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**MUTUAL RECOGNITION AGREEMENTS
THEIR ROLE TODAY AND TOMORROW**

This paper contains a presentation on the role of mutual recognition agreements made at the Workshop on Standardization and Conformity Assessment Matters in the Transition Economies, held on 12 and 13 December 2001 in Bratislava.

The presentation was made by Ms. Marie-Christine Poncin, Ministry of Economy, Finance and Industry, France.

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MUTUAL RECOGNITION AGREEMENTS THEIR ROLE TODAY AND TOMORROW

Ladies and Gentlemen,

I am delighted to be here today to address the issue of mutual recognition agreements. The topic that I need to address today presents in some regards a bit of a challenge, if the intended objective is to draw a complete and accurate overall picture of mutual recognition agreements currently in place in the world, to evaluate their impact and formulate projections for the future. This is an attractive assignment but one that could prove difficult to carry out: the mutual recognition agreements signed by various private or governmental institutions form a complex mosaic, and we may lack information regarding the impact of these agreements. Therefore, I will limit my discussion to an analysis that draws on experience in negotiating and implementing mutual recognition agreements signed by the EC with a number of its trade partners, including several countries that are candidates for membership in the European Union.

1 – PRESENTATION

1-1. PRINCIPLE OF MUTUAL RECOGNITION

Mutual recognition is:

- a **legal** principle, existing at the international, regional or bilateral level in the form of agreements, conventions or decisions adopted by governments, legal institutions or private economic players (WTO; the United Nations Economic Commission for Europe; OECD); jurisprudence of the European Court of Justice which formulated the principle of mutual recognition by the "Cassis de Dijon" ruling and made it a pillar of the internal Community market; in the private sector: work conducted with international fora, private arrangements or contracts reached on a bilateral or multilateral basis among institutions that provide testing, accreditation services or evaluate compliance with technical regulations;
- an **economic** principle. The principle of mutual recognition leads to or is intended to promote the free circulation of goods and services in fields where technical legislation has not been harmonised. It therefore serves as a tool of trade policy and contributes to economic integration;
- a principle whose **application** may take diverse forms, reflecting the interests at stake as well as considerations of a commercial or sometimes political, technical or legal nature.

1-2. BASIC PRINCIPLES OF MUTUAL RECOGNITION AGREEMENTS

1-2-1 Mutual recognition agreements negotiated by the European Community constitute one way in which the principle of mutual recognition is applied.

Globally, the European Community has been negotiating, on a formal basis, 16 mutual recognition agreements. Nearly 1 agreement out of 2 has been negotiated with the Central European Eastern countries. Negotiations are underway with the CEECs countries.

This is a big family of agreements with obvious differences, including two main categories identified in Community jargon as follows:

- * **MRA:** third country, conformity assessment, non harmonisation (exceptions)
- * **PECA**¹: candidate countries to the European Union, EC legislation, regulation and standards, useful step in the perspective of being a EU member State.

1-2-2 Scope

In a general way, the mutual recognition agreements negotiated by the European Community relate to trade in manufacturing products that, in order to be marketed, must be found to comply with regulatory technical requirements (testing, certificates of conformity, CE marking) and in some cases must receive market approval (including elements linked to experiments of substances and products in the field of chemistry and biotechnology).

Which sectors? (see annex)

1-2-3 Common characteristics

- *Aspects linked to the nature of the agreement and to the negotiating mandate for the EC:*
 - These agreements are negotiated within the framework of the EC external trade policy (article 133 of the EC Treaty/ legal basis, specific guidelines);
 - on a bilateral and intergovernmental basis;

¹ Protocol to the European Agreement (PECA).

- they are a tool for economic agents who wish to use it;
 - multi-sectorial scope;
 - they consist of a framework agreement (including guidelines for general application, conformity assessment procedures and relevant aspects of market approval procedures), and of sectorial annexes, or specific sections.
- *Key concepts:* trade interests, reciprocity, competence, confidence, appropriate regulatory framework, responsibility. These concepts refer to economic, technical, legal and cultural elements.

2- OVERVIEW OF AGREEMENTS NEGOTIATED BY THE EUROPEAN COMMUNITY

2-1. AGREEMENTS NEGOTIATED BY THE EC WITH THIRD COUNTRIES

2-1-1 Typology

These agreements are concluded for an unlimited length of time, except if the contracting parties decide to terminate the agreement, according to the agreed procedures.

