate for Switzerland was obtained in 1995 following Switzerland's decision not to accede to the Agreement Establishing the European Economic Area (EEA).

c) delegation of the right to certify products to bodies in the other party to the MRA represents a type of regulatory reform, particularly where regulation of a sector had previously been the preserve of a single regulatory agency. This can reduce the risk of conformity assessment being used to protect domestic manufacturers, or in a way which could lead to unauthorised technology transfer, problems over intellectual property rights, or other uncompetitive practices (a risk where testing and certification is carried out in conjunction with research for domestic industrial interests).

d) long term **regulatory cooperation**, and indeed regulatory convergence, may be stimulated by MRAs, since each party must understand and apply correctly the regulatory requirements of the other party. This implies regular contact between regulatory agencies and conformity assessment bodies in order to ensure continued and uniform application of each other's rules. This in turn creates an incentive to seek compatible solutions when developing new regulations, or conformity assessment procedures.

e) finally, mutual recognition can assist **regulatory efficiency**. Through being able to rely on assessments carried out by another competent party, the limited resources of the regulator can be reallocated.

MRAs and Harmonisation of Standards and Regulations

38. It was noted in paragraph 35 that mutual recognition of conformity assessment can operate irrespective of whether the parties' underlying product standards and requirements are the same or equivalent. In the case of the EEA, the EC-Turkey customs union, and future arrangements with Central European Countries, the goal of economic integration dictates that mutual recognition be based on common regulations. In most other cases however - such as negotiations with the USA or Canada - MRAs will also operate where the parties' underlying rules remain different.

39. It follows from this that mutual recognition and harmonisation are in no way mutually exclusive. Harmonisation brings economies of scale to the producer, enabling him to sell on multiple markets a product produced against a single or equivalent standard. However, harmonisation does not of itself guarantee market access in terms of product approvals: only mutual recognition will enable the product to be certified in the country of export, and then placed on the market of destination. Conversely, mutual recognition on its own does not allow one-stop approval for multiple markets, unless accompanied by harmonisation or equivalence of the regulations of each party. In general, the greatest gains are to be made where mutual recognition is achieved against a background of harmonised or equivalent rules, so that a single test and approval is sufficient for both domestic and foreign markets.

40. This distinction has not always been understood. Increasingly however, European industry and other interested groups have begun to recognise the separate though clearly complementary roles of MRAs and harmonisation initiatives, and have demanded that both be pursued in order to facilitate trade. The real question is not then whether to pursue MRAs or harmonisation, since their objectives and benefits are different, but rather if there are any circumstances in which one should receive priority over the other.

41. On this question we cannot be categorical. In some sectors the benefits of harmonisation, by removing the costs to industry of national differences in standards or technical regulations, may be judged more important than MRAs. In these cases mutual recognition may be perceived mainly as an important first step towards regulatory convergence, which remains the priority and should be pursued in parallel. Clearly, mutual recognition should not operate to hinder this objective, for example by diverting resources away from harmonisation work, or from inhibiting regulatory change. In cases where harmonisation is imminent, there may be an economic argument for basing mutual recognition arrangements upon such harmonisation, as in the field of pharmaceutical Good Clinical Practice (GCP) (paragraph 74 below), or vehicle approvals (paragraph 76).

42. In other cases, however, mutual recognition may be the priority or sole interest of industry. This may be the case where conformity assessment costs are particularly burdensome, where regulatory differences do not represent major additional costs in terms of product modification, - where harmonisation is considered achievable only in the very long term or, in particular, where harmonisation is not feasible because conditions and parameters are different in each country. The non-quantifiable

benefits of mutual recognition, such as their regulatory benefits, need also to be built into any such assessment.

43. The Commission draws from this assessment two general conclusions. First, the difference between harmonisation initiatives and mutual recognition needs to be well understood, and each be pursued on its own merits. In particular, in situations where mutual recognition has been identified as beneficial for the Community, harmonisation initiatives applicable to the same sector should not be allowed to interfere or delay mutual recognition unless the harmonisation is imminent.

44. Secondly, in view of the importance industry places on achieving greater international harmonisation of standards and regulations, and the frequent complementarity between harmonisation and mutual recognition, we should ensure that MRAs support this goal wherever possible.

45. In the light of these two conclusions, we must, first, ensure in future consultation of European industry groups that the relationship if any between mutual recognition and harmonisation initiatives can be established in each case, their technical feasibility understood, the appropriate timescale for each determined, and resources appropriately allocated. Such consultation should obviously take account of the separate but complementary nature of mutual recognition.

46. Secondly, MRAs should be used explicitly to enhance regulatory cooperation and promote harmonisation or convergence. While MRAs do not imply or require convergence, clearly their benefits may be greater, compliance easier to monitor, and regulatory efficiency maximised, to the extent that the regulatory systems of the parties to MRAs are similar. We should therefore seek within each MRA a commitment by the parties to increase regulatory cooperation and, as appropriate, greater convergence of technical requirements, which the agreement itself can support, and to identify within agreements those sectors where harmonisation or equivalence exists.

47. Thirdly, in determining future negotiating partners, and future sectors to negotiate, we should take account of the partner's commitment to harmonising rules in a given sector with international or European practice, as we are doing, for example, in the case of Central and Eastern European Countries. Where possible, mutual recognition should be a means to encourage greater convergence by partners who have developed divergent national rules. For those countries where technical assistance is being given, as a prelude to future mutual recognition, this assistance should continue to be used to facilitate convergence with European and international approaches. This will make future mutual recognition between the Community and these countries easier to establish, and maximise its value.

Current and Future Priorities

48. The Community's negotiating priorities and strategy for mutual recognition were last considered by the Council in March 1995, when the Commission's proposals to open additional negotiations or exploratory discussions with Korea, Singapore, Israel and Hungary were endorsed. The rationale for these proposals still holds, and on the basis that current negotiations with a number of countries should soon be successfully concluded, further negotiations can be progressively opened. Since that time however, a number of developments have taken place which necessitate further adjustments to this strategy.

49. First, requests have been made by some additional associated Central European countries to open MRA negotiations with the Community. This issue has been discussed several times by the Council, which has endorsed the principle of opening negotiations with associated countries which can fulfil the necessary technical conditions. It has also been stressed that any MRAs should both benefit

bilateral trade in the pre-accession phase, and be based on these countries' legislative alignment with Community rules. Against this background the Commission is now preparing for negotiations as provided for under the respective Europe agreements, once the countries concerned meet the relevant conditions.

