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**Priorities for Bilateral/Regional trade related activities
in the field of
Mutual Recognition Agreements for industrial products and related technical
dialogue**

I. EXECUTIVE SUMMARY

The aim of this document is to identify priorities for Commission bilateral and regional activities in the field of technical regulations, standards and conformity assessment, excluding agricultural products and services, under trade related agreements, existing or under negotiation, for which a negotiation mandate had been given to the Commission). The paper is based on an analysis of the experience the EU has had with external activities in this field (in particular mutual recognition agreements (MRAs) and related technical dialogue), and the potential of key trading partners/regions in terms of capacity in the field of technical regulations, standards and conformity assessment.

The analysis carried out has shown that:

- Mutual Recognition Agreements (MRAs) should be negotiated only in cases where there is clear equivalence of respective rules and a real prospect of making them operate almost "automatically".
- Priority countries/regions for the promotion of targeted technical dialogue and in due course even the possible negotiation of MRAs based on equivalence of rules: The countries participating in the Stabilisation and Association Process, the Mediterranean, Russia, Ukraine, China and the Gulf Co-operation Council.
- In the case of existing MRAs not based on equivalence of rules (with the US, Canada, AUS-NZ, Japan) efforts should concentrate on the management of sectors that operate satisfactorily and the simplification of the procedures. Sectors which have proven simply impossible to implement, and where there no political here or in the other party to force regulators to act, should be abandoned.
- The formal dialogue established in the context of these MRAs should be used to promote an informal dialogue on key issues under discussion in the TBT Committee (in particular with Japan and Canada).
- The EU should consider much lighter approaches than that of mutual recognition, including the recognition of conformity assessment bodies (CABs) outside the EU.

II. ANALYSIS

1. Elements to consider before setting priorities

The EU has concluded or is in the process of negotiating agreements with about 38 third countries, many of which foresee or offer the possibility for specific actions in the field of technical regulations, standards and conformity assessment. Moreover, the EU offers considerable technical assistance for third country needs in these areas.

One could assume that all these countries/regions should be considered for mutual recognition agreements (MRAs) for industrial products and related technical dialogue. However, the limited resources available and the need to use resources in the most efficient manner make it necessary to set priorities in terms of countries/ regions with which MRAs should be pursued.

In *selecting priority countries/regions* the following should be considered:

- Our political commitment to extend the EU borders to this country/region;
- The content of existing or under negotiation agreements with the country/region in question;
- Current and potential future trade flows with the country/region in question.

When *deciding on the most appropriate type of MRA and related technical dialogue for each country/region*, the following should be taken into account:

- The country's infrastructure and capacity in the field of standards and conformity assessment for industrial products;
- The country's rules for the industrial product sectors under consideration and its willingness to align them with EU or international rules;
- Our experience with use of the different trade tools, in particular the conclusion of mutual recognition agreements and technical dialogue (as the latter is linked to the negotiation and conclusion of MRAs);
- Other "tools" that have not yet been used, but merit consideration.

2. Experience with Mutual Recognition Agreements on conformity assessment

a) **Overall conclusions** from the experience so far are as follows.

- The "traditional" type MRA (mutual recognition of conformity assessment certificates without alignment of the relevant requirements) has proven difficult to negotiate and even more difficult to implement. It is not worth pursuing new negotiations on his type of MRA.
- The "enhanced" type MRA (mutual recognition of certificates based on equivalent or common requirements) is the one offering the best prospects of implementation and trade facilitation. This is the type of MRA worth pursuing in the future.

b) **An analysis** of our experience with the different types of MRAs is given below.

i. "Traditional" mutual recognition agreements (MRAs)

In a “traditional” mutual recognition agreement, one Party has the right to designate conformity assessment bodies (CABs) to assess conformity with technical regulations, standards of the other Party. In this type of agreement the regulatory requirements of the two parties may differ substantially. “Traditional” MRAs have been concluded with the US, Japan, Canada, Australia, New Zealand and Israel. Part of the MRA concluded with Switzerland is “traditional” in type.

Successful implementation of this type of MRA requires mutual confidence that the systems for certifying products in the other party are effective and can be relied upon to deliver an appropriate level of protection. This confidence may take some time to establish, since the authorities of each party are effectively placing part of the task of enforcement of technical requirements in the hands of bodies over whom they have no direct control. Confidence building becomes even more difficult where the technical requirements and overall regulatory approach of the two parties differ substantially. The routine maintenance cost of this type of MRA is not small, in particular for the EU because of its institutional rules.