- **Mutual Recognition Agreement (MRAs)** (primarily negotiated on conformity assessment)

- (a) **General principle:** Each party to the MRA agreement recognises the results of conformity assessment procedures (test reports, certificates of conformity and CE marking), conducted on the basis of its own specific technical regulations, and issued by the conformity assessment bodies (CABs) of the other party.

Another approach is taken:

- in some sectors (such as pharmaceuticals and motor vehicles). For pharmaceutical products, mutual recognition relates to the quality system inspections performed at the manufacturing site. The site inspection conducted by the authority of the exporting country is recognised by the authority of the importing country.
- with regard to certain countries (in the EC - Switzerland MRA), the principle of mutual recognition is applied on the basis of the Community's technical regulations and, when appropriate, on Switzerland's national regulations).

- (b) **Sectors covered from the EC side:** Community technical regulations ("New Approach" and "Old Approach"), as well as on, a case-by-case basis, technical regulations that have not been harmonised at the intra-Community level in force in the member States.
- (c) **With which countries?** 6 agreements have been concluded (**USA, Canada, Australia, New-Zealand, Switzerland, Japan**).

➤ **A variant of the MRA: the MRA plus**

- (a) **General principle:** This approach is founded on the recognition of equivalence between the two parties' conformity assessment procedures and technical standards. Such an agreement may also include a section on mutual recognition of conformity assessment results ("classical approach" for the EC).
- (b) **Sectors covered:** the EC negotiating strategy is applied on a case by case basis. Two sectors are covered at present: maritime equipment and metrology. Harmonising work is underway at the international level in these two sectors.
- (c) **With which countries?** 1 agreement initialled both with the U.S. (marine equipment), 1 agreement currently being negotiated (metrology)

➤ **GLP agreement** (good laboratory practices)

- (a) **General principle and sectors covered:** The mutual recognition applies to non-clinical safety studies related to health and the environment, particularly those performed in the chemical and pharmaceutical sectors. The technical references used are the GLP standards established by the OECD (Organisation for Economic Cooperation and Development).
- (b) **With which countries:** 4 relevant agreements (Israel and sectoral annex of EC-Switzerland, MRA, EC-Japan MRA and EC-Hungary PECA)

2-1-2 General Objectives

➤ **Objective 1: Facilitating trade exchanges**

The potential advantages for economic players who wish to benefit from these agreements are as follows:

- to make the regulatory process easier for introducing products on the importing country's market as far as the conformity assessment against the technical regulations of the importing country is performed before shipment (a reduction in the expense and time required to obtain product compliance with the importing country's technical guidelines, non-duplication of audits and inspections). Third-party conformity assessment of European products intended for export is conducted by one of the European bodies designated for this purpose (and vice versa).

For pharmaceutical products, the intended objective is to shorten the time of product market approval procedure. For the chemical sector, the goal is to avoid the needless repetition of testing.

- Greater legal security and enhanced predictability in trade (fewer inspections conducted by authorities of the importing country in the exporting country).

➤ **Objective 2 : a tool for deregulation**

For products subject to third party conformity assessment procedures, mutual recognition agreements are clearly meaningless unless:

- Conformity assessment bodies (CABs) have been set up with the necessary authority and technical competence to perform this work and are allowed to also perform on the basis of the third country's technical regulations;
- The regulatory authorities decide to recognise the results of conformity assessment procedures issued by CABs located in the other party's territory.

➤ **Objective 3: a step for regulatory convergence**

According to the EC, mutual recognition agreements may prove educational impact: an enhanced understanding of the technical regulations of the other contracting party and the experience gained in implementing these regulations in the context of the MRA agreement may be factors that could contribute to greater regulatory convergence.

2-2. AGREEMENT NEGOTIATED WITH THE CANDIDATE COUNTRIES

2-2-1 PECA agreement (Protocol to the European agreement establishing an association between the European Communities and its member States on conformity assessment and the acceptance of industrial products).

This agreement has a life-time limited to the pre-accession period. It is part of the European Association agreement concluded with the Central and Eastern European Countries (CEEC Country).

