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Implementation of Mutual Recognition Agreements on Conformity Assessment (MRA) and Protocol on European Conformity Assessment (PECA)

The purpose of this note is to identify the actions to be undertaken by the Commission Services for the implementation of both MRA and PECA and to plan the activities to be carried out after the entry into force of the Agreements and during the transitional periods.

A. Background

Mutual Recognition Agreements in relation to Conformity Assessment (MRA) and the Protocol on European Conformity Assessment (PECA) are government-to-government agreements according to which the importing country accepts certification of compliance to its *legal/regulatory* requirements performed in the exporting country.[1]

In the case of PECA the agreements form an important step of the accession process and are related to the implementation of EU technical regulations in the candidate countries.

Thus, the authorities of the importing country will accept a conformity certificate delivered by a *Conformity Assessment Body* located in the exporting country (i.e. a domestic certification body that is designated by the authorities of one Agreement Partner and recognised by the other), without need for additional technical evaluation/administrative intervention. In the case of PECA, the agreement will allow CEEC selected bodies to act as Notified bodies in the context of EC directives.

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[1] The principle for MRAs is mentioned in the Council Resolution of 21 December 1989 on a Global Approach to conformity assessment (O.J. C N°10 of 16.01.90) and the Commission communication of 15 June 1989 (O.J. C N° 267 of 19 10 89). MRA negotiations are based on the Council Decision of 21 September 1992 , which mandates the Commission to negotiate agreements between the Community and certain third countries on mutual recognition relating to conformity assessment for regulated products.

PECA principles were defined in the Internal Market Council of 13 March 1997 and the negotiating guidelines adopted by COREPER on 4 June 1997.

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The common expression to indicate the bodies in this context is "Conformity Assessment Bodies - CAB" or "Designated Bodies"; the authorities that designate them are "Designating Authorities". For the EU, the Designating Authorities are the national authorities of the Member states, normally the same as those responsible for the notification of certification bodies in the context of the directives.

It shall be also taken into account that the Council mandate on MRA covers also the EU non-harmonised area. This implies that a number of activities, such as supply of information, changes in domestic legislation to recognise certification carried out abroad, follow-up of designation, are under the direct responsibility of the Member States.

B.The implementation of MRAs and PECAs

General

The practical result of the agreements is that Designating Authorities of the contracting parties must ensure that suitable CABs are identified, designated and can operate according to the criteria and the procedures of the other Party's regulations as indicated in the text of the Agreement.

The general criteria and procedures for designation are indicated in the Framework part of the Agreements – and tend to be the same for all countries and all sectors in coherence with the general objectives of the MRA - while sector specific supplementary elements might be identified in the context of the Sectoral annexes to the agreement.[2] For the PECA the criteria are exactly the ones identified by each EC directive and implemented in the corresponing candidate country's legislation

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[2] The detail of sectors for MRA is as follows:

- **Australia** (initialled in July 1996)

Machinery, electro-magnetic compatibility (EMC), electrical equipment, medical devices, Pharmaceutical GMP, pressure equipment, automobiles and components, Telecommunication Terminal equipment (TTE).

- **New Zealand** (initialled July 1996)

Machinery, EMC, electrical equipment, medical devices, pharmaceutical GMP, pressure equipment, TTE.

- **United States** (initialled June 1997)

TTE, EMC, electrical equipment, medical devices, recreational boats, pharmaceutical GMP. (in process: fasteners + veterinary biologics).

- **Canada** (initialled June 1997)

Telecom Equipment, EMC, electrical equipment, medical devices, recreational boats and pharmaceutical GMP.

- **Japan** (start of negotiations May 1995)

TTE, machinery, EMC, electrical equipment, pressure equipment, medical devices.

- **Switzerland** (start of negotiations January 1995)

The sectors covered are identical to the products and risks under the scope of the New Approach Directives.

To ensure the proper implementation of the agreements, a *Joint Committee* is established, composed by representatives of the contracting parties, to be responsible for the effective functioning of the agreement. Among other responsibilities, the Joint Committee is responsible in particular to give effect to the designation or withdrawal of CABs.
In the case of MRA, the Joint Committee is in certain agreements supplemented by *Joint Sectoral Groups* under a sectoral annex and is responsible for activities specifically related to that sector.
For PECA, the Joint Committee is the one in the Association Agreement. Participation of the third country representatives to the Working Groups established under sectoral directives is examined.

