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Proposal for a

# **COUNCIL DECISION**

on the signature on behalf of the Community of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and Romania, of the other part, on Conformity Assessment and Acceptance of Industrial Products

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# **COUNCIL DECISION**

on the conclusion of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and Romania, of the other part, on Conformity Assessment and Acceptance of Industrial Products - PECA -

(presented by the Commission)

# EXPLANATORY MEMORANDUM

# **I. EXPLANATORY MEMORANDUM**

On the basis of negotiating directives adopted by the Council on 21 September 1992 and of the specific decision issued by the Council in June 1997 addressing guidelines to the Commission for the negotiation of European Conformity Assessment Agreements with Central and Eastern European Countries, the Commission has negotiated and initialled an additional protocol to the Europe Agreement with Romania (Protocol to the Europe Agreement on Conformity assessment and Acceptance of industrial products, hereinafter referred to as "PECA").

The text of this Protocol is attached to this Communication. The following provides an assessment of the Protocol in the light of the negotiating directives approved by the Council, and proposes that the Council authorises the signature of the additional Protocol to the Europe Agreement and decides to approve its conclusion on behalf of the Community. This assessment and these proposals are similar to the relevant documents for the PECAs concluded by the Council with the Czech Republic, Hungary, Slovenia, Slovakia, Estonia, Latvia and Lithuania before their accession to the European Union.

# I.1 ASSESSMENT OF THE AGREEMENT

Considering that this agreement is intended to work only during the pre-accession period, and that an appropriate legal framework was offered by the Europe Agreement, it was decided, in consultation with the 133 Committee, to adopt this agreement as a Protocol to the Europe Agreement.

The draft PECA follows the general principles laid down in the Commission's communication on Community External Trade Policy in the field of standards and conformity assessment<sup>1</sup> under its paragraph 49. The PECA is a transitional arrangement, and thus will terminate with the candidate country's accession.

The PECA provides for an extension of certain benefits of the Internal Market in sectors already aligned. The PECA thus facilitates market access by eliminating technical barriers to trade with respect to industrial products. To this end, the PECA provides for two mechanisms,

(a) for the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties, and

(b) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent national law.

The first mechanism, i.e., the mutual acceptance of industrial products, confirms that Articles 10.3 and 11.4 of the Europe Agreement with Romania apply without other restriction as referred to in Article 36 of the Europe Agreement. This provision adds the predictability that is necessary to manufacturers and exporters, confirming in advance that industrial products under this mechanism may freely move between the Parties. Annexes making this mechanism operational remain to be negotiated.

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COM(1996) 564 final, 13.11.1996.

The second mechanism is a particular type of mutual recognition agreement (MRA) in which the mutual recognition operates on the basis of the *acquis communautaire*. It allows industrial products certified by Notified Bodies in the European Union to be placed on the Romanian market without having to undergo any further approval procedures, and vice-versa. Initially, only the following sector is covered: pressure equipment.

Romania has taken over the Community technical legislation in the sector covered by the Protocol and participates in the European organisations in the field of standards, metrology, testing laboratories and accreditation.

The PECA consists of a framework agreement and annexes as referred to above. A unilateral Community declaration inviting the Romanian representatives to experts meetings and committees established under the Community law referred to in the annexes is attached to the Final Act, making it clear that this will not entail any participation in the Community decision-making process. An assessment of the PECA is made in the next paragraphs.

# **I.1.1 Framework Agreement**

An article-by-article assessment follows:

**Preamble**. This sets out the basic objective of the PECA which is that, as the application for membership of the European Union implies the implementation of the *acquis communautaire* by the applicant country, it provides the opportunity to extend certain benefits of the Single Market in certain sectors already aligned before.

**Article 1: Purpose.** This article establishes the purpose of the PECA, namely the elimination of technical barriers to trade in respect to industrial products. The PECA provides for two mechanisms, a) for the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties, and b) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent national law.

**Article 2: Definitions.** This is self-explanatory. Definitions of industrial products, Community and national law have been included. All pieces of legislation and implementation measures (administrative provisions, guidelines and other means of /implementation of the legislation) are covered by the definitions of Community and national law.