50. Secondly, the prospect in the near future of the Community having a series of bilateral MRAs raises questions as to whether they could be made plurilateral. Discussions in the QUAD framework and elsewhere have shown interest in networking future bilateral agreements to create a plurilateral framework. We should support this idea, provided that we first secure a number of bilateral agreements, that any future plurilateralisation preserves our trade benefits, and that such a "networking" is consistent with ensuring that health and safety objectives are in no way compromised.

51. Thirdly, mutual recognition arrangements are now being developed within the APEC region. To ensure that the Community's interests in this field are safeguarded, we should seek the greatest possible consistency between these arrangements and our own approach and objectives in mutual recognition. This can in practice be achieved by progressively negotiating MRA's with those members of APEC, which fulfil the technical and other conditions for MRAs. In practice, the geographical priorities identified by the Council in 1992 also include a number of APEC member economies.

52. Fourthly, the growth of regional trading agreements may become over time relevant to our ~~future~~ MRA policy. Currently a number of regional groupings, including Australia and New Zealand via its Closer Economic Relations Agreement, NAFTA, ASEAN, the Gulf Cooperation Council, Mercosur and the Central European Free Trade Agreement (CEFTA), all plan to introduce forms of mutual recognition, once a common regulatory framework has been introduced. With some exceptions (eg the Australia - New Zealand Tryears-Tasman MRA), these arrangements are at a nascent stage. While in the medium term the Commission will continue to negotiate bilateral MRAs, we should be sensitive to any future regional arrangements, and seek to benefit from them. If, in the future, such arrangements constitute a regulatory union like that of the European single market, and provide the necessary technical guarantees, there may be economies of scale in concluding MRAs at regional level. In discussing technical assistance programmes in Section III below, we suggest giving greater emphasis on encouraging regional arrangements through our programmes. In doing so, the scope for such arrangements to lead to regionally-based mutual recognition in the long term should be kept in view.

53. Fifth, the Community must remain sensitive to the importance attached to mutual recognition by other countries and regions, in for example the Mediterranean and Latin America, with whom we have important bilateral economic relations, for whom the Community is the principal market or whose domestic regimes approximate to or may be guided by European standards and regulatory approaches. For many such countries and regions, mutual recognition is seen as a specific long term aim, and an objective of technical assistance, or can create an incentive for approximation to Community standards and rules. The Community also has an interest in MRAs which can facilitate its exports to these regions and stimulate compatible standards and regulations. While our policy should continue to be guided by the geographical priorities set out in Council negotiating mandates, and must take account of resource constraints, we should nonetheless be open to consider negotiations in future with additional countries, once they are able to meet the technical conditions for mutual recognition.

54. Finally, we note that the implementation of a number of MRAs in the future will have resource implications, for both Member States and ~~for~~ the Commission services. They will need to coordinate relations between authorities and conformity assessment bodies of each party, track legislative changes, and ensure the continued good operation of agreements, ensuring in particular the good functioning of their testing and certification bodies. As far as the Commission is concerned, priority should be given to ensuring that resources are identified among the existing ones, both at headquarters and in delegations to ensure the proper functioning of future MRAs.

SECTION III: TECHNICAL ASSISTANCE PROGRAMMES IN THE FIELDS OF STANDARDISATION, CERTIFICATION, METROLOGY AND QUALITY

55. Since 1990 the Community has provided a growing number of countries with technical assistance programmes in standards, certification, metrology and quality. Some of these have been executed on the Community's behalf by the Comité Européen de Standardisation (CEN). Programmes are currently being provided to numerous trading partners, including those of Central and Eastern Europe, Russia and the CIS, several countries in the Mediterranean and Middle East, Latin America, Asia, and ACP countries. Some of these programmes are delivered within the framework of trade or cooperation agreements with our partners. A list of current and planned programmes is at Annex 2

56. When a technical assistance policy was first established, it was for the following purposes:

- to respond to developing countries' requests for information on European standardisation and regulations, particularly those developed for the Single Market. In this way the transparency of the Community system could be demonstrated, and developing countries would find it easier to export to the Community;
- to assist developing countries to develop a standards and conformity infrastructure that would facilitate international trade;
- and to encourage the adoption by developing countries of International and European standards, as a form of technology transfer.

57. Over time, the scope of programmes has often gone beyond these original elements. Programmes are now typically multi-annual undertakings, and may include : providing information on Community standards and regulations; training and advice on the establishment or improvement of standardisation bodies; assistance in upgrading physical infrastructure; assistance in setting up accreditation systems; training of personnel in standards writing, conformity assessment and accreditation; assistance in developing technical regulations; and training and awareness programmes in the field of quality, from developing quality systems certification capabilities to improving the capacity of industry to meet European quality requirements at both the regulatory and private levels.

58. In setting priorities for such programmes, the Commission takes into account a number of factors, in particular: the importance of such cooperation in the context of overall relations with the third country; its economic or technological level; the capacity of programmes to reduce technical barriers; and their capacity to facilitate trade and investment through promoting the acceptance of international and European standards and regulatory approaches, including where these compete with other countries' standards and rules. In terms of programme design, the Commission has also taken in account the specific priorities established by the Community and the partner country; sectoral needs; budgetary limitations; and whether the programme should be purely bilateral or could benefit from a regional focus.

59. Technical assistance programmes have certainly helped to demonstrate the openness of the Community's regulatory regime, and in doing so have helped third countries' understanding of that regime and the exports of their products. This continues to be the main goal of programmes for lesser-developed countries. It has also been in the interest of both the Community and the third country in question to be assisted in producing better quality or safer products, while the Community has an obvious interest in promoting in third countries a consumer demand for quality which Community products are often best able to supply. It is less clear however, whether all programmes have effectively reduced barriers to trade, or have propagated international or European standards and practices to the maximum extent.

60. The Commission has identified some areas which need more attention if the value of technical assistance is to be maximised. First, Community trade interests have not always been explicitly determined, or fully integrated into programme implementation. Companies and individuals chosen to

carry out programmes have not always been adequately aware of their trade, as opposed to technical and industrial objectives. Programmes can be designed and executed so as to take more account of the specific needs or characteristics of the partner country and priorities of European industry.