This type of MRA can only work if there is good will on both sides. Our particular experience with the US and Canada MRAs has shown that despite considerable investment on our side, good will is difficult to obtain in cases where there are substantial differences in the regulatory requirements/approach. It has also become apparent that in areas where confidence building has been particularly difficult and implementation of the MRA delayed, the market has found other ways of achieving the same result in a more efficient way.

ii. “Enhanced” mutual recognition agreements (MRAs)

As already indicated, the “traditional” MRA is based on recognition of certificates of compliance to the *other* party’s technical regulations and standards. An "enhanced" MRA is one that also foresees recognition of certificates, but is also based on equivalent or totally aligned regulatory requirements.

- "Enhanced" MRAs based on equivalent rules

Equivalence of regulatory requirements can be determined on the basis of adherence to rules or standards developed by a "treaty" organisation (for example, the Conventions of the International Maritime Organisation (IMO)) or where the two parties have agreed, through screening of the relevant legislation, that the respective rules are equivalent.

The **MRA with Switzerland** is in part based on this principle as it covers sectors where legislation is equivalent and others where it is not. The functioning of the MRA with Switzerland in the sectors deemed equivalent has proven smooth and without administrative cost. The difference in ease of implementation between equivalent and non-equivalent sectors is such that we have decided not to proceed with the extension of the agreement to sectors that are not equivalent. Moreover, as expected, confidence

building in equivalent sectors has presented no difficulties. It has however to be borne in mind that Switzerland is probably a unique case. A European, highly developed economy with infrastructure equivalent to that of the EU and with strong incentive to align its rules with those of the EU, its main trading partner.

We are now in the final stages of the process of concluding another "enhanced" type MRA, **on marine equipment with the US** (in this case, based on rules of the International Maritime Organisation (IMO)). In such an agreement there is automatic recognition of the other party's CABs and no need for confidence building. The maintenance cost is expected to be minimal. Moreover, confidence already exists as both parties apply equivalent rules and are member of the IMO.

- "Enhanced" MRAs - based on common rules

Such a type of agreement foresees recognition of conformity assessment certificates and adoption by the other Party of the *acquis communautaire* as a basis for its own legislation.

The Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) concluded with Candidate Countries are based on this principle. The same applies to the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACCA) concluded with Malta. Such agreements can only be concluded with countries where there is a political commitment for extension of the internal market to them, which *de facto* requires them adopting the *acquis communautaire*.

By the end of 2003 such agreements had been concluded with all Candidate Countries, except Cyprus and Poland. Bulgaria and Romania also fulfil the above-mentioned criteria for conclusion of PECAs and discussions with them are ongoing.

There is an authorisation by the Council covering the negotiation of MRAs, which was amended in 1992 and again in 2001. The amended mandate now entitles the Commission to negotiate MRAs with countries with which the Community has concluded Association, Free Trade or Partnership Agreements. This would include most of the countries mentioned above. The amended mandate also provides that where possible, MRAs may be based on sectoral and horizontal rules and requirements similar to those applicable in the Community. This authorises the negotiation of enhanced MRAs.

3. Technical dialogue

In many cases issues related to technical regulations, standards and conformity assessment are included in technical dialogues with third countries. Some of these dialogues are integral part of formal Agreements concluded with third countries/regions, while others are conducted independently and are not subordinate to any formal Agreement.

While many of these dialogues treat the issue of standards, technical regulations and conformity assessment in a general way, others can go beyond this general level and focus on specific sectors with the aim of influencing each other's regulatory approach

in these sectors. Such focused technical dialogue is often necessary before the parties embark on the negotiation of an MRA.

Many of our trading partners consider the mere existence of a bilateral technical dialogue on technical regulations, conformity assessment and standards as a prelude to the negotiation of an MRA with the EU. It is therefore important for the EU to determine its level of ambition for each dialogue, in terms of the possibility of concluding MRAs.

This paper does not intend to cover the wider issue of regulatory cooperation, which will be addressed separately.

4. Other possible measures

If any of the approaches described below were to be followed, the Commission would submit the appropriate recommendations to the Council.

a) Recognising Conformity Assessment Bodies in other countries and making wider use of international accreditation

Experience with the implementation of the "traditional" type MRAs has shown that while regulators are not prepared to concede their right of recognising competent CABs to the authorities of the other party, they may, under certain conditions, be prepared to recognise certification bodies in other countries.

Users need confidence in the certification, inspection and testing work carried out on their behalf, but which they cannot check for themselves. This checking is the job of accreditation bodies. Certifiers of systems and products, and testing and calibration laboratories need to demonstrate their competence, which they can do by being accredited by a nationally recognised accreditation body.

The EU regulatory system requires certification and assessment bodies ("notified bodies") to be limited to the territory of one of the EU Member States or EEA States. Accreditation is not a formal criterion for the nomination of a Notified Body, which is rather done under the responsibility of the individual Member State authority. Nonetheless, in practice most notified bodies in Member States (and in candidate countries) are accredited by national accreditation bodies affiliated to European Accreditation.

