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**Agreements on
Conformity Assessment and Acceptance of Industrial Products
(ACAAs)**

Executive Summary

This document on Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs) describes the content of a specific type of mutual recognition agreement (MRA), based on the alignment of the legislative system and infrastructure of the country concerned with those of the European Community. It outlines the necessary conditions for starting negotiations. The conclusion of an ACAA would be the end result of extensive dialogue and assistance in the fields of technical regulations and standards for industrial products. The intention is to share this document with countries interested in negotiating and concluding ACAAs with the European Community and its Member States.

1 INTRODUCTION

Trade offers great opportunities for economic growth and sustainable development for all parties involved. The European Union has always been at the forefront of support for international co-operation regarding the areas of technical regulations, standards, conformity assessment and the elimination of technical barriers to trade for products.

One of the main approaches used by the European Community to eliminate technical barriers to trade was to enter into negotiations with several trading partners, leading to the conclusions of Mutual Recognition Agreements (MRAs). Indeed, this type of activity was specifically encouraged in the WTO TBT (technical barriers to trade) agreement. MRAs currently exist between the EU and the United States, Canada, Australia, New Zealand, Japan, Israel and Switzerland.

As far as the acceding and candidate countries are concerned, the main principles of MRAs were used to develop the so-called PECA (Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products) agreements. PECAs are specific types of MRAs, which have been concluded between most of the acceding and candidate countries¹ and the EC. Contrary to MRAs, which are traditional trade agreements concluded only on the basis of Article 133 of the EC Treaty, PECAs are protocols to the existing Europe Agreements with candidate countries (with the exception of Malta, which negotiated a self-standing agreement similar to a PECA). Although their legal base is also Article 133 of the EC Treaty, they have certain specific features that are not shared by traditional MRAs.

Whereas MRAs reinforce the principle of mutual recognition on an international level and, therefore, do not require or presuppose any approximation of legislation between the parties involved, the aim of a PECA is to achieve the acceding or candidate country's full conformity with Community technical regulations and European standardisation and conformity assessment procedures. Not only do acceding and candidate countries transpose the *acquis* but they also ensure that the necessary infrastructure is in place for its full enforcement.

Our experience with existing PECA agreements shows that the benefits have been numerous and have paved the way by bringing the acceding and candidate countries' systems into line with that of the EC. The benefits of such agreements are both economic and political, for both parties. The internal market is widened for products in the sectors included in the agreements. Trade between the EC and third countries is facilitated. For the negotiating country, access to the internal market is improved, as its products are better able to compete with those from EU Member States.

Politically, the EU benefits from the effective 'export' of the Community system. For third countries, the conclusion of an agreement can be regarded as an indication of the alignment of their legislative systems and infrastructure with those of the European Union.

Based on its experience in this field, the Commission has reached the conclusion that it should explore the possibility of extending the application of these principles to other third

¹ PECAs were concluded with the Czech Republic, Hungary, Latvia, Lithuania, Slovenia, the Slovak Republic and Estonia.

countries. However, it is necessary to adapt the PECA model to a new context, bearing in mind that most countries potentially concerned are not currently candidates for EU membership, and in some cases cannot be.

2 ACAAS IN THE CONTEXT OF EU INTERNATIONAL, TRADE AND ENTERPRISE POLICY

It is necessary to situate the approach to the negotiation of ACAA agreements within the context of the European Union's general international, trade and enterprise policy objectives. In this respect, including within the framework of the European Neighbourhood Policy, the European Commission has made clear its particular intention to intensify cooperation with the EU's eastern and southern neighbours, including in the areas of trade, market access and regulatory structures². These issues are also addressed by the Stabilisation and Association Process with the western Balkan countries.

In the field of technical barriers to trade, the Commission's experience has led it to consider a broad variety of instruments that can be applied, on a case-by-case basis, according to the situation encountered. In 2001, these ideas were addressed in a Commission services' working paper regarding implementing policy for external trade in the fields of standards and conformity assessment: the Tool Box³. The paper argued that selection of the right instrument depends on the characteristics of the markets, the regulatory environment in the third country or region concerned, and the willingness on the part of industries, regulators and other parties to achieve the agreed objectives. The paper identified agreements on the mutual recognition of conformity assessment of industrial products (MRAs) as one such tool to facilitate international trade in products. A further paper produced by the Commission services, which accompanies this one, proposes priorities for Commission bilateral and regional trade related activities in the field of mutual recognition agreements and related technical dialogue, and provides the general context within which ACAAs, which are essentially a bilateral instrument, should be considered.