61. Secondly, programme coordination can be further improved so as to better fix priorities and ensure a consistent approach between programmes. We can be more active in ensuring exchange of information with Member States, to avoid duplication of resources, and ensure common objectives between Community and Member States' programmes. Similarly, synergy with programmes in related fields such as consumer protection policy, customs procedures, pre-shipment inspection and market surveillance could be beneficial. Programmes could also in some cases benefit from a more resources, and more systematic follow up or evaluation of their success. Improved coordination and management are thus possible.

Programme Objectives and Content

62. In terms of the content of technical assistance in this field, we believe that while the original objectives listed above remain relevant, they need to be complemented in at least four areas.

63. First, we must integrate into future programmes a clearer concept of their trade and economic objectives. Mutual economic and trade interest should be a more explicit factor in programme design, the means to accomplish these objectives specified, and programmes evaluated in terms of whether these goals have been achieved. Training and assistance in applying and complying with multilateral trade disciplines, notably the WTO TBT Agreement, can also be incorporated into more programmes as a specific component. Programmes can also provide more systematically for the identification of priority industrial sectors, to be carried out in consultation with partner countries and European industry, and on the basis of mutual economic interest.

64. Secondly, some partner countries have now reached a stage of economic and industrial development where basic infrastructures - such as a functional standards body, a range of basic industrial standards, and testing laboratories - are in place. Assistance may therefore be better targeted towards areas such as improving the regulatory regime for specific sectors, or refining the infrastructure necessary for mutual recognition agreements to be concluded. The potential to promote the absorption of European and international regulatory approaches, as opposed to solely standards, should receive more attention, since an increasing number of trade barriers are related not to standardisation but to regulatory activity, including conformity assessment.

65. Thirdly, we should ensure that, where appropriate, and where technical conditions are met, mutual recognition can be one of the objectives pursued by technical assistance.

66. Fourthly, the rapid growth of regional arrangements and groupings in the last five years can in future be better reflected in the aims of technical assistance, which is still mostly delivered bilaterally or geared to national, rather than regional solutions. Today a number of regional groupings, including ASEAN, Mercosur, the Gulf Cooperation Council and the CIS, are developing common standards and regulatory systems. To the extent these and other regions develop, over the next decades, regulatory unions like that of the Community, these should where possible be reflected in and supported through our programmes. We have an interest in encouraging standardisation, and the development of technical regulations and conformity assessment on a regional basis, in view of the economies of scale it brings to producers, the potential to access multiple markets on the strength of a single product assessment and the likelihood of regional structures using international standards and practices. At the same time the Community's own single market experience may be a relevant model for many areas of the world considering regional systems. The solutions we have found can be shared. We therefore consider that we should encourage other countries seeking to establish regional regulatory systems, and that our programmes should to a greater extent than heretofore be designed to facilitate such developments.

Programme Coordination and Management

67. In order to improve programme coordination and management in future, we need :

a) to ensure that European industry is aware of, and able to indicate its priorities in the provision of technical assistance programmes. We propose to inform industry federations on a regular basis about both current and forthcoming programmes, and to seek the involvement of European industry and other interested parties in programme implementation where this can be beneficial.

b) to ensure the best possible synergy, and to avoid duplication between Community programmes and those provided by Member States or other international organisations (eg ISO, World Bank, UN, WTO), through regular exchange of information about the broad lines of current and planned programmes. Programmes can then be designed or modified to dovetail with other programmes. Basic information can be shared between the Commission and Member States through the mechanism of the 113 Committee Technical Group on Mutual Recognition. The Commission will aim to secure similar information exchange with the international organisations, and inform Member States of these through the same channel. The Commission will also seek closer coordination with programmes in related fields, as consumer protection, customs procedures, pre-shipment inspection and market surveillance practices. It is not intended that this exchange of information would in any way replace the established mechanisms for consultation on technical assistance and cooperation with developing countries²; instead it will offer a forum which is broader in scope.

c) to provide a new means to administer programmes in future through a new framework contract envisaged with the CEN, which will allow programmes to be administered by CEN on the Community's behalf. Use of this mechanism while optional, and not replacing existing tendering procedures, can nonetheless bring advantages. First, CEN can maximise resource efficiency by having a reliable medium term forecast of programming needs and budget. Secondly through CEN we can better promote the European nature of programmes. Today many partner countries are virtually unaware that the programmes are Community ones. Thirdly, CEN will be charged with building up a repository of information on third country systems, agencies and consultants used, and a library of programme information and training materials, which can be drawn on in designing and carrying out programmes. In this way a focal point for the different European organisations competent in this field can be provided.

d) to improve choice of programme executors, first by ensuring in the framework contract with CEN access to the best possible sources, and by giving the Commission a clearer say in the choice of programme sub-contractors. To a greater extent than in the past, we should give public sector organisations (European and Member State standards bodies and accreditation organisations, Member States regulatory authorities) the opportunity to participate in programmes. These have a long-term public interest in the success of programmes and can establish permanent links with partner organisations and officials. Greater involvement of regulators is also desirable to the extent that future programmes place greater emphasis on improving the regulatory framework in third countries (paragraph 64 above).

e) finally, to incorporate in programmes the possibility of their independent review in order to evaluate whether they are achieving their objectives.

² In particular the Committee established under Article 15 of Council Regulation (EEC) N) 443/92 of 25 February 1992 on financial and technical assistance to, and economic cooperation with with, the developing countries in Asia and Latin America (OJ L 52 of 27.2.1992); and the Committee established under article 21 of the Internal Agreement on the financing and administration of Community aid under the Fourth ACP-EEC Convention (91/401/EEC; OJ L 229 of 17.8.1991)

SECTION IV: REGULATORY COOPERATION

68. The term regulatory cooperation is used broadly, encompassing both :

a) multilateral and plurilateral initiatives for the harmonisation or equivalence of standards, regulatory requirements and conformity procedures, or promoting best practices; and

b) bilateral cooperation with our trading partners in developing technical regulations, standards harmonisation, and regulatory reform.

69. An overview of multilateral and plurilateral initiatives is presented first, followed by a review of principal bilateral activities. Technical assistance programmes, while an important form of regulatory cooperation, and indeed the major form of cooperation with developing countries - are not discussed here in detail, having been presented in Section III above. Bilateral mutual recognition agreements, which may be a vehicle for regulatory cooperation, have been dealt with separately in Section II above.