**Article 3: Alignment of legislation**. This contains a commitment for Romania to take appropriate measures in order to maintain or complete the take-over of Community law, namely in the field of technical legislation and for the purpose of the PECA. Together with the 4<sup>th</sup> whereas, it means that the alignment is an ongoing process and the Parties agree to iron out any problems of transposition that could appear later.

Article 4: Mutual acceptance of industrial products. The principle under Article 1.1) is detailed in this article. It provides that listing industrial products in such annexes will confirm that these products can freely circulate between the Parties. As already stated, no such annex has been negotiated yet.

Article 5: Mutual recognition of the results of conformity assessment procedures. This provision expands the principle under Article 1.2). This kind of recognition is similar to the one in Mutual Recognition Agreements, with the special feature that all legislation and standards are aligned. The sectoral annexes will contain the references to the relevant Community and national legislation.

**Article 6: Safeguard clause**. This sets up the right of each Party to deny market access when such Party is able to demonstrate that a product might endanger the legitimate concern which is protected by legislation listed in the annexes (safety and/or public health of users or other persons mainly). The annexes provide for the detailed procedures to be used in such cases.

Article 7: Extension of coverage. The Parties may modify the scope and coverage of this Protocol through an amendment of the annexes or by the addition of new annexes as soon as all alignment conditions are met.

Article 8: Origin. The provisions of this Protocol apply to industrial products irrespective of their origin.

Article 9: Obligations of Parties as regards their authorities and bodies. This article obliges the Parties to ensure that their respective authorities continuously monitor the technical competence and compliance of the notified bodies and have the necessary power and expertise for designating, suspending, and withdrawing their bodies. In addition, it obliges the Parties to ensure that their respective notified bodies continuously comply with the requirements of Community or national law and maintain their technical competence to carry out the tasks for which they have been notified.

**Article 10: Notified bodies**. This describes the procedure for the notification of bodies to assess conformity in relation to the legal requirements specified in the corresponding annexes. The procedure is simplified and similar to the one applied within the Community. The second paragraph sets out the procedure for the removal of notified bodies.

Article 11: Verification of notified bodies. This article gives the right to one Party to request a verification of a body notified by the other Party. The verification may be done either by the authorities which have designated the body or together by the authorities of both Parties. If the Parties do not agree on appropriate steps to take, they may notify the Chair of the Association Council of their dissent, and leave to the Association Council to decide on appropriate action. The notified body would then be suspended from the notification of the Association Council until a final decision is taken.

Article 12: Exchange of information. A transparency provision to ensure a correct and uniform application and interpretation of the Protocol. The Parties are advised to encourage their bodies to co-operate in order to establish mutual recognition agreements in the voluntary sphere.

Article 13: Confidentiality. A classical provision to avoid disclosing information acquired under this Protocol.

Article 14: Management of the Protocol. The Association Council will be responsible for its effective functioning and may delegate its duties in conformity with the relevant Articles of the Europe Agreement.

Article 15: Technical co-operation and assistance. This confirms the Community policy on technical co-operation and assistance with a view to properly implementing this Protocol.

Article 16: Agreements with other countries. This confirms that, unless otherwise agreed, the PECA does not entail any obligation, for one Party, to accept conformity assessments carried out in another country, even if there is an agreement on recognition of conformity assessment between the other Party and any other third country.

Article 17: Entry into force. This is a standard provision that provides the arrangement for the entry into force.

Article 18: Status of the Protocol. This establishes the fact that the PECA is an integral part of the Europe Agreement.

# **I.1.2 The Annexes to the Protocol**

# I.1.2.1 Annexes on Mutual Recognition of Results of Conformity Assessment

There follows an assessment of the content of the annexes in terms of their coverage, and other implications where relevant. In making this assessment, the Commission has kept in mind the following elements:

- a) the overall consistency with the Community policy objectives in the field of standardisation, certification and conformity assessment for the sectors and industrial products covered;
- b) the overall consistency with Community policy objectives in the field of the removal of technical barriers to trade;

The sectoral assessment is followed in item I.2 by an overall appreciation of the benefits of the Protocol.

