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**Conformity Assessment**

**MRAs between the EU and third countries and PECAs  
between the EU and its candidate countries**

This paper has been submitted by the European Commission on the status of Mutual Recognition Agreements (MRAs) and Protocols on European Conformity Assessments (PECAs).

It is presented for information to delegates and is reproduced in the form in which it was received by the secretariat.

## **Introduction**

1. Mutual Recognition Agreements (MRAs) are treaties established between the Community and the Governments of third countries that are on a comparable level of technical development and have a compatible approach concerning conformity assessment. These agreements are based on the mutual acceptance of certificates, marks of conformity and test reports concerning industrial products issued by the Conformity Assessment Bodies (CABs) of one of the Parties of the Agreement in conformity with the legislation of the other Party. Their objective is to facilitate international trade by reducing approval costs for industrial products and simplifying their placing on the market. MRAs are also a tool for regulatory convergence. As far as the EU is concerned, their legal basis is Article 133 (Common Commercial Policy) of the EC Treaty. The MRAs the EU has concluded so far consist of a framework agreement and annexes (generally) covering several sectors.

2. PECAs are Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products. The aim is to facilitate the integration of the candidate countries into the internal market before their expected formal accession to the European Union in 2004. PECAs are mutual recognition agreements with the particularity of providing recognition of conformity assessment of industrial products when the legislation of the candidate countries are aligned with that of the Community. They also provide for mutual acceptance of industrial products that are legally placed on their markets, along the lines of the mutual recognition of products within the Community. PECAs can, therefore, be considered as the major instrument of the pre-accession strategy in the field of the free movement of goods as they create an enlarged internal market for products in certain industrial sectors. Each PECA is made up of a framework agreement that establishes general principles and procedures for the mutual recognition of results of conformity assessment procedures and the mutual acceptance of industrial products. This framework is completed by sector annexes, depending on the level of implementation of EC technical legislation by the applicant country.

## **I. State of Play regarding MRAs:**

### **Negotiation results**

3. So far the EC has signed 7 MRAs i.e. with Japan, Switzerland, USA, Israel, Australia, New Zealand and Canada.

4. The MRA with Japan was signed in April 2001 and entered into force on 1 January 2002. It covers telecommunications terminal equipment, electrical products, pharmaceutical good manufacturing practice (GMP) and good laboratory practice for chemicals (GLP).

5. The MRA with Switzerland was signed in June 1999 and entered into force on 1 June 2002. It covers agricultural and forestry tractors, (noise from) construction plant and equipment, electrical equipment and electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmospheres (ATEX), gas appliances and boilers, good laboratory practice for chemicals (GLP), machinery, measuring instruments and pre-packaging, medical devices, medicinal products inspection and batch certification (GMP), motor vehicles,

personal protective equipment, pressure vessels, telecommunication terminal equipment and toys.

6. The MRA with the USA was signed in May 1998 and entered into force on 1 December 1998. It covers electrical safety, electromagnetic compatibility, medical devices, good manufacturing practices (GMP) for pharmaceuticals, recreational crafts and telecommunication terminal equipment. This agreement included a three-year transitional period for confidence building, which expired on the 1 December 2001. For the time being, only the recreational crafts, radio and telecommunication terminal equipment and electromagnetic compatibility sectors are fully operational.

7. The MRA with Israel was signed in July 1999 and entered into force on 1 May 2000. It only covers good laboratory practice for chemicals (GLP). The MRAs with Australia and New Zealand were signed in July 1996 and entered into force on 1 January 1999. They cover electromagnetic compatibility, low voltage equipment, machinery, medical devices, medicinal product (GMP) inspection and batch certification, pressure equipment, and telecommunication terminal equipment.

8. The MRA with Canada was signed in May 1998 and entered into force on 1 November 1998. It covers recreational crafts, electromagnetic compatibility, telecommunication terminal equipment, electrical safety, medical devices and pharmaceutical good manufacturing practice (GMP). The original agreement included an 18-month transitional period for confidence building. However, in September 2001, the MRA Joint Committee (co-chaired and composed of representatives of both parties) decided to postpone the start of the operational phase by a further 12 months for all sectors (apart from the recreational crafts).

9. The MRA with Israel involves only one sector, GLP, which is now fully operational. However, there are no CABs, as such, in this sector. Israel has one Monitoring Authority inspecting laboratories or test facilities for GLP compliance. For the time being, 5 such laboratories have been approved. In the EU there is one or more Monitoring Authority per Member State, which is responsible for inspecting a certain number of laboratories or test facilities. The Swiss MRA also includes a GLP Chapter with the same set up.