Any kind of third party assurance will always raise the question of how the third party's assessments are themselves to be assessed. In the case of accreditation, this question is answered by systems of peer review. At the global level, memoranda of understanding or similar arrangements between various regional accreditation bodies and the global accreditation bodies, such as the International Accreditation Federation (IAF) and International Laboratory Accreditation Co-operation (ILAC), have gone a long way to assist in the broader recognition of conformity assessment through the mechanisms of co-operation and peer review fostered by these bodies and their national and regional participants.

Consideration may thus be given to the possibility of recognising bodies in non-EU countries to act as notified bodies, on the basis of their having a reliable accreditation in the fields for which they could certify (which is also foreseen by article 6 of the TBT Agreement). The Community and its Member States might under certain conditions consider accepting the conformity assessment of products carried out by an appropriately accredited CAB located in a non-EU country. Such recognition would of course have to lay down the conditions to be fulfilled by the body, perhaps in terms of reciprocity from the country in which it is located. This would require an amendment of current EU rules.

b) Making wider use of “enhanced” type MRAs covering voluntary schemes

Another element to be considered is the promotion of "enhanced" type MRAs for voluntary schemes (e.g. environmental labelling (the “flower” mark)) .

An example of such an MRA is the EC-US agreement on energy-efficiency labelling programs for office equipment, known as “Energy Star” labelling. In this particular case, the Community has concluded a sectoral mutual recognition agreement with the US Environmental Protection Agency and has laid down implementation requirements in an EC Regulation. As part of the implementation of this Agreement, the Commission has decided to establish an EC “Energy Star” board of national representatives and other interested parties. Discussions have started with the EFTA - EEA countries on extending the scope to the EEA.

In other cases, where voluntary schemes are run by private organisations, there exist agreements between private organisations (certification bodies) in third countries to have the right to certify those products and affix the voluntary marking.

While not a regulatory issue, such schemes clearly have a potential impact on trade. Differences in voluntary schemes have a clear potential to impede trade as customers demand such labelling (for example, eco-labelling) in a form they recognise (that may be national or regional); on the other hand, the mutual recognition of such schemes, or the use of common marking for systems considered equivalent can reconcile the aims of the original marking schemes with openness in trade.

III. ACTIONS BY COUNTRY/REGION

Having considered the elements outlined above, it is considered that the following actions are worth pursuing under existing or under negotiation agreements at bilateral/regional level.

1. Candidate countries

PECAs should be pursued with Bulgaria and Romania. Turkey has concluded with the EU Customs Union, under which Turkey should adopt the *acquis communautaire* for industrial products. There is therefore no need for the conclusion of any type of MRA with Turkey.

2. Countries participating in the Stabilisation and Association Process

Make use of the stabilisation and association agreements to initiate dialogue and provide technical assistance towards capacity building (e.g. Community Assistance for Reconstruction, Development and Stabilisation). Moreover, the Thessaloniki Agenda (June 2003) for the Western Balkans proposes the establishment of European Partnerships with all countries of the region which could serve the same purpose.

Ultimate objective: adoption by these countries of the *acquis communautaire* and EU standards and the negotiation of "enhanced" type MRAs (ACAAs) in certain sectors. ACAAs can only be negotiated on a bilateral basis with interested countries that fulfil the necessary conditions. Document.....on Agreements on Conformity Assessment and Acceptance of Industrial Products describes the content of ACAAs and the necessary conditions for starting negotiations. This document can be shared with countries interested in concluding an ACAA with the EU. This will include the recognition of conformity assessment bodies (CABs) with these countries.

3. Russia, Ukraine, Moldova and the NIS

Pursue and intensify dialogue and technical assistance in the framework of the Partnership and Co-operation Agreements and the Common European Economic Space. Dialogues exist already with Russia, Ukraine and Moldova.

Ultimate objective: adoption by these countries of EU standards and legislative approach in key sectors, in line with the recent Commission's Strategy Paper on the European Neighbourhood Policy, which aims, among others, to extend the benefits of the internal market to its neighbours¹.

With Russia and Ukraine in particular the dialogue could in the longer term and under the umbrella of the Common European Economic Space be used to prepare the negotiation of an "enhanced" MRA (ACAA) in certain sectors.

4. The Mediterranean region

Ultimate objective: adoption by these countries of the *acquis communautaire* and EU standards in key sectors, in line with the recent proposal made by the European Commission to extend the benefits of the internal market to its neighbours². Given the region's political importance for the EU, activities should aim at building these countries' infrastructure and implementation ability in the field of standards and conformity assessment, acquainting them and integrating them in the EU system. "Enhanced" type MRA (ACAA) negotiations could only be envisaged on a bilateral basis once the conditions set out in document SEC(2004)1071 on ACAAs are fulfilled.