# Annexe on Pressure Equipment.

Annexes on mutual recognition of results of conformity assessment cover a range of industrial products subject to third party conformity assessment under the New Approach Directives in the relevant sectors All these annexes present the same structure.

Coverage is determined by the relevant Community or national law, listed under *Section I* of the annex. *Section II*, on notifying authorities, lists the authorities responsible for the designation of bodies in the Member Sates and Romania. *Section III*, on notified bodies, makes reference to the notification of all Conformity Assessment Bodies notified by the Member States and by Romania. *Section IV*, on specific arrangements, fixes the two procedures for the safeguard clause, relating to industrial products and to harmonised standards.

# I.1.2.2 Annexes on Mutual Acceptance of Industrial Products

No such annexes have been negotiated for the moment. The PECA, in line with the Europe Agreement, provides nevertheless the basis for such acceptance of products, similar to the one which operates in the Community.

# I.1.2.3 Unilateral Declaration

This is attached to the Final Act and is annexed to this Communication.

Unilateral Community Declaration relating to attendance of the Romanian representatives to Committees. Through this declaration, Romania is invited to send observers to the meetings of the Committees established or referred to under the Community legislation included in the annexes. This declaration follows the principles of the Commission Communication on "Participation of candidate countries in Community programmes, agencies and committees"<sup>2</sup>.

# **I.1.3 Relations with EFTA /EEA Member Countries**

In accordance with the general information and consultation procedures set out in the European Economic Area-Agreement and Protocol 12 of that Agreement, the Commission kept EFTA/EEA Member Countries regularly informed on the progress of the negotiations and informed them on the final result thereof. The EFTA/EEA Member Countries are in the initial stage of negotiating a parallel mutual recognition agreement with Romania.

#### **I.2 OVERALL APPRECIATION**

The Commission considers that the proposed PECA creates an acceptable balance of benefits for all parties in the pre-accession framework. In all sectors the Community has secured effective market access - in terms of access to all mandatory procedures of the other party. The PECA confirms that Romania has taken over the Community legislation in certain sectors before its accession. Both political and commercial benefits are achieved with the PECA.

The Protocol will allow Community exporters, if they so choose, to test and certify their industrial products to the same (aligned) requirements prior to export, and then access that market without any further conformity assessment requirements. The certification procedures will only need to be carried out one time for both markets and against the same aligned requirements or standards. The recognition of certification will permit savings and stimulate exports. European industry federations were consulted and supported unequivocally the Protocol.

It has not been able to quantify the costs or time taken to obtain conformity assessment of industrial products in Romania. The precise extent of savings in time, cost and market opportunity of this Protocol is therefore not feasible in every case to determine. However, on the basis of a rough calculation, it is estimated<sup>3</sup> that this Protocol would create cost saving opportunities of around  $\in 8$  millions per year for the European exporting industry and to Romanian exporters to the EC. Some of these savings will be passed on to European importers and consumers.

In fact, most benefits are clearly not quantifiable, such as reduced time for accessing markets, better predictability, less protectionism, and harmonisation of systems. What can be ascertained is that any agreement provides reciprocal levels of market access, in terms of conformity assessment.

<sup>&</sup>lt;sup>2</sup> Point 4.2.b. COM(1999) 710 final, 20.12.1999.

On the hypothesis that certification and other related costs amount to an average of 1.5 % of trade.

In terms of the benefits to Romania, the PECA will facilitate access to the Community market and will give political credit for having aligned its legislation. Romania regards the PECA as a means to develop closer industrial relations with the EU and fully to integrate certain sectors with the Single Market before accession.

# I.3 FINANCIAL IMPACT

There are no financial implications to this proposal. Maintenance activities of the Protocol are expected to be minimal, and are already covered by funding already established for the maintenance of the Europe Agreement to which this is a Protocol.

# I.4 IMPACT ON BUSINESS

Exporting companies, business associations, chambers of commerce and public institutions of the European Union and the general consumer will benefit, or have an interest in, the mutual acceptance of industrial products and recognition of results of conformity assessment certification.