- (a) **General principle:** Each party recognises the results of conformity assessment procedures conducted on the basis of Community legislation or legislation that has been transposed into country law. The agreement also includes a mutual acceptance clause for manufactured products that meet the necessary conditions for being introduced onto the market of the parties to the agreement.
- (b) **Sectors covered:** the EC legislation and regulations that the CEEC has transposed into country law.
- (c) **With which countries?** 2 agreements concluded (Hungary and Czech Republic, 2 agreements initialled by the EC Commission (Latvia, Lithuania), 3 agreements currently being negotiated (Estonia, Slovenia, Slovakia).

2-2-2 Objectives

- **Objective 1: Preparing for membership in the European Union**
This tool acts as an incentive for the CEECs to align their legislation on the “acquis communautaire”. The results of the entry into force of a PECA will be to offer the advantages of the single market, limited however to the areas covered by the Agreement.
- **Objective 2: Facilitating market access**
Common technical regulations, provisions of mutual recognition and of mutual acceptance of industrial products.
- **Objective 3: a tool for deregulation**
Similar comments to those on MRA agreements. Deregulation in conformity with the EC system is one prerequisite for negotiating PECA agreements and for becoming an EC new member State.

One complementary point to raise: It is important for the candidate country interested in negotiating a PECA agreement to select only testing and metrology laboratories that meet highest quality technical criteria (expertise, trained staff, equipment) and meet the technical conditions for a PECA negotiation. The choice must also satisfy the needs of the national economy.

2-3. EXAMPLES OF KEY CONCEPTS

In particular, for the candidate countries which have been negotiating PECA agreements and for economies in transition,

- * **The competence of conformity of assessment bodies (CABs):** the ability to carry out the necessary technical tasks (equipment, working method, staff training) in order to assess conformity; to provide quality organisation to be able to perform these tasks and monitor them; major role of accreditation for assessing the CAB's ability;
- * **The competence of regulatory authorities** with regard to the designation and surveillance of CABs and monitoring in the pharmaceutical sector;
- * **Regulatory framework:** concepts of market surveillance, general product safety, and drug monitoring.

Market surveillance has two objectives:

- * Ensuring that products placed on the market comply with public requirements regarding public-health protection, consumer and worker protection, and environment protection;
- * Ensuring that trade transactions take place in compliance with the principle of fair competition.

As regards **the concept of responsibility**, in the EC the economic players take on the responsibility: i.e. those placing products on the market for the first time (manufacturers and importers) are under a legal obligation to ensure beforehand that their products comply with existing law and be able to prove it, when requested.

3 - MUTUAL RECOGNITION AGREEMENTS: THEIR ROLE TODAY

To give an answer to the problematic issue- which role today and tomorrow for mutual recognition agreements, information on the impact and assessment data on these agreements is needed. The points I would like to make are my own personal evaluations based on our experience in France on this subject.

With regard to the MRA agreements, we do not yet have, at the Community level, an assessment of the impact of these agreements, on a global, sectorial and geographical basis. However, an exercise is underway regarding the MRAs concluded with Australia and New Zealand.

3-1 TRADE ASPECTS

Question 1: Is it a tool for eliminating non-tariff technical barriers to trade?

Answer: No, it is not, neither for MRA nor for PECA agreements.

If we identify technical barriers to trade as they are defined by the WTO, then mutual recognition agreements, as they are being negotiated by the EC, are not and cannot be a relevant tool for eliminating these technical barriers. Indeed, the EC could not envisage negotiating an agreement with a third country whose technical regulations, system and normative practices do not comply with the WTO rules. However, an additional factor should be noted: countries with which the EC has negotiated agreements have signed the GATT Code on technical barriers to trade or the WTO/TBT agreement.

Question 2: Is it a tool for facilitating trade?

Answer: information on real impact is missing

➤ **With regard to MRA agreements,**

On the basis of information collected at a national level, we can note that, in spite of some delay for the entry into force of the operational phase of the EC-USA and EC-Canada MRA agreements:

- *In the medical devices sector*, manufacturers continue to have positive expectations regarding the projected benefits such as improved export facilities and reduction in costs of conformity assessment;
- *In the electrical equipment and telecommunication equipment sectors*, feelings are more reserved since the MRA which could have important trade impact have not yet entered into force in their operational phase or have not been implemented according to the principle of mutual confidence. Moreover, questions were raised on governmental MRA's usefulness in the telecommunications sector, which is a globalised market dominated by big companies;
- *Some concerns expressed by European/ French CABs*, according to the relevant sectors, concerns linked to the conditions for carrying out their conformity assessment activities under the terms of the mutual recognition agreements (costly exercise) as well as on information policy.