Multilateral and Plurilateral Initiatives

70. Below is a description of the key multilateral and plurilateral activities of the Community in the field of regulatory cooperation, together with the objectives of each.

The following is not comprehensive, but identifies the priority initiatives underway.

a) OECD

71. The Community and Member States have been active in developing within OECD a multi-disciplinary study on Regulatory Reform. This aims at an agreed statement of the principles, arguments for, and trade benefits of regulatory reform, and encompasses deregulation, harmonisation, and mutual recognition. The process has let the Community share its experience of the single market, and promote Europe's regulatory approach as an example of good practice. By extending the OECD process to non-OECD countries via the organisation's "outreach" policy, this will spread internationally the argument for regulatory reform.

72. A parallel exercise in the OECD Consumer Policy Committee aims to clarify the relationship between consumer policy, certification, and international trade. This has led to a study and recommendations for consideration by Ministers. The study underlines the consumer and trade importance of standards and conformity assessment, and how to align consumer, regulatory and trade objectives. The work draws on the Community's regulatory approach as an example of how to achieve alignment, and again will be shared with non-OECD countries.

73. Finally, since the 1980's the OECD Chemicals Committee has promoted harmonisation of testing practices used when approving chemical products, and the mutual recognition of data from laboratories complying with Good Laboratory Practice (GLP). OECD principles of GLP have progressively become the international standard, and the Community and others have integrated them in their own regulations. The common OECD standards, and the cooperation between members organised through OECD, have provided a technical basis to negotiate MRAs between the Community and third countries. The OECD's work in this area is expected soon to be opened to non-OECD countries, which will further internationalise the OECD standards.

b) Pharmaceuticals : the International Conference on Harmonisation

74. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals (ICH) brings together the regulatory authorities of the European Union, Japan and the United States and pharmaceutical industry experts to discuss scientific and technical aspects of pharmaceutical registration. The purpose is to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines, so as to achieve a more rational use of human, animal and material resources. Harmonised guidelines are adopted by the regulators of the three regions under a stepwise process. It is anticipated that all the current ICH guidelines could be

finalised in the next ICH to take place in July 1997, with follow-up work continuing thereafter. ICH work is likely to facilitate conclusions of MRAs, notably in the area of GCP (Good Clinical Practice).

The International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) was launched in April 96 with a similar purpose and participation.

Separately, the Community acceded in 1994 to the Convention on the Elaboration of a European Pharmacopoeia drawn up by the Council of Europe. This aims to harmonise specifications for the manufacturing and quality control of pharmaceuticals in order to enable them to circulate within Europe. The monographs of the European Pharmacopoeia become official technical rules applicable within the territories of parties to the Convention.

c) Food and Agriculture Organisation (FAO)

75. The Codex Alimentarius Commission, a joint programme of the FAO and the World Health Organisation (WHO), adopts standards, guidelines and recommendations covering certain aspects of food safety and hygiene. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures presumes that Members are in conformity with their WTO obligations if their measures are based on Codex standards, guidelines and recommendations. WTO Members who adopt other measures may be called upon to justify them on the basis of scientific evidence or as a consequence of the need to achieve a higher level of protection. The Community has based much of its legislation in the fields of food safety and hygiene on Codex standards and will continue to do so where they are appropriate to our needs. Furthermore, the Commission will continue to monitor the sanitary and phytosanitary measures of our trading partners to ensure that they conform to their international obligations. The Commission has received a mandate to start negotiations with the Codex secretariat in order to become a full member of Codex in order to ensure that the Community can play its proper role in international harmonisation in this field.

d) United Nations Economic Commission for Europe (ECE)

76. Under the UN-ECE an agreement has existed since 1958 on the harmonisation of standards and technical regulations for motor vehicle equipment and parts, and mutual recognition of approvals. The Community, fourteen of whose Member States are contracting Parties to the Agreement, has introduced a large number of UN-ECE rules into domestic legislation. With the anticipated accession of the Community itself to the UN-ECE Agreement, which is currently under discussion in the Council and the European Parliament, the Community will be better placed to integrate more ECE rules into the EC type approval system in the future.

77. The Community has spearheaded efforts to turn the ECE agreement into a global regime, in order to encourage adoption internationally of ECE-based vehicle regulations, and approvals. This goal was recently brought nearer through a renegotiation of the 1958 Agreement which opens it to non-European countries. Japan has committed itself to joining the Agreement, while the EU and the US have designated the establishment of a revised agreement to develop international standards for automotive products in the UN-ECE on a worldwide basis as a priority under the New Transatlantic Agenda for the second half of 1996. The Community will continue to seek participation of other important car producing and importing countries, so as to ensure the widest possible adoption of ECE-based rules, and mutual recognition of approvals. Any bilateral MRA's in this sector should be designed in such a way that they serve as a stepping stone for the partner countries' accession.

e) Global Harmonisation Task Force for Medical Devices

78. Established in 1992 as a forum for exchanging experience on medical devices regulation, the Global Harmonisation Task Force has become a focal point for efforts to introduce harmonised quality system requirements among the major economies. Supported by both European and US industry, the Task Force has allowed the Community's regulatory approach in the field of quality systems certification to gain acceptance as the international model. Canada, Australia and Japan have been influenced through this to adopt rules close to those of the Community, while evidence is appearing that the USA is starting

to do the same. The Task Force is an example of how the Community single market experience - resulting in a flexible regulatory approach - offers a model which may be referred to elsewhere. The Commission will continue to give priority to the Task Force's work, in particular as a basis for promoting the quality systems approach in other countries, notably in East Asia, which are overhauling their medical device rules.

f) Civil Aviation

79. Extensive regulatory cooperation in civil aviation matters is carried out at the international level by the International Civil Aviation Authority (ICAO), and at European level through the Joint Aviation Authorities (JAA). The latter, which groups the EC Member States and 12 other European Countries, cooperates to harmonise aviation regulations and promote the mutual recognition of aircraft certification throughout Europe.