The specific objectives of the PECA are to avoid duplication of certification by economic operators. The PECA will promote exports, employment, competitiveness and investment, and to reduce costs, in particular for small and medium-sized enterprises and ultimately for the consumer, by extending certain benefits of the Internal Market to Romania, and by ensuring the effective operation of the Internal Market in Romania in the sectors that it covers, before Romanian accession.

# **II. THE DRAFT COUNCIL DECISIONS**

A proposal for two Council decisions is attached. Both are similar to the Commission proposals for the previous Council decisions on the signature on behalf of the Community and conclusion of the PECAs with the former acceding countries.

The first one is concerned with the signature of the Protocol. Signature is required by Romania for the adoption of this Protocol. It is accordingly proposed that the President of the Council be authorised to designate the person empowered to sign the Protocol on behalf of the Community, subject to conclusion later, on the basis of Articles 133 and 300 of the Treaty.

The proposal for a second decision is concerned with the adoption of the PECA. In this context, the Council should, in line with the previous Council decisions on the conclusion of PECAs and mutual recognition agreements, establish the appropriate Community procedure for the implementation and management of the Protocol.

In particular, the Council should confer on the Commission, in consultation with the special committee appointed by the Council, the necessary powers for the management and implementation of the Protocol. Moreover, the Council should delegate to the Commission, acting in consultation with the special committee, the necessary powers to determine in certain cases the Community position with regard to this Protocol in the Association Council, or where applicable the Association Committee. The delegation of powers to the Commission includes delegation of the power to add new Annexes, since, as indicated in the Preamble, membership of the European Union, for which Romania has applied, implies the effective implementation of all the Community *acquis*.

In all other cases the Community position with respect to the Protocol shall be determined by the Council, acting by qualified majority, on a proposal from the Commission.

The Commission therefore proposes that the Council adopts the attached decisions on the signature and conclusion of the PECA.

#### 2006/0137(ACC)

#### Proposal for a

# **COUNCIL DECISION**

### on the signature on behalf of the Community of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and Romania, of the other part, on Conformity Assessment and Acceptance of Industrial Products

#### THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133, in conjunction the first sentence of the first subparagraph of Article 300(2) thereof,

Having regard to the proposal from the Commission<sup>4</sup>,

Whereas:

- (1) The Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and Romania of the other part,<sup>5</sup> entered into force on 1<sup>st</sup> February 1995.
- (2) Article 75 of the Europe Agreement provides that co-operation in the fields of standardisation and conformity assessment shall seek to achieve the conclusion of agreements on mutual recognition.
- (3) The Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products has been negotiated by the Commission on behalf of the Community.
- (4) Subject to its possible conclusion at a later date, the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products initialled in Brussels on 18 April 2006 should be signed.

<sup>&</sup>lt;sup>4</sup> OJ C ..., p. ...

<sup>&</sup>lt;sup>5</sup> OJ L 357, 31.12.1994, p. 2.

## HAS DECIDED AS FOLLOWS:

# Sole Article

Subject to a possible conclusion at a later date, the President of the Council is hereby authorised to designate the person empowered to sign, on behalf of the Community, the Protocol to the Europe Agreement with Romania on Conformity Assessment and Acceptance of Industrial Products.

Done at Brussels,

For the Council The President

2006/0138(ACC)

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# **COUNCIL DECISION**

#### on the conclusion of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and Romania, of the other part, on Conformity Assessment and Acceptance of Industrial Products - PECA -

#### THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof, in conjunction with the first sentence of the first subparagraph of Article 300(2), the first sentence of the first subparagraph of Article 300(3) and Article 300(4) thereof,

Having regard to the proposal from the Commission<sup>6</sup>,

Whereas:

- (1) The Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and Romania of the other part,<sup>7</sup> entered into force on 1<sup>st</sup> February 1995.
- (2) Article 75(2) of the Europe Agreement provides that co-operation in the fields of standardisation and conformity assessment shall seek to achieve the conclusion of agreements on mutual recognition.
- (3) Article 110 of the Europe Agreement provides that the Association Council may delegate to the Association Committee any of its powers.
- (4) Article 2 of Decision 94/907/EC, ECSC, Euratom of the Council and the Commission of 19 December 1994 on the conclusion of the Europe Agreement between the European Communities and their Member States, of the one part, and Romania, of the other part,<sup>8</sup> provides for the Community decision-making procedures and for the presentation of the Community position in the Association Council and in the Association Committee.