➤ **With regard to PECAs**, it may be premature to collect trade data on impact; agreements concluded with Hungary and Czech Republic have recently come into force. The question remains, however, of interest.

3-2 REGULATORY ASPECTS

Question 1: Is it a tool for stimulating deregulation?

Answer: Yes, it can be a means

- **With regard to MRA** (e.g. MRA/USA in the sectors of medical devices and of telecom, MRA/Japan in the electrical sector), the agreements have been concluded or have come into force only after changes have been introduced in the regulatory system to ensure that there were CABs to perform conformity assessment tasks at a national level and that the authority could recognise the results of conformity assessment procedures issued by CABs located in the other party's territory.

Question 2: Is it a tool for regulatory dialogue/cooperation and regulatory convergence?

- **With regard to MRA agreements**, these concepts are not among the overall objectives cited in the preamble to the agreements, nor are basic principles. Nonetheless, they may be applied on a temporary and sectorial basis (without prejudice to confidence and mutual recognition principles).
 - **In the context of the implementation.** For example, in the sectorial annex on medical devices of the EC-Canada MRA, confidence building measures have been provided for, such as mutual training, and comparative assessment of quality audits. Similar measures have been implemented in the sectorial annex on pharmaceuticals of the EC-Canada and EC-US MRA agreements.
 - **As a result of the implementation of these agreements.**

With regard to *the pharmaceutical sector*, the agreement contributes to the establishment of an institutional and normative framework which leads to the recognition of French agencies (AFSSAPS and AFSSA, which monitor the safety of health products and food). This encourages the understanding and harmonisation of monitoring methods used by the appropriate authorities (but it is a costly exercise).

In the *medical devices sector*, changes towards convergence with the EC legislation have been noted in Australia (adoption of the CE marking system). However, the effective role played by the MRA agreements with respect to these regulatory changes remains to be determined. This should be part of the EC assessment of the MRA agreements which is underway.
- **As regards the EC-US MRA plus** negotiated in the area of marine equipment, it includes a section on regulatory cooperation.

- **As for the PECA agreements**, the issue must be dealt with differently as negotiations are meaningful only if the CEECs have aligned their regulations with those of the EC and have adopted Community standards. However, exceptionally and for some sectors, PECA agreements may include transition periods to allow compliance with European standards (pharmaceuticals).

3-3 POLITICAL ASPECTS

For the candidate countries, PECA negotiation is a tool favoured by the EC in order to bring candidate countries to profit from the benefice of the EC internal market and to allow these countries to play the role of EU member States when acceding to the European Union. When becoming new member States, these countries will benefit from mutual recognition agreements negotiated by the EC with third countries.

3-4 MUTUAL RECOGNITION - HARMONISATION: CONFLICT OR COMPLEMENTARITY ?

- **For MRA and GLP agreements**, the assessment which is being performed by the European Commission will give elements of answer on this issue. Elements e.g. on trade impact and on financial costs linked to the negotiation and the implementation of these agreements will give elements to assess whether this approach is efficient and will help to draw lessons for the future.

As regards the relevant MRAs and those few sectors for which mutual recognition is based on harmonised regulations and standards, some positive results have been noted. E.g. in the motor vehicle sector (EC-Australia MRA), Australia has taken over a larger part of the ECE-NU 1958 Agreement on motor vehicles and became a member of this international organisation. In the good laboratory practices sector, Israel has applied for the OECD relevant working group. For the maritime equipment sector, the MRA agreement negotiated with the US has not yet been formally concluded, objectives of coherence and complementarity between harmonisation, mutual recognition conducted at multilateral and bilateral levels are essential concepts to reach.

With regard to the issue of mutual recognition and harmonisation, French authorities are giving priority to the elaboration, adoption and implementation of internationally-recognised standards that meet high safety levels and consider it necessary to have a coherent approach between actions taken in the fields of the mutual recognition and harmonisation.

- **For PECA agreements:** the harmonisation of technical regulations is the foundation of this type of agreement, and the joint technical framework is provided by the European harmonized technical regulations and standards.