The Community's role in these activities has in the past been limited, but is expected to grow in future. First, the further development of the Community's regulatory regime for civil aviation will in both international fora and bilaterally strengthen its capacity to cooperate with third countries. Secondly, as part of a future aviation safety strategy, the Commission envisages launching technical cooperation programmes aimed at improving safety standards in these countries and promote adoption of the European regulatory approach. These programmes are likely, in the first instance, to be carried out in collaboration with ICAO or the JAA.

g) The Organisation for Asia Pacific Economic Cooperation (APEC)

80. In 1995 the APEC members launched a long term programme of cooperation in the field of standards and conformance. This encompasses harmonisation of standards and regulations, based on international ones, cooperation to improve certification and accreditation systems, and mutual recognition agreements. The Community's trade can potentially benefit from these APEC initiatives. We have an interest in seeing maximum possible compatibility between the standards, regulations, and conformity assessment infrastructure developed by APEC economies - especially their newly industrialising members - and Community ones. In view of the technical cooperation being offered to some APEC Members by both the Community and the more developed APEC members, there should also be an interest in seeking coherence between these programmes, so as to maximise their value.

81 The Commission considers that our interest in the APEC process can be served first, by continuing to monitor developments, and secondly to seek a dialogue with the APEC Working Group on Standards and Conformance, which would be used to exchange information and experience on our respective activities.

Bilateral Initiatives

82. At the bilateral level the objectives of regulatory cooperation with the Community's principal trading partners can be summarised as follows:

- a) to improve transparency through exchanging information on current and planned initiatives, such as forthcoming laws and technical regulations affecting industrial products;
- b) to minimise divergences in regulatory approaches, and the risk of ensuing trade friction with our trading partners, through pre-legislative consultation;
- c) to facilitate harmonisation, or recognition of equivalence of standards, technical regulations and conformity assessment procedures between the Community and third countries, in those sectors where these have been judged achievable and of economic benefit to Community exporters.

In some cases bilateral cooperation can lay the foundations for the development of standards or regulations in the multilateral framework.

a) USA

83. Regulatory cooperation between the world's two largest trading entities has always been a priority, and in recent years has been extended and formalised. In 1995 the Community and the USA adopted, at sub-cabinet level, a document setting out "Principles of Regulatory Cooperation". This statement of principles encompasses the objectives listed above, and is meant to guide officials and regulatory agencies in their work. EC-US regulatory cooperation is currently being pursued, taking these principles into account, in many areas including: industrial standards (DGIII-CEN/YEARSI-Dept of Commerce); Environment (DGXI/EPA); civil aviation (DG VII/FAA); telecommunications (DGXIII/FCC); foodstuffs and pharmaceuticals (DGIII/FDA); energy (DGXVII/EPA-Dept of Energy); pesticides (DGVII/EPA); and biotechnology (DG III/VI/XI/FDA/USTR). At the sub-cabinet meeting in May 1996, five pilot projects on regulatory cooperation (covering smoke measurement, dioxins, biotechnology, diesel engines and port state control) were proposed for future work.

84. Regulatory cooperation has been significantly boosted through the announcement, at the Ministerial summit of December 1995, of the EC-US Transatlantic Agenda and Action Plan, which instituted a comprehensive and forward-looking agenda for further cooperation in the field of standards, technical regulations and conformity assessment in several industrial sectors. Industry on both sides of the Atlantic has contributed to setting priorities through a Transatlantic Business Dialogue (TABD), in which different sectors have identified the short, medium and long term actions to reduce technical barriers, and enhance convergence of EC and US regulatory systems.

b) Japan

85. Although regulatory cooperation with Japan has not been as comprehensive as with the USA, dialogue between the two sides has increased in recent years. The main bilateral activities linked to standards and regulatory issues are :

- Japan's autonomous deregulation initiative, in which changes to Japan's standards and conformance regime figures prominently, and where the Community has indicated priorities for improving access to Japan's regulatory regime in several sectors.
- the annual Industrial Policy and Industrial Cooperation dialogue, through which the EC and Japan facilitate cooperation programmes between key industrial sectors, and which includes consideration of regulatory issues;
- the EC-Japan Standards and Quality dialogue, which aim to improve understanding of each party's standardisation and quality certification approaches.
- annual high level consultations on telecommunications policy.
- the annual high level consultations on environmental issues aimed at cooperating in the development of environmental regulations;

86. Regulatory cooperation with Japan also occurs in several of the plurilateral fora, described above. There is nonetheless scope for intensifying bilateral cooperation with Japan, as was recognised in the 1995 Communication to the Council "Europe and Japan: The Next Steps". There, we indicated that the dialogue on regulatory cooperation should be perceived as a continuous one, in which the EC's experience in regulatory reform, acquired particularly through the Single Market exercise, could be put to use. This remains a priority for the Community, and we intend to seek from Japan a commitment to such an ongoing exercise which could over time become comparable to that with the USA.

c) Canada

87. The regulatory dialogue with Canada has in the past been pursued mainly through plurilateral fora. Recently however Canada has sought to strengthen the framework for bilateral cooperation with the Community through concluding an accord comparable to the EU-USA Transatlantic agenda. Although an agreement with Canada may be not as comprehensive in its scope, it will nonetheless provide an important vehicle to increase convergence in the future in sectors of common trade interest, while enhancing the scope for future NAFTA cooperation, which can bring obvious economies of scale..

d) The Associated Countries of Central and Eastern Europe

88. A special case is that of the Central and Eastern European countries with whom the Community has concluded Europe Agreements. To prepare these countries for eventual EU accession, major programmes have been launched to assist institutional reform enabling alignment of their standards and regulatory systems with those of the Community. Implementation of the Europe Agreements, in particular through the Committees of the Association Councils dealing with legislative alignment, and industrial cooperation; PHARE programmes of technical cooperation; the development of progressively closer relations with European-level standardisation, certification and accreditation bodies; and possible mutual recognition agreements, are the main means to promote regulatory alignment in the pre-accession period.

e) Other Countries

89. With the exception of Switzerland, with whom there is a sustained regulatory cooperation in several fields, most regulatory cooperation with other trading partners is pursued through plurilateral or multilateral means, which were described above. As further needs arise in a particular sector or field of cooperation, these will be pursued.

SECTION V: CONCLUSIONS AND SUMMARY OF RECOMMENDATIONS

Conclusions

90. In the preceding pages the Commission has underlined the need for a more active and outward-looking strategy to reduce technical barriers to trade, to facilitate the wider use of European and international standards and regulations, and to bring nearer the goal of one-stop testing and certification. We consider such a strategy to be both necessary and timely. It is necessary if we are to stem the proliferation of unjustifiably divergent standards and rules in a growing number of countries, and encourage approaches which are compatible with multilateral obligations, tryearsparent, proportionate and advantageous to European exporters on world markets. It is timely because the regulatory system underpinning the Community's own internal market has now matured to the stage where we can afford both to focus more on our partners' regimes, and draw on our own experience to propose solutions to some of the problems faced.