The Commission represents the Member States in the Joint Committee and in the Joint Sectoral Groups. This according to the proposed internal decision-making mechanism, that includes consultation with the special committee of the Council (Mutual Recognition) set up under Article 113 of the Rome Treaty, for most matters relating for example to the daily management of the Agreement or the modification of the Agreement, after decision by the Council.

The actors

The main actors in the context of MRA/PECA are:

The *Parties to the Agreement*: the European Community and the third country: they are the legal contractors and must ensure the fulfilment of the obligations of the agreement via the Joint committee;

The *Designating Authorities* of the Parties (15 or more for the Member States), in each sector: they shall identify and designate the CABs;

The *Designated Bodies*, CABs: they are located in the territory of one Party and shall certify products according to the requirements of the other Party;

The *Industry*, particularly manufacturers exporting to the Parties. They are the clients of CABs and, ultimately, the beneficiaries of the Agreements.

The activities

It must be noted that a number of activities shall already be carried out ideally before the operational start/implementation of the Agreements.[3] These consist mainly in:

nomination of the members of the Joint Committee and Joint Sectoral Groups;

exchange and dissemination of information on legislative, regulatory and administrative provisions applicable;

review and clarification of the designation criteria. (In the case of MRA, these could be substantially different between the EU and the third countries) ;

[3] See note from DG1/M/2 of 23/04/98 on Ratification and Entry into force of MRAs.

drawing up of an initial list of CABs;

drawing up programmes for the confidence building period (US and Canada);

For PECAs:

- review CEEC legislation implementing EU directives on "technical requirements for products"
- general assessment of the adequacy of each CEEC system for the designation of CABs. This may also imply visits to Conformity assessment bodies in those countries.

Taking into account the actors of the Agreements, the main activities of the implementation phase can be summarised as follows:

(1) For the Parties to the Agreement:

- ensure proper functioning of the Agreements (including managing the Committees).
- in case confidence building periods exist, to implement the specific programmes.

[A detailed list of activities to be carried out by the Commission services is provided in Annex]

In the non-harmonised area, Member States' responsible authorities have to carry out directly a number of activities needed to ensure a proper implementation of the agreements, such as identification and nomination of contact points, supply of information on legislative, regulatory and administrative provisions applicable, changes in the legislation if these are needed in the context of implementation to allow recognition of conformity assessment carried out by foreign CABs.

(1) For the *Designating Authorities:* designation of CABs, which means a twofold responsibility.

- for the CABs in their own territory: apply the designation criteria of the other Party and ensure/monitor that the selected bodies fulfil and continue to fulfil these criteria. In the case of PECAs, EU Authorities might be invited to participate in the assessment of CEEC candidate bodies and Technical assistance to these countries is provided in this area;

- for the CABs designated by the other Party: adopt measures to ensure recognition and acceptance of the certificates: in the EU this implies a number of measures with direct impact on the management of the "acquis communautaire" and the implementation of directives (e.g. participation in committees/working groups, co-ordination of national authorities and notified bodies, market surveillance actions, etc.).

For the *Designated Bodies*: certify according to the requirements of the other Party and continue to fulfil the criteria for designation. This can imply participation in inter-

comparisons and co-ordination activities for certification bodies. It shall be noted that designated bodies nominated by third countries to operate on the basis of EU legislation will have exactly the same role and responsibilities of the Notified bodies in the context of the directives.

For *Industry*: being the main beneficiary of the agreements, industry has an important role to play also in the implementation phase. The activities carried out by industry can be summarised in the monitoring of the implementation at all levels:

- identification of clusters in the work carried out by the designated CABs;

- promotion of confidence building between the parties through the recourse to common procedures whenever possible;

- identification of new sectors to be included in the agreements;

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ANNEX

The Role of the Commission services

Responsibilities

The goal of the *Commission services* involved in the implementation activities of the MRA/PECA can be summarised in ensuring the functioning of the Joint Committee and Joint sectoral Groups, and of ensuring the essential conditions in order that Member States and PECA authorities correctly designate and that the European accreditors satisfy their relevant tasks. This implies a series of responsibilities, the main of which can be described as follows:

represent the European Community in the Joint Committee and the Joint sectoral groups, including prepare the work of these fora;

support and follow-up of the process of CABs designation by the Member States, via proper information on the third Party requirements, desk review and field assessment where necessary;

ensure proper control over the Pharmaceutical Agency's relations with the authorities of the Third countries;

ensure coherence in the designation process (including attribution of identification numbers to CABs) and that the procedures set by the agreement are properly applied;

ensure exchange of information by the parties on implementation of regulations, including modifications to legislative, regulatory or administrative provisions pertaining to the agreement;

address any issue related to challenge or contestation of CABs by one of the parties, including contacts with the relevant national authorities.