One of the Commission's strategic objectives for the years 2000-2005 is 'to establish genuine strategic partnerships with the countries adjoining the enlarged Europe'⁴. Account must also be taken of the need to manage increasing globalisation in order to ensure that international trade benefits the maximum number of participants⁵. Progress is ongoing in the implementation of the stabilisation and association process with the

² COM (2003) 104 final, Communication from the Commission to the Council and the European Parliament, Wider Europe – Neighbourhood: a New Framework for Relations with our Eastern and Southern Neighbours.

³ SEC (2001) 1570.

⁴ COM (2000) 154 final, Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, Strategic Objectives 2000-2005, 'Shaping the New Europe', p. 7.

⁵ COM (2002) 590 final, Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, The Commission's Legislative and Work Programme for 2003, p. 12.

countries of south-east Europe⁶. Beyond those countries that have already or are likely to apply for membership of the European Union, the Commission is developing its policy with a view to promoting stability and prosperity in neighbouring countries following the enlargement of the EU in 2004⁷. This process should address the issue of the expansion of the internal market to these countries and the adoption of common regulatory structures wherever possible.

The Commission's Communication on industrial policy in an enlarged Europe⁸ identified the difficulty of reconciling globalisation with divergent approaches to standards and technical regulations between the EC and other countries. It specifically lent its support to the extension of EC regulatory approaches to the Euro-Mediterranean area, the western Balkans, Russia and other eastern European countries⁹. The use of the Community system of standardisation and conformity assessment by third countries, building on the experience gathered from the negotiation and implementation of PECA agreements with candidate countries, is designed to facilitate trade and market access in both directions, while avoiding the problems that are evident from the operation of traditional MRAs.

Key aims are, therefore, the encouragement of approximation of third countries' product legislation with that of the EC and their adoption of appropriate implementing structures, particularly in the field of standardisation. In its conclusions on standardisation of 1 March 2002¹⁰, the Council already called upon the Commission to explore further the potential of the New Approach *'both within the Community and at the international level, systematically identifying both opportunities and any limitations to be addressed'* and supported the promotion of standards-respective regulatory models with the EU's trading partners.

As a result of the adoption of the EC system by other third countries, it is hoped to consolidate that model as one appropriate for product regulation beyond the EC. At the same time, it will contribute to the elimination of technical barriers to trade, thereby increasing the accessibility of third country markets to products from the EU. At the same time, the level of health and safety protection existing in the EU is ensured and not compromised by the widened access to the single market for third country products.

The preparation of alignment may be regarded as a means of sharing the proven experience of the European system with other countries. The benefits for both parties should be emphasised, with particular attention paid to the advantages for third countries of adopting established common principles, within the context of existing WTO objectives. There is also a political advantage in consolidating and strengthening existing links between the markets of third countries and that of the EU.

⁶ COM (2003) 163 final, Report from the Commission, The Stabilisation and Association process for South East Europe, First Annual Report.

⁷ COM (2003) 83 final, Communication from the Commission to the European Parliament and the Council, Annual Policy Strategy for 2004, pp. 7-8.

⁸ COM (2002) 714 final, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, Industrial Policy in an Enlarged Europe, p. 15.

⁹ *ibid.*, p. 29.

¹⁰ OJ C66 of 15.3.2002, pp. 1-2.

3 NECESSARY CONDITIONS FOR AN ACAA

Four conditions have to be fulfilled for the creation of a successful ACAA.

- Adequate infrastructure in the fields of standardisation, accreditation, conformity assessment and metrology in the partner country;
- Adoption of the relevant part of the *acquis* by the partner country;
- Regulatory co-operation and technical assistance;
- Formal agreement between the EU and the partner country setting out the relationship;

3.1 Adequate infrastructure in the fields of standardisation, accreditation, conformity assessment and metrology in the partner country

Adequate infrastructure in the fields of standardisation, accreditation, conformity assessment and metrology should be in place in the partner country before the formal opening of ACAA negotiations. A particular problem to be dealt with is participation in European standardisation and European accreditation work

In particular, in the ‘New Approach’ sectors, the following requirements would have to be fulfilled:

- all relevant European harmonised standards should be transposed and all conflicting standards withdrawn;
- the competence of all conformity assessment bodies to be notified must be proven;
- a suitable market surveillance system and suitable safeguard procedures must be used. Furthermore, any conflicting national procedures such as pre-market authorisation schemes would have to be dismantled;

Institutionally, some degree of separation of the regulatory, standardisation, accreditation and certification functions is necessary for the proper implementation of an ACAA. Ideally, public authorities should retain only legislative and enforcement (market surveillance) functions and ensure that the system of third party certification to regulatory requirements has sufficient technical competence and independence.