CONCLUSION

- **With regard to the mutual recognition agreements negotiated by the EC with third countries,** it is important when assessing the appropriateness of a negotiation to:
 - take into account trade, technical and legal elements and assessment factors,
 - to consider it in a broader context that encompasses current law with respect to legal security, intellectual property, the responsibility of third parties, and actual practices in the field.
 - to take into account the experience gained in the negotiation and the implementation of these agreements.

These elements and data to be given by the assessment will be used by the European Community to formulate projections for the future of mutual recognition agreements.

- **With regard to PECA agreements,** they can be considered as an important step in the preparation of CEEC countries for membership in the European Union.

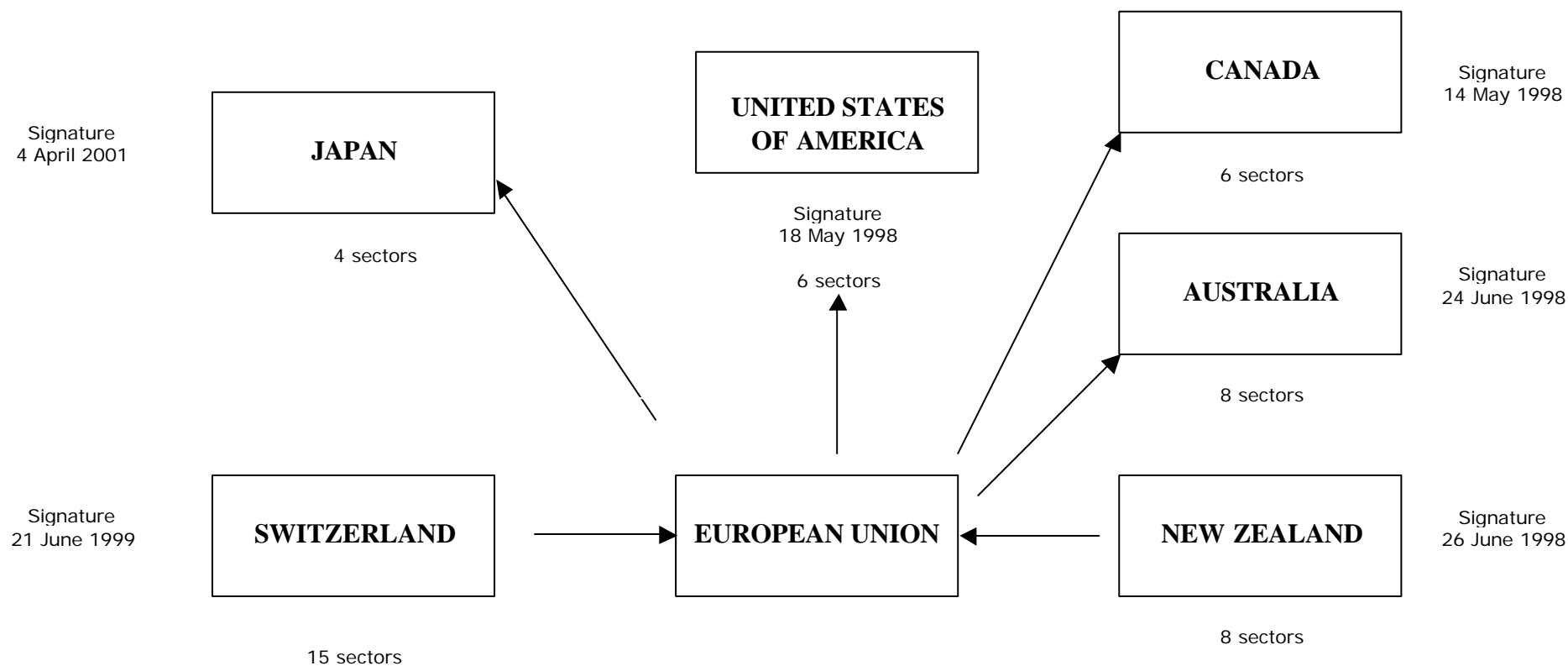
Annex

SECTORS AND REGULATIONS COVERED