In addition, because some of the Agreements include **Transitional Periods** that are designed to ultimately enhance confidence between the Parties, the Commission shall ensure adequate co-ordination of the activities during these transitional periods. These are designation of contact points, establishment of procedures to compare methods used by each party to verify CAB competence, definition of alert system, organisation of seminars, drafting of guidance documents, etc.

Activities

While in the negotiating phase DG I is Chef de file (this is the primary responsibility of the Directorate for External Relations, Unit in charge of Investments, TRIMS, dual-use goods, standards and certification - DG I/M/2), in the implementation process DG III shall be Chef de file for the sectors under its responsibility.

A close co-operation has been developed during negotiations between DG I and all other DGs whose sectors are represented in the PECA/MRA, particularly DG III (Chemicals GLP, Mechanical and electrotechnical sectors, Medical devices, Pressure

Equipment, Recreational boats, Pharmaceuticals and all the sectors affected by the implementation programme of EC legislation by CEEC countries) and DG XIII (Telecom equipment).

The managing tool of the agreements is represented by the Joint Committee. Because MRA/PECA are concluded in the context of EC External Trade policy (Article 113 in conjunction with Article 228 of the Treaty), DG I represents the European Community in the Joint Committee set up in the MRA/PECA. However, DG III and DG XIII have the role of representation in the Joint Sectoral Groups foreseen in the agreements, because of their competence in the specific sectors. Even when Joint Sectoral Groups are not created by the agreements, DG III and XIII will represent sectoral interest in the Joint Committee. In fact, preparation work for both Committees and Groups will mainly rely on DG III and DG XIII services**.**

The Inter-service meeting on "External Aspects on Standardisation and Certification" is the main co-ordination forum between DG I and the other Commission services and includes the MRA/PECA aspect.

Within each DG, it is essential to closely co-ordinate the MRA/PECA implementation activities among the numerous sectoral services involved. In DG III for example, the MRA/PECA Steering Committee assures the tasks of co-ordination. Its main tasks shall be the following:

- contact point for DG I for all aspects related to the implementation of the agreement, including organisation and functioning of the Joint Committee, preparation of reports to the Council 113 Committee ;

- co-ordination of sectors with respect to the Joint Committee and the Joint Sectoral Groups;

- Reporting to the Senior Officials Group for Standardisation on all MRA/PECA implementation activities, with particular attention to their impact on the EU “New Approach” system ;

- Dissemination to sectors of info on legislative, regulatory and administrative provisions applicable to the relevant sectors;

- management of the information concerning CABs: reception from Member states of info on their Designated Bodies for proper transmission to the Joint Committee; reception from Third Countries (via the Joint committee) of all relevant info on their Designated Bodies to be included in the EU database of Notified bodies;
- assist the sectors in the general assessment of the adequacy of each CEEC system for the designation of CABs.

The main tasks of the sectoral Units can be summarised as follows:

- contact point for all issues concerning MRA/PECA implementation within a specified sector;

- preparation of the work and representation of the EU in the Joint sectoral Groups where necessary. This involves extensive contacts with other Commission services and the national authorities in charge of that sector in each Member state;

- ensure co-ordination of the MRA/PECA implementation for the sector under their responsibility: this involves promotion of exchange of information, ensure coherence in the designation process performed by Member states, provide support to all interested parties in the interpretation of the designating criteria, etc. Such activities might be supported by the existing Committees/Working groups for the implementation of the directives: it can be expected that at least one meeting of these committees each year shall be dedicated to MRA/PECA implementation issues. In the field of pharmaceuticals, the Pharmaceutical Agency will of course play a important role under control of DG III/E/3;

- ensure setting and implementation of a programme and of instruments for assessing equivalence of acceptance criteria and setting of an alert system in the transitional periods (Pharmaceuticals and Medical devices sectors);

- co-operate in organising joint inspections (MRA)/evaluation missions (PECA), in the sectors where needed, and define objectives, instruments**,** rules/procedures and common reporting formats.

The services in charge of the sectors covered in MRA/PECA have already started after the end of the negotiation phase a series of activities to properly implement the agreements: identification of contact points in the Commission and in the Member States, information to all interested parties through the meetings of the sectoral standing committees or ad-hoc meetings, meetings with the corresponding sectoral authorities of the other Parties and also the organisation of Seminars for confidence building (with Australia/New Zealand and CEEC).

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