91. In reviewing the elements of this strategy - the instruments of the WTO, and bilateral agreements, technical assistance, regulatory cooperation and mutual recognition - we have recommended ways to make them more effective or respond better to a rapidly changing trading environment. The recommendations made are summarised in paragraph 96 below.

92. At the same time we have stressed the importance of coherence between different components of this strategy. We have noted the importance of WTO instruments in reducing technical barriers to trade and in promoting use of international standards and regulations, and have suggested how these instruments can be used more fully. Technical assistance programmes can also however support the goals of the WTO: we have argued that such programmes, given a suitable trade orientation, provide a major means to assist compatibility with WTO rules. They also constitute a major vehicle for promotion in other countries of European standards and regulatory practices - themselves substantially based on international rules - in sectors of mutual commercial interest. Technical assistance programmes can also help prepare more advanced partners to meet the necessary conditions for future mutual recognition agreements, which may provide an important incentive for good programme implementation.

93. We have presented mutual recognition as a response to the legitimate - but increasing - use of third party conformity assessment in international trade. MRAs can facilitate trade in sectors which will continue to require government regulation, and whether or not underlying product requirements are or can be harmonised. We have argued however that mutual recognition may often bring the greatest trade benefits in sectors which have been harmonised, and that the necessary confidence between MRA partners may be more rapidly gained and maintained in these circumstances. Membership of the WTO TBT Agreement, while a precondition to conclude MRAs, is of itself not enough to provide this confidence.

94. Finally, we have noted that harmonisation of standards and regulatory requirements is achieved through regulatory cooperation taking place both at the multilateral level and bilaterally. These initiatives, like technical assistance, help to prevent trade barriers and may establish a good technical basis for mutual recognition. Regulatory cooperation in particular at the multilateral level ensures that the Community's interests in the development of international standards and regulations - vital for our international trade, besides being the basis on which our WTO obligations largely rest - are safeguarded.

95. The policy goals set out in this paper can only succeed however with good coordination and the right institutional framework. Some specific recommendations have been made: to consult industry more widely when setting priorities; to improve exchange of information on technical assistance programmes, to strengthen external delegations' coverage of standards issues. But the full benefit of the strategy set out in this Communication can only be reaped through proper coordination and monitoring. Within the Commission, we will consider the case for strengthening the resources of the services responsible for oversight and interservice coordination of policies set out in this document.

At the level of the Council however, we see merit in broadening the current mandate of the 113 Committee Technical Group on Mutual Recognition to encompass technical barriers to trade, technical assistance and regulatory cooperation in the field of standards and conformity assessment. This Council committee comprises both trade and regulatory expertise and is well placed to give guidance on this issues while remaining subject to the strategic guidance and oversight of the 113 Committee. The Commission therefore recommends such an extension of the MRA Group's mandate.

Summary of Recommendations

96. Below is a summary of the recommendations made :

- a. To ensure improved implementation and operation of the WTO Agreement on Technical Barriers To Trade (TBT), the Community should seek, at the WTO Singapore Ministerial meeting in December 1996:
 - 1) reaffirmation by all WTO Member of their commitment to fully implement the TBT Agreement;
 - 2) commitment to ensure a comprehensive and in-depth review of the TBT Agreement as foreseen in 1997 (paragraph 18).
- b. Furthermore, to consider whether, and in which circumstances, the Community should be involved more closely in the work of the international rule-making/standards bodies, so as to ensure continued consistency between international rules and standards, Community rule-making, and our WTO obligations (paragraph 19).
- c. To seek thorough coverage of standards and conformity issues in future TPRM reviews, notably those of our major trading partners or in countries where barriers have been identified as particularly acute. In addition, to be open to thorough TPRM review of the Community's regulatory system (paragraph 24).
- d. In the context of current and forthcoming negotiations on accession of new WTO Members, to ensure that standards and conformity assessment issues are given prominence (paragraph 26).
- e. Within the framework of the Market Access Strategy, to ensure that market access problems relating to technical barriers to trade are comprehensively documented, and that adequate consultation and exchange information on these issues takes place between the Commission, Member States and European industry (paragraph 31).
- f. To ensure that key external delegations make coordination on standards and conformity issues a priority (paragraphs 32-33).
- g. As concerns Mutual Recognition Agreements (MRAs), to ensure that the differences between harmonisation on the one hand and mutual recognition on the other be better understood, and each continue to be pursued on its own merits. Consistent with this, the objective of regulatory harmonisation should be taken into account in future MRA negotiations, in particular through using such agreements to enhance cooperation and promote harmonisation. At the same time, in determining future negotiating priorities, commitment to harmonising its regulatory regime in a given sector with international or European practice should be taken into account (paragraphs 43-47).
- h. To open negotiations on mutual recognition with associated countries of Central and Eastern Europe to the extent they can fulfil the technical and other conditions for such agreements (paragraph 49).
- i. To be open to the principle of plurilateralising bilateral MRAs, once concluded, and where consistent with both our trade interests and regulatory objectives. In addition, to be open to the possibility in the long term, of establishing agreements on a regional basis (paragraph 50).