<sup>&</sup>lt;sup>6</sup> OJ C ..., p. ...

<sup>&</sup>lt;sup>7</sup> OJ L 357, 31.12.1994, p. 2.

<sup>&</sup>lt;sup>8</sup> OJ L 357, 31.12.1994, p. 1.

- (5) The draft Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products, has been signed in Brussels on [...], on behalf of the Community, and should be approved.
- (6) The appropriate internal procedures should be established to ensure the proper functioning of the Protocol.
- (7) It is necessary to empower the Commission to make certain technical amendments to this Protocol and to take certain decisions for its implementation,

HAS DECIDED AS FOLLOWS:

# Article 1

The Protocol to the Europe Agreement with Romania on Conformity Assessment and Acceptance of Industrial Products (hereinafter referred to as "the Protocol"), as well as the declaration annexed to the Final Act thereto, are hereby approved on behalf of the European Community.

The text of the Protocol, and of the declaration annexed to the Final Act thereto, is attached to this Decision.

# Article 2

The President of the Council shall, on behalf of the Community, transmit the diplomatic note provided for in Article 17 of the Protocol<sup>9</sup>.

#### Article 3

- 1. The Commission, after consultation with the special committee appointed by the Council, shall:
  - (a) carry into effect the notifications, acknowledgements, suspensions and withdrawals of bodies, and appointments of joint team or teams of experts, in accordance with Articles 10, 11 and 14, indent c) of the Protocol;
  - (b) bring about the consultations, exchange of information, the requests for verifications and for participation in verifications, in accordance with Articles 3, 12 and 14, indents d) and e), and Sections III and IV of the Annexes to the Protocol;
  - (c) if necessary, reply to requests in accordance with Article 11, Sections III and IV of the Annexes to the Protocol;

<sup>&</sup>lt;sup>9</sup> The date of entry into force of the Protocol will be published in the *Official Journal of the European Communities* by the General Secretariat of the Council.

- 2. Following consultation of the special committee referred to in paragraph 1 of this Article, the Commission shall determine the position to be taken by the Community in the Association Council and, where applicable, in the Association Committee, with regard to:
  - (a) amendments to the Annexes in accordance with Article 14, point (a) of the Protocol;
  - (b) addition of new Annexes in accordance with Article 14, point (b) of the Protocol;
  - (c) any decisions regarding disagreements on the results of the verifications and the suspensions, in part or totally, of any notified body in accordance with the second and third subparagraphs of Article 11 of the Protocol;
  - (d) any measures taken in the application of the safeguard clauses in Section IV of the Annexes of the Protocol;
  - (e) any measures concerning the verification, suspension, or withdrawal of industrial products as having mutual acceptance under Article 4 of the Protocol.
- 3. In all other cases the position to be taken by the Community in the Association Council and, where applicable, in the Association Committee, with regard to this Protocol shall be determined by the Council, acting by qualified majority on a proposal from the Commission.

Done at Brussels,

For the Council The President

# DRAFT

# PROTOCOL

## TO THE EUROPE AGREEMENT ESTABLISHING AN ASSOCIATION BETWEEN THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES, OF THE ONE PART, AND ROMANIA, OF THE OTHER PART, ON CONFORMITY ASSESSMENT ANDACCEPTANCE OF INDUSTRIAL PRODUCTS (PECA)

#### THE EUROPEAN COMMUNITY AND ROMANIA,

hereinafter referred to as "the Parties",

WHEREAS Romania has applied for membership of the European Union and such membership implies the effective implementation of the acquis of the European Community,

RECOGNISING that the progressive adoption and implementation of Community law by Romania provides the opportunity to extend certain benefits of the internal market and to ensure its effective operation in certain sectors before accession,

CONSIDERING that, in the sectors covered by this Protocol, Romanian national law substantially takes over Community law,