In order to meet Member States’ demands for safe products on the internal market, accreditation should be used to assure the competence of notified conformity assessment bodies in the ACAA countries. The use of European harmonised standards would also be considered important, even if their use would be voluntary. Therefore, as a basic requirement, 100% of the European harmonised standards should be transposed in the ACAA sectors. Consequently, it would be beneficial for the countries concerned to have the possibility of adopting such standards into their national regulatory frameworks.

As European standards are an important part of an ACAA, the ACAA countries should be able to participate in the work of the European standardisation bodies (CEN, CENELEC and ETSI). Under current rules, full CEN and CENELEC membership is only available to standards bodies of countries that are members of the European Economic Area (EEA) or candidates for EU membership. Countries neighbouring the EEA can participate in the

work of CEN through a newly established cooperation status called partner standardisation body. Partner standardisation bodies can take part in the work of CEN but do not have voting rights. CENELEC is reflecting on the introduction of a similar cooperation status for bodies from countries that are not candidates for EU membership. Countries that are members of another regional standardisation organisation can co-operate through such an organisation with CEN and CENELEC if the organisation has a co-operation agreement with CEN and CENELEC. Full ETSI membership is open to organisations from countries in the geographical area of the CEPT (European Conference of Postal and Telecommunications Administrations). Associate membership is open to organisations in countries outside this area. Such organisations can fully participate in the work of ETSI but do not have voting rights on European standards or on matters for regulatory use by the EC.

The participation of ACAA countries in ongoing work of the international accreditation organisations is equally important. For example, countries that are outside the EEA or not candidates for EU membership can conclude co-operation agreements with the European Cooperation for Accreditation (EA). It is also possible for them to conclude with EA bilateral agreements with the same content as the multilateral agreements (MLAs) for EA members. Such agreements already exist, for example, with South Africa, New Zealand and Australia. The co-operation agreements are in principle available to all countries with ACAAs.

Although the use of harmonised standards and accreditation form a part of the negotiation process, it is up to the relevant European organisations, and not the Commission, to define their position with regard to the criteria governing participation and membership. The Commission services, however, can advise in the establishment of appropriate cooperation mechanisms and should be kept informed about relevant discussions.

3.2 Adoption of the relevant part of the acquis by the partner country

A basic requirement for an ACAA is legislative alignment. The ACAA product sectors could be New Approach or Old Approach sectors. An ACAA would not be applicable for the non-harmonised sectors as, without the existence of relevant product-specific technical requirements and standards at European level on which to base negotiation, agreement on sectoral coverage would be much more difficult to reach.

The horizontal legislation setting up standards, metrology, certification and accreditation infrastructure, and market surveillance, when applicable, in accordance with the EU system in these areas must be transposed and implemented. Depending on the number of sectors intended to be covered by the ACAA, two different alternatives are possible.

- If the ultimate goal for the ACAA country is to participate in the EU internal market or at least to include many sectors in the agreement, the clearest solution is first to take over and implement the EU horizontal legislation and include some sectors and then gradually add new sectors.
- However, if the ACAA is intended to cover only a few sectors, with no longer term political perspective, it would be easier to use a lighter alternative. In this case the country would take over the EC legislation relating to the selected sectors only and would include the necessary horizontal elements in its sector legislation.

3.3 Regulatory co-operation and technical assistance

3.3.1 General

EU technical assistance to developing countries is provided either bilaterally, on a multi-country, or on a regional basis. The multi-annual indicative programming of technical assistance is handled by the Commission in Brussels. The setting up of specific programmes and projects, except for those for candidate countries, is almost totally decentralised to the EU Delegations in the beneficiary countries and in some areas to the EU agency in the country or region.

There is no funding reserved specifically for technical assistance for ACAA purposes, as has been the case for the candidate countries where PHARE funds could be used for PECA needs. Technical assistance programmes and projects in potential ACAA regions and countries could also be used to support preparation for ACAAs.

3.3.2 Activities for which technical assistance may be needed when preparing for ACAAs

- a) Information about trade between the EC and the country or region and within the region. Which sectors are most important and where have TBT type problems been encountered?
- b) Information about the general legislative and administrative structures (can anything be used for an ACAA?).
- c) Assessment of current technical legislation and standards (to what extent have EC legislation and EN standards been taken over?) and the quality infrastructure.
- d) Determination of the development needs in the country (is there a need/interest in an ACAA, which sectors are of interest, what infrastructure should be developed?).
- e) Support for transposition of legislation and standards and for creation of necessary organisational framework.
- f) Support for developing standardisation, accreditation, conformity assessment, metrology and market surveillance, both institution building and investment support.
- g) Support for awareness raising about the EC approach and ACAAs among the public administration and economic operators.
- h) Support for specific information to and technical training of experts in different fields of the quality infrastructure.
- i) Support for proficiency tests and other benchmarking.
- j) Support for participation in the work of international and regional bodies in quality infrastructure (standardisation, accreditation, metrology, etc.).
- k) Support for multi-country and regional co-operation and establishing joint use of facilities.