- j. To continue to attach priority to MRAs with individual members of APEC in order to maximise consistency between these arrangements and APECs work in this field (paragraphs 51)
- k. Taking account of existing guidelines and mandates, to continue to be open to negotiating mutual recognition with other countries which meet the necessary technical requirements (paragraph 53).
- l. To ensure the means are available to allow the proper implementations of MRAs, both at the national level and within the Commission (paragraph 54).
- m. In respect of technical assistance programmes, to integrate trade objectives fully into current and future programmes including, where appropriate, assistance in complying with WTO obligations and disciplines (paragraph 63). The specific trade/market access needs of lesser-developed countries should continue however to be served by programmes.
- n. To ensure that technical assistance programmes concentrate adequately on regulatory issues, where necessary in a more sector-specific way (paragraph 64).
- o. To continue to utilise technical assistance to establish a basis for mutual recognition agreements and other forms of regulatory cooperation (paragraph 65);
- p. To take full account of the regional dimension in providing programmes, including the encouragement of regional systems of product regulation and conformity assessment, and to promote where appropriate the Community's regulatory approach in such programmes (paragraph 66).
- q. To consult with and seek involvement of European industry groups on a regular basis about current and forthcoming technical assistance programmes (paragraph 67a).
- r. To establish through the 113 Committee of the Council a mechanism for systematic exchange of information between the Commission, Member States, European and international organisations on programmes in this field, so as to enhance transparency, reduce duplication of effort and create synergies between programmes (paragraph 67b). Noting however that this is without prejudice to existing provisions for information exchange and consultation.
- s. To offer as an option a new mechanism for programme administration through a framework contract with the Comité Européen de Standardisation. This will assist programme planning, enable the creation of an information base for use by programme planners, the Commission, Member States, industry and other interested parties, and promote the European profile of programmes (paragraph 67c).
- t. To improve the means of choosing programme consultants and contractors, and in particular to use to a greater extent than in the past European level or national organisations and Member States regulatory authorities (paragraph 67d).
- u. In the field of regulatory cooperation, to continue to give priority to the work being carried out in the OECD in the area of regulatory reform, in order to improve international understanding and consensus on its benefits, to share experience with the single market exercise, and to promote the use of Europe's regulatory approach. In addition, to continue to support ongoing OECD activities in the field of harmonisation and mutual recognition of data in the chemicals field (paragraphs 71-73).
- v. To ensure that the current work under the International Conference on Harmonisation in the pharmaceutical sector is completed by July 97, in order to allow a reallocation of resources towards harmonisation of the registration dossier and inclusion of GCP in MRAs with the USA, Canada, Japan, Australia and others. (paragraph 74).
- w. To promote actively the adoption by our trading partners of the standards set by the Codex Alimentarius in order to reduce technical barriers and facilitate trade in foodstuffs (paragraph 75).

- x. In respect of the UN-ECE Agreement on harmonisation of regulations and mutual recognition of approvals for vehicles and parts, to seek participation in the Agreement of other important trading partners, so as to ensure the widest possible adoption of UN-ECE-based rules, and mutual recognition of approvals. Any bilateral agreements on mutual recognition of vehicle approvals in this sector should serve as a stepping stone for the accession of partner countries to the UN-ECE system (paragraph 77).
 - y. To continue to support the work of the Global Task Force on Harmonisation in the medical device sector, as a means to promote the quality systems approach in other countries (paragraph 78).
 - z. To strengthen the Community's regulatory cooperation in the field of civil aviation, in particular through developing technical cooperation programmes which promote safety and the wider use of European regulations (paragraph 79).
 - aa. In respect of APEC, to monitor the work of the APEC Working Group on Standards and Conformance, and to establish a dialogue with APEC on this matter (paragraphs 80-81).
 - bb. As regards bilateral regulatory cooperation, to continue to attach priority to such cooperation with the USA, in particular through implementation of the Transatlantic Action Plan decisions in this respect; and with the associated countries of Central and Eastern Europe; and to strengthen cooperation with other major trading partners such as Japan and Canada (paragraphs 82-89).
 - cc. To ensure that standards and conformity assessment issues receive appropriate attention and to improve coordination of the various policy instruments described in the document, to consider resource and needs within the Commission services (paragraph 95).
 - dd. At the level of the Council, to broaden the current mandate of the 113 Committee Technical Group on Mutual Recognition to encompass technical barriers to trade, technical assistance in the field of standards and conformance, and regulatory cooperation (paragraph 95).
97. The Council is invited to note the contents of this Communication, and to endorse both its broad conclusions and the specific proposals made.

**ANNEX 1 : SUMMARY OF CURRENT MRA NEGOTIATIONS
BY COUNTRY / SECTOR**

Sectors under discussion	USA	CANADA	AUSTRALIA	NZ	JAPAN	SWITZERLAND
MEDICAL DEVICES	X	X	X	X	X	X
PHARMACEUTICALS GMP	X	X	X	X	X	X
GLP	X	X			X	X
TELECOMS EQUIPMENT	X	X	X	X	X	X
ELECTRICAL EQUIPMENT & EMC	X	X	X	X	X	X
PRESSURE VESSELS			X	X	X	X
MACHINERY			X	X	X	X
PPE	X	X			X	X
AIRCRAFT	X	X	X	X		
AUTOMOTIVE PRODUCTS			X			X
RECREATIONAL CRAFT	X	X				X
LAWN MOWERS	X					X
MEASURING INSTRUMENT						X
TOYS						X
PHYTOPHARMACEUTICALS						X
DANGEROUS SUBSTANCES AND PREPARATIONS						X
CONSTRUCTION SITE EQUIPMENT						X
ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERS (ATEX)						X
GAS APPLIANCE						X
TRACTORS						X

ANNEX 2 B

PROGRAMMES IN PREPARATION

THIRD COUNTRIES	NATURE OF PROGRAMME	SECTORS	DURATION	AMOUNT
Pakistan	Certification, standardisation and quality assurance			
Chili	Certification standardisation, quality assurance, metrology	Certification, quality, Awareness Training	2 years	500000
Mongolia	Standardisation, certification			
China	Certification standardisation, quality assurance, metrology	not specific	4 years 1997-2000	5210000
Cyprus	Standardisation, certification, metrology, quality assurance			
ASEAN	Standards, quality assurance of conformity	not specific	5 years 1997-2002	not yet determined
Jordan	Identification mission certification, standardisation, quality assurance	horizontal	1996 -	30.000
Lebanon	Industrial and Commercial standards	horizontal	3 years 1997-1999	6.000.000
Marocco	alignment of rules, legislation, mission to identify needs	horizontal	1996 2 months	30.000
Paraguay	Certification, standardisation, quality assurance, metrology	industrial products	2 - 3 years (to be determined)	+/- 900.000
Brazil	Metrology, certification	industrial products	8 months	+/- 400.000
MERCOSUR	Certification, standardisation, procedures of notification, metrology and quality assurance and management	industrial products	3 years 1993/1996	3950000
AIDMO	Certification, standardisation	not specific	3 years 1997/2000	750000
GCC	Certification, quality, standardisation	to be determined	3 years 1996/1999	700000
ANDEAN PACT (5 countries)	Regulations, notification, standardisation, testing, certification, quality assurance, metrology	to be determined	3 years 1997-2000	2.300.000