Telecom terminal equipment (TTE) MRA EC/USA, CAN, AUST, NZ, JAP, CH No PECA	Electromagnetic compatibility (EMC) MRA EC/USA, CAN, AUST, NZ, JAP, CH PECA EC/CZECH, HUNG	Electrical safety (LVD) MRA EC/USA, CAN, AUST, NZ, JAP, CH	Recreational craft MRA EC/USA, CAN	Pharmaceutical products (GMP. Good manufacturing practices) MRA EC/USA, CAN, AUST, NZ, JAP, CH PECA EC/CZECH
Medical devices MRA EC/USA, CAN, AUST, NZ, CH PECA EC/HUNG	Machinery MRA EC/AUST, NZ, CH PECA EC/CZECH	Pressure equipment MRA EC/AUST, NZ, CH PECA EC/CZECH, HUNG	Motor vehicles MRA EC/AUST, CH	Personal protective equipment MRA EC/CH PECA EC/CZECH, HUNG
Lifts PECA EC/CZECH, HUNG	Equipment and protective systems intended for use in potentially explosive atmospheres MRA EC/CH PECA EC/CZECH	Hot-water boilers PECA EC/CZECH, HUNG	Gas appliances MRA EC/CH PECA EC/CZECH, HUNG	Chemical sector (GLP, good laboratory practices) MRA EC/ISRAEL PECA EC/HUNG
Agricultural and forestry tractors MRA EC/CH	Measuring instruments and construction plant and equipment MRA EC/CH	Maritime safety equipment MRA + EC/USA		

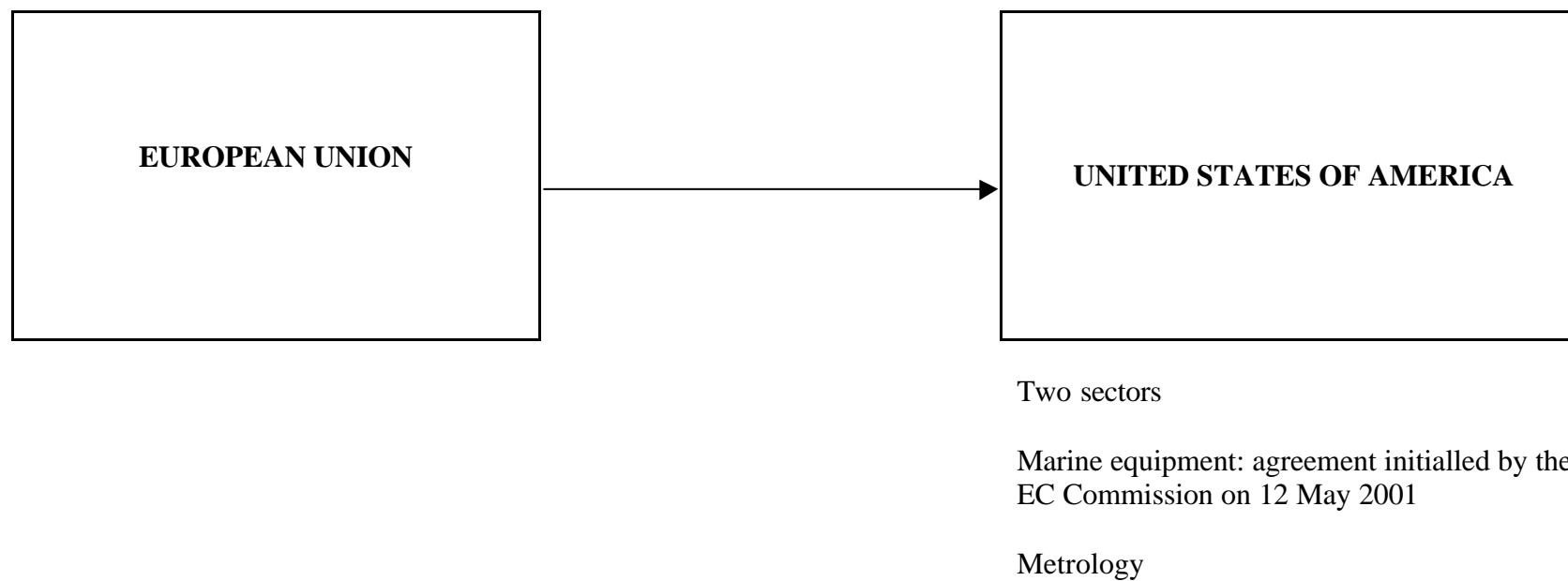
Overview of agreements negotiated by the European Community (December 2001)