10. The transitional periods concerning the USA and the Canada MRAs (to build confidence, to exchange information, and finalise detailed work programmes for approval of conformity assessment bodies CABs between the Parties) have all expired except the periods concerning the medical devices sector for both MRAs. In the case of the USA this transitional period for confidence building expired on the 1st of December 2001 but was extended for a further 2 years. In the Canadian agreement the transitional period for confidence building was extended indefinitely.

## **Implementation**

11. The medical devices, electrical safety and pharmaceuticals GMP sectoral annexes of the US-MRA have raised some implementation problems. Some difficulties have also been encountered in the implementation of the pharmaceuticals GMP, electrical safety, recreational crafts and medical devices sectoral annexes of the MRA with Canada. The European

Commission is very active in ensuring that all the existing MRAs and their sectoral annexes are fully implemented. So far about 630 Conformity Assessment Bodies (CABs) have been notified and mutually accepted. This includes 160 CABs related to the MRA with the USA, 149 to the MRA with Australia, 137 to the MRA with New Zealand and 133 to the MRA with Canada. For the MRA with Japan, which entered into force on 1 January this year, there are 2 applications, one from each party, received so far.

12. The MRA with Switzerland involves several sectors. So far Switzerland has designated 50 CABs in various sectors, which includes national authorities responsible for type-approval, technical and testing services related to the motor vehicles sector, as well as competent national authorities responsible for measuring instruments and pre-packaging. Switzerland will accept the EU Notified Bodies in a «block designation» for those Chapters of the Agreement, where the legislation is deemed equivalent. At present 10 sectors are concerned.

## **Evaluation**

13. The European Commission has also launched a survey to verify the concrete impact of the MRAs on trade flow. The MRA with Australia and New Zealand has been chosen as a case study. The survey is still on going.

14. Proposals to simplify the management of existing MRAs are currently under discussion. The experience of the Commission, however, has led to the view that MRAs are not the only instrument to facilitate trade. Many other measures can be applied to achieve this goal. Indeed, conditions for open trade include compatibility of approach, coherence of regulations and standards, transparency of rules, appropriate levels and means of regulation, impartiality in certification, compatibility of market surveillance measures and an appropriate level of technical administrative infrastructure.

## **II. State of Play regarding PECAs:**

### **Negotiation results**

15. PECAs with Hungary and the Czech Republic were signed on 26 February 2001. The annexes of the PECA Agreement with Hungary cover the following sectors: machinery, electrical safety, electromagnetic compatibility, hot water boilers, gas appliances, medical devices, good laboratory practice for medicinal products and good manufacturing practices for medicinal products. The annexes of the PECA Agreement with the Czech Republic cover the following sectors: machinery, lifts, personal protective equipment, electrical safety, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmospheres, hot water boilers, gas appliances, pressure equipment and good manufacturing practice for medicinal products. Both agreements are enforced.

16. PECAs with Latvia and Lithuania were signed on 21 May 2002. The annexes of the PECA Agreement with Latvia cover the following sectors: electrical safety, electromagnetic compatibility, safety on toys and construction products (cement was the only harmonised standard by the date of the signature). The annexes of the PECA Agreement with Lithuania cover

the following sectors: machinery, lifts, personal protective equipment, electrical safety, electromagnetic compatibility and simple pressure equipment. Both agreements are enforced.

17. Negotiations on PECAs are also at different stages with Estonia, Slovakia, Slovenia and Poland. Bulgaria and Romania have made formal requests to open PECA negotiations. A PECA type agreement is also being negotiated with Malta.

## **Evaluation**

18. The PECA agreement with Hungary covers trade worth €8,000 million and €14,000 million with the Czech Republic. It is estimated that these PECAs will create cost saving opportunities for the exporting industry of around €320 million in the EC and the two candidate countries. The agreement with Latvia will cover trade worth one thousand million Euro, and 250 million Euro with Latvia.

19. Besides the facilitation of trade, the obvious benefit of PECAs is the adoption of legislation with a high level of health and safety requirements for consumers and the creation of the appropriate administrative infrastructure by candidate countries in the period before accession to the European Union. This ensures that their preparation for participation in the internal market is carried out well in advance and is not left until the day of accession. The adoption of the Community legislation and system of conformity assessment of products acclimatises candidate countries' administrations and economic operators to the demands and the responsibilities placed upon them by the internal market.

20. The PECAs are also important as they extend the benefits of the internal market using a sector approach, on the basis of the sectors identified by the candidate countries. The market is widened as the need for additional testing and certification of products with the accompanying increase in costs, is removed. The obligations undertaken by candidate countries in the negotiation and implementation of PECAs will minimise impact on the internal market caused by the accession of the candidate countries. If a candidate country is able to implement a PECA without difficulty, its full participation in the internal market after accession should be easier as a result of the experience gained.

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