CONSIDERING their shared commitment to the principles of free movement of goods and to promoting product quality, so as to ensure the health and safety of their citizens and the protection of the environment, including through technical assistance and other forms of cooperation between them,

DESIRING to conclude a Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (hereafter referred to as "this Protocol") providing for the application of the mutual acceptance of industrial products which fulfil the requirements for being lawfully placed on the market in one of the Parties and of the mutual recognition of the results of conformity assessment of industrial products which are subject to Community or national law, noting that Article 75 of the Europe Agreement provides, where appropriate, for the conclusion of an agreement on mutual recognition,

NOTING the close relationship between the European Community and Iceland, Liechtenstein and Norway through the Agreement on the European Economic Area, which makes it appropriate to consider the conclusion of a parallel European Conformity Assessment Agreement between Romania and these countries equivalent to this Protocol,

BEARING IN MIND the Parties' status as Contracting Parties to the Agreement establishing the World Trade Organisation, and conscious in particular of their obligations under the World Trade Organisation Agreement on Technical Barriers to Trade,

## HAVE AGREED AS FOLLOWS:

# ARTICLE 1

#### Purpose

The purpose of this Protocol is to facilitate the elimination by the Parties of technical barriers to trade in respect of industrial products. The means to this end is the progressive adoption and implementation by Romania of national law, which is equivalent to Community law.

This Protocol provides for:

(a) the mutual acceptance of industrial products, listed in the Annexes on mutual acceptance of industrial products, which fulfil the requirements for being lawfully placed on the market in one of the Parties;

(b) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent Romanian national law, both listed in the Annexes on mutual recognition of results of conformity assessment.

# ARTICLE 2

#### Definitions

For the purpose of this Protocol,

(a) "industrial products" means products as specified in Article 9 of the Europe Agreement and in Protocol 2 thereto;

(b) "Community law" means any legal act and implementing practice of the European Community applicable to a particular situation, risk or category of industrial products, as interpreted by the Court of Justice of the European Communities;

(c) "national law" means any legal act and implementing practice by which Romania takes over Community law applicable to a particular situation, risk or category of industrial products.

The terms used in this Protocol shall have the meaning given in Community law and Romanian national law.

#### Alignment of legislation

For the purpose of this Protocol, Romania agrees to take appropriate measures, in consultation with the Commission of the European Communities, to maintain or complete the take-over of Community law, in particular in the fields of standardisation, metrology, accreditation, conformity assessment, market surveillance, general safety of products, and producer liability.

# ARTICLE 4

#### Mutual acceptance of industrial products

The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the annexes on mutual acceptance of industrial products, which fulfil the requirements for being lawfully placed on the market of a Party, may be placed on the market of the other Party, without further restriction. This shall be without prejudice to Article 36 of the Europe Agreement.

# ARTICLE 5

# Mutual recognition of the results of conformity assessment procedures

The Parties agree to recognise the results of conformity assessment procedures carried out in accordance with the Community or national law listed in the Annexes on mutual recognition of the results of conformity assessment. The Parties shall not require procedures to be repeated, nor shall they impose additional requirements, for the purposes of accepting that conformity.

# ARTICLE 6

#### Safeguard clause

Where a Party finds that an industrial product placed on the market on its territory by virtue of this Protocol, and used in accordance with its intended use, may compromise the safety or health of users or other persons, or any other legitimate concern protected by legislation identified in the Annexes, it may take appropriate measures to withdraw such a product from the market, to prohibit its placing on the market, putting into service or use, or to restrict its free movement. The Annexes shall provide for the procedure to be applied in such cases.

# ARTICLE 7

#### **Extension of coverage**

As Romania adopts and implements further national law taking over Community law, the Parties may amend the Annexes or conclude new ones, in accordance with the procedure laid down in Article 14.

# Origin

The provisions of this Protocol shall apply to industrial products irrespective of their origin.

## ARTICLE 9

#### **Obligations of Parties as regards their authorities and bodies**

The Parties shall ensure that authorities under their jurisdiction which are responsible for the effective implementation of Community and national law shall continuously apply it. Further, they shall ensure that these authorities are able, where appropriate, to notify, suspend, remove suspension and withdraw notification of bodies, to ensure the conformity of industrial products with Community or national law or to require their withdrawal from the market.