3.4 Agreements providing the necessary basic structures for the relationship

The potential countries should have a general agreement with the EU, whether an Association, Partnership or Free Trade Agreement, which includes provisions to promote the use by the country of Community technical rules and European standards for industrial products and certification procedures.

Such agreements also provide an institutional framework that can be used or adapted for the management of ACAA agreements. The aim should be to create a flexible mechanism to facilitate the smooth functioning of the agreements, without creating unnecessary procedural burdens.

For the countries neighbouring the EU that are potential candidates for ACAAs, it is possible to distinguish between several types of existing agreements:

3.4.1 Euro-Mediterranean association agreements

The objective is to create a Euro-Mediterranean free trade area by 2010. Association Agreements between the EU and Tunisia, Israel, Jordan, Morocco and the Palestinian Authority (interim agreement) have already entered into force. Negotiations with Egypt were concluded in June 1999 and the agreement signed in June 2001. Negotiations with Algeria were concluded in December 2001 and with Lebanon in January 2002, followed by an interim agreement effective from March 2003. Negotiations with Syria are not yet concluded. These agreements provide for the establishment of a bilateral free trade area, including the field of industrial products. The bilateral agreements provide for economic cooperation, including cooperation in the fields of standardisation and conformity assessment. The aim is to reduce divergences in standardisation and certification through the encouragement of the use of European standards and conformity assessment procedures and techniques, the upgrading of conformity assessment and metrology bodies and the eventual negotiation of mutual recognition agreements in these fields. Approximation of legislation is also envisaged.

3.4.2 Stabilisation and Association Agreements (western Balkans)

The EU is following a policy of stabilisation and association with five western Balkan states (Albania, Bosnia and Herzegovina, Croatia, Serbia and Montenegro and the former Yugoslav Republic of Macedonia). To date, stabilisation and association agreements have been signed with the former Yugoslav Republic of Macedonia and Croatia. Similar to Europe Agreements with candidate countries, these agreements contain provisions on the approximation of laws and law enforcement. They state that these countries shall take the necessary measures in order gradually to achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures. To this end, the parties shall seek to promote the use of Community technical regulations and European standards, tests and conformity assessment procedures and to conclude, where appropriate, European Conformity Assessment Protocols. As these countries are potential candidates for EU membership (indeed, Croatia and the former Yugoslav Republic of Macedonia have lodged official applications), negotiation of an ACAA, which would take the form of a protocol to the stabilisation and association agreement with the country concerned, should accompany and facilitate the adoption and application of the relevant *acquis communautaire*.

3.4.3 Other European agreements

Partnership and Co-operation Agreements (PCAs) are now in force with a number of Eastern European and Central Asian countries (Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Ukraine and Uzbekistan). PCAs are legal frameworks setting out the political, economic and trade relationship between the EU and the partner countries. Each PCA is a ten-year bilateral treaty signed and ratified by the EU and the individual state. PCAs recognise that an important condition for strengthening the economic links between the countries concerned and the Community is the approximation of their existing and future legislation to that of the Community. Such approximation should extend to a number of areas, including technical rules and standards.

4 TASKS WHEN DEVELOPING ACAAS

There are four groups of tasks when developing an ACAA:

Political responsibilities for ACAAs include preparing a political decision to start developing an ACAA with a country/region; negotiating the formal agreements when the country/region is ready for an ACAA; following up the approval of the agreements in the Commission, the Council and the beneficiary country; and handling the same formalities when adding sectors to existing ACAAs.

Country and region responsibility for developing ACAAs including fact finding, needs assessment, implementation planning, including monitoring of harmonisation of legislation and development of infrastructure, and follow up of implementation. This also includes assessment of the transposed horizontal legislation and its implementation.

Sector responsibilities for assessment of transposed sector legislation.

Contribution to establishing *technical assistance* to support an ACAA, its specification, implementation and follow up.

ANNEX

Current or planned technical assistance programmes and projects that could be used to support the development of ACAAs in specific regions

1. CARDS (COMMUNITY ASSISTANCE FOR RECONSTRUCTION, DEVELOPMENT AND STABILISATION)

The CARDS programmes provide technical assistance to the western Balkan countries Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia and Serbia and Montenegro. There are multi-annual indicative programmes (MIPs) covering all these countries. Below are projects that have recently been set up or are being planned within the MIPs.