ANNEX 2 A

ACTIONS IN PREPARATION

THIRD COUNTRIES	NATURE OF PROGRAMME	SECTORS	DURATION	AMOUNT(ECU)
India	Metrology, standardisation, certification, quality assurance, testing	Vehicle, foodstuffs, domestic electrical appliances and ITT	Part 1 1988/1992 Part 2 : 1992-1997	2000000 2.528.000
Sri Lanka	Normes, quality assurance	Horizontal	2 years	450.000
Vietnam	Normes, quality, assurance	Horizontal	3years	3.500.000
Malta	Standardisation, certification metrology, quality assurance, testing	Horizontal		2200000
Mexique	Certification, accreditation, standardisation	Not specific	4 years 1992/1996	1650000
Marocco	Certification, accreditation, metrology, quality promotion	Horizontal	3 years 1993/1996	1575000
Algeria	Certification, standardisation, intellectual property, quality assurance	Plumbing Cement	6 years 1992-1997	400.000
Tunisia	Certification, standardisation, quality assurance	Horizontal	1995/1997 3 years	5.000.000
Israel				200000
Egypt	Identification mission to design a comprehensive programme		1996	35000
Argentina	Certification and assistance to laboratories	electrical and electronic products	2 phases 91-95 ; 96-98	1089000
Bulgaria	Certification, standardisation, methodology, quality assurance, testing	Not specific	3 years 1996/1998	2.000.000

ANNEX 2 A (cont'd)
PROGRAMMES IN PREPARATION

THIRD COUNTRIES	NATURE OF PROGRAMME	SECTORS	DURATION	AMOUNT (ECU)
Romania (Phare)	Quality assurance, Standardisation, Certification, Accreditation, testing	various sectors	5 years 1993/1997	500000
Hungary (Phare)	Metrology, Certification, Accreditation and Quality assurance	not specific	5 years 1991/1995	
Hungary (Phare)	Certification, type approval	Telecoms	3 years 1995/1997	500000
Czech Republic (Phare)	Metrology, Standardisation, Testing	Quality infrastructure	5 ans 1991/1995	690.000
Czech Republic (Phare)	Standardisation and Metrology	Quality infrastructure	4 years 1992/1995	1580000
Czech Republic (Phare)	Testing, Standardisation, Accreditation	Quality infrastructure	4 years 1995/1998	4000000
Czech Republic (Phare)	Testing & Certification	Telecoms	4 years 1991/1994	700000
Slovak Republic	Standardisation, Science et Technologie	Not specific	3 years 1995/1997	5000000
Lithuania (Phare)	Standardisation, Approximation of legislation	Foodstuffs industry Pressure equipment. Electrical equipement	3 years 1996/1998	3800000
Latvia (Phare)	Standardisation Approximation of legislation	Not specific	3 years 1996/1998	2055000
Estonia (Phare)	Standardisation, Accreditation, Metrology, conformity assessment	Quality Infrastructure	4 years 1995/1998	1800000
Romania (Phare)	Standardisation, Consumer protection	Not specific	3 years 1996/1998	600000
Bulgaria	Certification Methodology quality assurance, Standardisation	Not specific	1996/1998 3 years	2000000
Multicountry Programmes PRAQ 91, PRAQ 93 PRAQ III	Metrology, Certification, Standardisation, Accreditation, Testing, Legislation	Various sectors		35500000

FICHE D'INFORMATION

COMMUNITY EXTERNAL TRADE POLICY IN THE FIELD OF STANDARDS AND CONFORMITY ASSESSMENT

This Communication sets out the European Community's trade policy objectives in the field of standards and conformity assessment, and the strategy to achieve these objectives. Its aim is twofold. First, to establish better understanding of the Community's policy and strategy in this area, so that it may be promoted coherently. Secondly, to review and where necessary modify the strategy.

The Communication rests on two assumptions. First, that trade barriers related to product standards and conformance - technical barriers to trade - appear to be increasing, demanding greater attention and action than in the past. Secondly, that the completion of the single market regulatory regime now places the Community in a position to pursue a more outward looking trade policy in this field.

The Community's trade objectives can be summarised simply. First, to reduce technical barriers in overseas markets and prevent the emergence of new ones. Secondly, to encourage our trading partners to adopt standards and regulatory approaches based on, or compatible with international and European practice. Achievement of both objectives will facilitate our trade and market access for regulated products.

These trade objectives are being pursued through a four-fold strategy comprising: reliance on under the WTO, notably the Agreement on Technical Barriers To Trade, in the multilateral framework, and on agreements in the bilateral framework to reduce barriers and open markets; negotiation of mutual recognition agreements to reduce the costs of testing and certification in other markets; technical assistance to a large number of countries to ensure that regulatory regimes are transparent and trade friendly, and regulatory cooperation aimed at harmonising standards and regulations with other trading partners.

Concerning the **WTO**, we need to carry out a comprehensive review of the operation and implementation of the Agreement on Technical Barriers To Trade, as a means to ensure full adherence by all WTO members, and where necessary improve its operation. This implies also more systematic use of the WTO Trade Policy Review mechanism, and greater attention to technical trade barriers in the context of WTO accessions. Bilateral negotiations can also secure adherence to WTO rules, as part of the Community's Market Access Strategy.

On **Mutual Recognition Agreements** a clear line needs to be drawn between the benefits of mutual recognition on the one hand and harmonisation of standards and regulations, since each can be pursued on its own merits. We should however place greater emphasis on using mutual recognition as a vehicle for greater harmonisation. In the longer term, we should be open to plurilateralising MRAs and consider the case for MRAs on a regional basis.

Technical Assistance programmes to developing countries already promote the adoption by partner countries of international and European standards and practices. But there are ways in which technical assistance can better serve external trade objectives in future, and provide a basis for future mutual recognition agreements. We can also improve coordination of programmes and achieve better coherence between Community and Member States' programmes, so as to maximise economies of scale.

As concerns **Regulatory Cooperation**, the principal Community initiatives in this field, whether multilateral, plurilateral, or bilateral, cover key industrial sectors such as vehicles, pharmaceuticals, medical equipment, foodstuffs and chemicals. These different forms of cooperation promote international harmonisation or acceptance of the Community's regulatory approach, and in many cases provide a basis for mutual recognition.

In all these areas, cooperation and coordination between the Commission, Member States, European Industry, and the European Standards and Certification Community, is essential. We consider it possible to improve this cooperation, and have made specific recommendations to this effect.

The Communication ends with a summary of conclusions, and asks the Council to endorse both the broad strategy set out in this document, and the specific proposals made.