Annex (Cont'd)
MUTUAL RECOGNITION AGREEMENTS
ON CONFORMITY ASSESSMENT PROCEDURES / THIRD COUNTRIES (MRA)



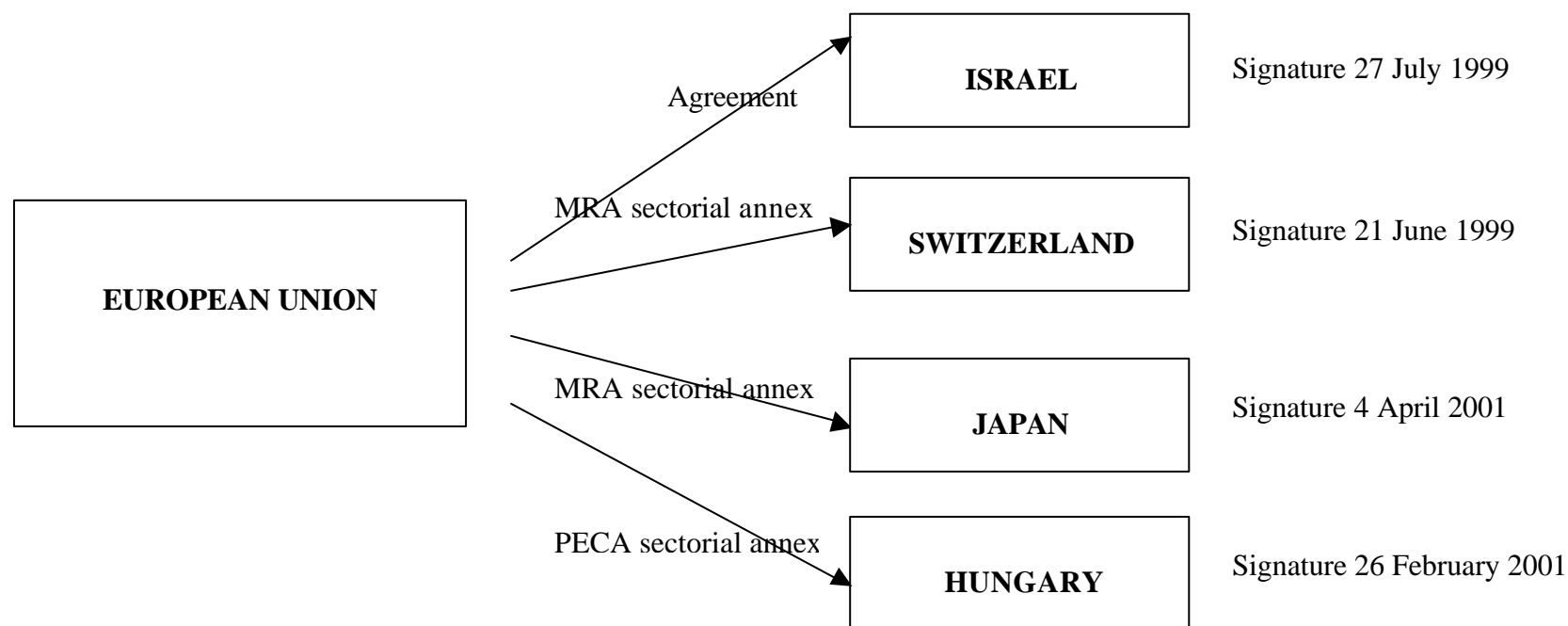
Overview of agreements negotiated by the European Community (December 2001)

Annex (Cont'd)
MRA PLUS AGREEMENTS
EQUIVALENCE / NEGOTIATION WITH THIRD COUNTRIES



Overview of agreements negotiated by the European Community (December 2001)

Annex (Cont'd)
GOOD LABORATORY PRACTICES (GLP)
AGREEMENTS / SECTORIAL ANNEXES OF MRA AND MECA AGREEMENTS



Annex (Cont'd)

**PECA AGREEMENTS ON CONFORMITY ASSESSMENT AND MUTUAL ACCEPTANCE OF
THE PRODUCTS /CANDIDATE COUNTRIES (December 2001)**