¹ COM(2004) 373 final, European Neighbourhood Strategy Paper
² see infra

5. Latin American countries

Although this is a geographical region where acceptance of EU standards and rules may be difficult to envisage in the near future, it represents a substantial potential market. So far technical discussions under the FTAs with Mexico, Chile and the MERCOSUR have not at this point gone beyond an exchange of views and experiences in the context of a "loose" type of technical dialogue. It cannot however be excluded that in *the medium term* sectors can be identified where there is a trade interest and where there is the possibility to work towards equivalence of rules. Priority sectors have already been identified in the framework of the dialogues with Chile and MERCOSUR. In such a case, the conclusion of an "enhanced" type MRA, i.e., on the basis of equivalent/common rules and standards, could be envisaged.

6. The United States

No more "traditional" type MRAs should be concluded with the US. As far as the existing MRA is concerned, efforts should be concentrated on the correct implementation of those sectors that are already operational. No more sectors should be added to the existing MRA.

Other "enhanced" type MRAs should be pursued only where there are strong indications that the Agencies responsible for implementation are interested (our experience with the existing MRA has been that political agreements cannot guarantee their implementation, in particular where implementation is an independent agency's responsibility).

7. Canada

No more "traditional" type MRAs should be concluded with Canada. As far as the existing MRA is concerned, efforts should be concentrated on the correct implementation of those sectors that are already operational. No more sectors should be added to the existing MRA.

Other "enhanced" type MRAs should be pursued (e.g. on aviation) only where there are strong indications that the Agencies responsible for implementation are interested (our experience with the existing MRA has been that political agreements cannot guarantee their implementation, in particular where implementation is an independent agency's responsibility).

8. Japan

A "traditional" type of MRA has recently entered into force and it still remains to be seen how successful its implementation will be. There is a formal commitment to start negotiations with the aim of extending the MRA to medical devices and pressure equipment, but given the difficulties encountered with the implementation of "traditional" type MRAs, this should only begin after very careful consideration of the potential trade benefits as compared to the maintenance costs.

The formal discussions under the MRA should be used to promote an informal dialogue on key issues under discussion in the TBT Committee.

9. Australia and New Zealand

The MRAs with Australia and New Zealand have mostly been operating without significant obstructions, but an analysis of their economic impact has not demonstrated any significant impact on trade relative to the total of trade covered by them. Some extension of these MRAs to cover additional sectors was envisaged at the time they were negotiated, but any such negotiations should be conditional on the expectation of a positive economic impact.

The informal technical dialogue held on the fringes of the formal dialogue foreseen by the MRA has been useful in providing information on each party's regulatory approach, but has not resulted in any convergence between the EU-Australia and New Zealand on issues under discussion in the TBT Committee. Further dialogue on technical regulations, standards, and conformity assessment should be explored on the basis of economic advantage and of alignment of rules.

10. The Gulf Co-operation Council

Negotiations are in progress for a free trade agreement with the GCC area, which include co-operation on technical regulations, standards and conformity assessment issues, including alignment on international standards. Moreover, there is a co-operation agreement that includes standards. A general technical dialogue could be envisaged in the medium term. It is premature to envisage at this stage a more focused dialogue which could ultimately lead to the conclusion of MRAs.

11. China

Our objective should be capacity building and dialogue aimed at fostering adoption by China of an open and transparent system of regulation based on international standards. The on-going EU-China Consultation Mechanism on Industrial Products should continue to focus on sectors where there is current or potential trade interest. The EU's long term objective should be to achieve alignment of rules in priority sectors of mutual interest. Alignment of regulatory requirements would be a prerequisite for the conclusion of an MRA.

12. ASEAN

A dialogue on technical regulations, standards and conformity assessment should be pursued under the *Trans-Regional EU ASEAN Trade Initiative (TREATI)*. Such a dialogue would at the beginning cover exchange of information on regulatory approaches with the overall objective of promoting international standards. In the longer term the objective should be to promote regulatory equivalence in sectors of mutual trade interest. An “enhanced” MRA with certain countries, or preferably with the region as a whole, could in the longer term be foreseen for sectors where there is equivalence of rules and standards.

13. ACP countries

The EU-South Africa Free Trade Agreement does not include specific provisions on technical regulations, standards and conformity assessment for industrial products. There are on going negotiations on the conclusion of Economic Partnership Agreements with ACP regions, which are expected to include specific provisions in this field. It is difficult to envisage at this stage acceptance and implementation of EU standards and rules in most of these countries and regions. A general technical dialogue could be envisaged in the medium term, with emphasis on strengthening the regional approach and building up regional regulatory systems, infrastructure and implementation capacity. It is premature to envisage at this stage a more focused dialogue which could ultimately lead to the conclusion of MRAs based on equivalent rules.