The Parties shall ensure that bodies, notified under their respective jurisdiction to assess conformity in relation to requirements of Community or national law specified in the Annexes, continuously comply with the requirements of Community or national law. Further, they shall take all necessary steps to ensure that these bodies maintain the necessary competence to carry out the tasks for which they are notified.

# ARTICLE 10

#### **Notified bodies**

Initially, the bodies notified for the purpose of this Protocol shall be those included in the lists which Romania and the Community have exchanged before the completion of the procedures for entry into force

Afterwards, the following procedure shall apply for the notification of bodies to assess conformity in relation to the requirements of Community or national law specified in the Annexes:

(a) a Party shall forward its notification to the other Party in writing;

(b) on the acknowledgement of the other Party, given in writing, the body shall be considered as notified and as competent to assess conformity in relation to the said requirements specified in the Annexes from that date;

If a Party decides to withdraw the notification of a body under its jurisdiction, it shall inform the other Party in writing. The body will cease to assess conformity in relation to the said requirements specified in the Annexes from the date of its withdrawal at the latest. Nevertheless, conformity assessment carried out before that date shall remain valid, unless otherwise decided by the Association Council.

# Verification of notified bodies

Each Party may request the other Party to verify the technical competence and compliance of a notified body under its jurisdiction. Such request shall be justified in order to allow the Party responsible for the notification to carry out the requested verification and report speedily to the other Party. The Parties may also jointly examine the body, with the participation of the relevant authorities. To this end, the Parties shall ensure the full cooperation of bodies under their jurisdiction. The Parties shall take all appropriate steps, and use whatever available means may be necessary, with a view to resolving any problems which are detected.

If the problems cannot be resolved to the satisfaction of both Parties, they may notify the Chairman of the Association Council of their disagreement, giving their reasons. The Association Council may decide on appropriate action.

Unless and until decided otherwise by the Association Council, the notification of the body and the recognition of its competence to assess conformity in relation to the requirements of Community or national law specified in the Annexes shall be suspended in part or totally from the date on which the disagreement of the Parties has been notified to the Chairman of the Association Council.

# ARTICLE 12

# Exchange of information and cooperation

In order to ensure a correct and uniform application and interpretation of this Protocol, the Parties, their authorities and their notified bodies shall:

(a) exchange all relevant information concerning implementation of law and practice including, in particular, on procedure to ensure compliance of notified bodies;

(b) take part, as appropriate, in the relevant mechanisms of information, coordination and other related activities of the Parties;

(c) encourage their bodies to cooperate with a view to establishing mutual recognition arrangements in the voluntary sphere.

# ARTICLE 13

# Confidentiality

Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Protocol which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Protocol.

# Management of the Protocol

Responsibility for the effective functioning of this Protocol shall be borne by the Association Council in accordance with Article 106 of the Europe Agreement. In particular, it shall have the power to take decisions regarding:

- (a) amending the Annexes;
- (b) adding new Annexes;

(c) appointing a joint team or teams of experts to verify the technical competence of a notified body and its compliance with the requirements;

(d) exchanging information on proposed and actual amendments to the Community and national law referred to in the Annexes;

(e) considering new or additional conformity assessment procedures affecting a sector covered by an Annex;

(f) resolving any questions relating to the application of this Protocol.

The Association Council may delegate the above responsibilities set out under this Protocol, in accordance with Article 110(2) of the Europe Agreement.

# ARTICLE 15

#### Technical cooperation and assistance

The European Community may provide technical cooperation and assistance to Romania where necessary in order to support the effective implementation and application of this Protocol.

# ARTICLE 16

#### Agreements with other countries

Agreements on conformity assessment concluded by either Party with a country which is not a Party to this Protocol shall not entail an obligation upon the other Party to accept the results of conformity assessment procedures carried out in that third country, unless there is an explicit agreement between the Parties in the Association Council.

## **Entry into force**

This Protocol shall enter into force on the first day of the second month following the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective procedures for entry into force of this Protocol.