A CARDS 2001 project with Albania on “Standardisation and certification” has been established. It has been contracted and is being started. The project budget is €2.0 million and the duration is 24 months. A follow up project to this is planned. The budget is €1.5 million and the duration is 24 months. There are also planned 2003 CARDS projects for Albania on metrology (€1.3 million and 36 months’ duration) and on market surveillance (€1.0 million and 24 months’ duration).

The CARDS 2001/2002 project with Croatia on EU industrial standards has the purpose of harmonising the system of standardisation, metrology and accreditation in accordance with the Stabilisation and Association Agreement (SAA). The EU funding is €3.0 million. The project duration is 21 months and will last until the end of 2004. A follow up CARDS 2003 programme is presently being negotiated with Croatia. The programme covers the development of accreditation systems and support to national testing and calibration laboratories. The project will support the implementation of the Croatian national strategy for harmonisation of technical legislation with the legislation of the European Union. One of the aims of this strategy is to support the development of a PECA type agreement. The EU funding foreseen is €2 million. The duration of the project will be 24 months.

In the former Yugoslav Republic of Macedonia, a CARDS 2001 project worth €1 million for Support to Accreditation and Quality Validation (SMAQVA) Institutes started in July 2003. The project aims at ensuring the development of structures and operational procedures for the implementation of standards and norms within the new framework of institutes and services. A CARDS 2003 project worth €2.75 million, to be started in the course of 2004, envisages the supply of equipment to the institutes for SMAQVA and related training on SMAQVA issues.

In Serbia and Montenegro, CARDS has already been financing a variety of trade-related actions over the last years and will continue to do so in 2004. These programmes have included, *inter alia*, support to small and medium-sized enterprises and restructuring of state owned enterprises to improve export performance, the horizontal improvement of product quality infrastructure (€6 million in 2003), and specific economic and trade policy advice via the EC-funded Policy and Legal Advice Centre SCEPP.

Finally, there is a regional CARDS 2002 programme on “Trade Technical Assignments, Standards and Certification” for all the western Balkan countries. The project budget is €1.0 million and the duration is 30-36 months. It will be contracted to CEN.

2. TACIS (EASTERN EUROPE, CAUCASUS AND CENTRAL ASIA)

A TACIS 2001 project for Russia “Approximation of Technical Rules and Standards” has been contracted to a consortium led by AFNOR (Association Française de Normalisation). The project budget is €4.0 million and the duration is 33 months. A project to be financed from the Small Policy Actions Programme 2000 for the “Harmonisation of Russian technical regulations with EU legislation on equipment intended for use in mines” is being proposed to the Delegation in Moscow. The budget is €0.2 million.

The TACIS 2000 project for Ukraine “Application of Foreign Trade Regime – Standards, Technical Regulations and Conformity Assessment” is starting. The project budget is €1.75 million and the duration is 17 months.

The TACIS 2001 project for Moldova on “Harmonisation of Moldova’s system of standardisation, technical regulation and conformity assessment with PCA and WTO requirements” has been tendered, the contractor has been selected and the project is starting. The project budget is €1.4 million and the duration is 24 months.

3. MEDA (EURO-MEDITERRANEAN PARTNERSHIP FINANCIAL AND TECHNICAL MEASURES)

Technical assistance is provided bilaterally and on a regional basis under the MEDA programme:

“Euro-Med Market” is a regional programme with a budget of €10 million on the key mechanisms of the EU single market. Its main objective is to help Mediterranean partners identify the mechanisms that could most usefully be transposed in the context of the Euro-Mediterranean Free Trade Area. Four specific information and training seminars on the free movement of goods have been scheduled so far. The programme started in the summer of 2002 and will end in 2005.

“Euro-Med Quality” is a more specific regional programme on the EU approach to quality and product regulation with a budget of €7.26 million. Its main objective is to help Mediterranean partners improve their quality infrastructure. Main activities will include an analysis of the partners’ quality infrastructure, an analysis of gaps in national legislation, tailor-made information and training seminars, and the setting up of a regional network of key players in the field of quality promotion. CEN started the implementation of this three year programme in early 2004.

Bilateral projects aimed at strengthening the quality infrastructure are ongoing or planned in Morocco, Tunisia, Egypt, Jordan, Lebanon, and Syria. For instance, in Tunisia, €8.5 million out of €50 million earmarked for industrial upgrading will be devoted to quality, metrology and standardisation.