# ARTICLE 18

# **Status of the Protocol**

This Protocol shall constitute an integral part of the Europe Agreement.

This Protocol is drawn up in two originals in the Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Italian, Hungarian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Slovak, Slovene, Spanish, Swedish and Romanian languages, each text being equally authentic.

Done at Brussels,

# ANNEXES ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS

(for the record)

# ANNEXES ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

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# (1) Pressure equipment

#### DRAFT ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT PRESSURE EQUIPMENT

#### SECTION I

#### COMMUNITY AND NATIONAL LAW

- Community law: Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment
- National law: Government Decision no. 584/2004 establishing the conditions for placing on the market of pressure equipment, as subsequently amended.

#### SECTION II

#### NOTIFYING AUTHORITIES

#### European Community

| Belgium:        | Ministère des Affaires Economiques/Ministerie van Economische Zaken.   |
|-----------------|--|
| Czech Republic: | Úřad pro technickou normalizaci, metrologii a státní zkušebnictví.   |
| Germany:        | Bundesministerium für Arbeit und Sozialordnung.  |
| Greece:         | Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry). |
| Estonia:        | Majandus- ja Kommunikatsiooniministeerium.   |
| France:         | Ministère de l'emploi et de la solidarité, Direction des relations du travail, Bureau CT 5.                    |
| Ireland:        | Department of Enterprise and Employment.   |
| Italy:          | Ministero dell'Industria, del Commercio e dell'Artigianato.  |
| Latvia:         | Ekonomikas ministrija.   |
| Malta:          | Under the authority of the Government of Malta:  |
|                 | Consumer and Industrial Goods Directorate of the Malta Standards Authority.                                    |
| Hungary:        | Gazdasági és Közlekedési Minisztérium.   |
| Austria:        | Bundesministerium für Wirtschaft und Arbeit.   |

| Poland:          | Ministerstwo Gospodarki, Pracy i Polityki Społecznej.                  |
|------------------|--|
| Slovak Republic: | Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky. |
| Sweden:          | Under the authority of the Government of Sweden:                       |
|                  | Styrelsen för ackreditering och teknisk kontrol (SWEDAC).              |
| United Kingdom:  | Department of Trade and Industry.                                      |
| Romania          | Ministerul Economiei si Comertului – Ministry of Economy and Commerce. |
|                  |  |

# SECTION III

# NOTIFIED BODIES

#### European Community

Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Romania in accordance with Article 10 of this Protocol.

#### Romania

Bodies which have been designated by Romania in accordance with the Romanian national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

#### SECTION IV

#### SPECIFIC ARRANGEMENTS

#### Safeguard Clauses

- A. Safeguard clause relating to industrial products:
- 1. Where a Party has taken a measure to deny free access to its market:

for industrial products subject to this Annex bearing the CE marking;

or,

for industrial products subject to this Annex which are referred to in Article 3 (3) or article 14 of Directive 97/23/EC corresponding to Articles 10 and Article 17 respectively of Government Decision No. 584/2004, but for which CE marking is not required;

it shall immediately inform the other Party, indicating the reasons for its decision and how non-compliance has been assessed.

- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In the case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In the case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council which may decide to have an expertise carried out.
- 5. Where the Association Council finds that the measure is:
- (a) unjustified, the national authority of the Party which has taken the measure shall withdraw it;
- (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- B. Safeguard clause relating to harmonised standards:
- 1. Where Romania considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons therefore.
- 2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Association Council and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

#### DECLARATION BY THE COMMUNITY ON THE ATTENDANCE OF ROMANIAN REPRESENTATIVES AT COMMITTEE MEETINGS

In order to ensure a better understanding of the practical aspects of the application of the acquis communautaire, the Community declares that Romania is invited, under the following conditions, to the meetings of the committees established or referred to under the Community law on electrical safety, electromagnetic compatibility, machinery and gas appliances.

This participation shall be limited to meetings or parts thereof during which the application of the acquis is discussed; it shall not entail attendance at meetings intended to prepare and issue opinions on implementation or management powers delegated to the Commission by the Council.

This invitation may be extended, on a case-by-case basis, to groups of experts convened by the Commission.