

- D R A F T -  
Without prejudice

**PROTOCOL TO THE [*BASE AGREEMENT*]**  
**BETWEEN THE EUROPEAN UNION**  
**AND ITS MEMBER STATES, OF THE ONE PART,**  
**AND [*PARTNER COUNTRY*], OF THE OTHER PART,**  
**ON CONFORMITY ASSESSMENT AND**  
**ACCEPTANCE OF INDUSTRIAL PRODUCTS**

**ACAA**

**THE EUROPEAN UNION AND [PARTNER COUNTRY],**  
hereinafter referred to as “the Parties”,

WHEREAS [*partner country*] is a party to the [*base agreement*]

RECOGNISING that the adoption and implementation of Union law by [(*partner country*)] provides the opportunity to extend certain benefits of the internal market and to ensure its effective operation in certain sectors,

CONSIDERING that, in the sectors covered by this Agreement, [*partner country's*] national law substantially takes over Union 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 as a Protocol to the [*base agreement*] an Agreement on Conformity Assessment and Acceptance of Industrial Products (hereafter referred to as “this Agreement”) 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, including where appropriate the mutual recognition of the results of obligatory conformity assessment of industrial products, noting that Article [...] of the [*base agreement*] provides, where appropriate, for the conclusion of a European conformity assessment agreement,

NOTING the close relationship between the European Union 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 [(*partner country*)] and these countries equivalent to this Agreement,

[(*where the partner country is a WTO Member*) 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,]

[(*where the partner country is not a WTO Member*) BEARING IN MIND the status of the EU as a Contracting Party to the Agreement establishing the World Trade Organisation, and of the application for such status by [*partner country*], and conscious in particular of the obligations on such Contracting Parties under the World Trade Organisation Agreement on Technical Barriers to Trade,]

**HAVE AGREED AS FOLLOWS:**

## **Article 1**

### *Purpose and means*

1.1 The purpose of this Agreement is to facilitate the elimination by the Parties of technical barriers to trade in respect of certain industrial products, listed in the Annexes to this Agreement.

1.2 The means to this end are:

(a) the adoption and implementation by [*partner country*] of national technical regulations, standards and conformity assessment procedures which are equivalent to those of the Union (“Union law”);

(b) the implementation by [*partner country*] of a regulatory infrastructure which is equivalent to that in place in the Member States of the Union; and

(c) the mutual acceptance on their markets of both Parties of industrial products which fulfil the requirements for being lawfully placed on the market in one of the Parties, including where appropriate the mutual recognition of the results of obligatory conformity assessment of industrial products subject to Union law and to the equivalent [*partner country’s*] national law.

(d) the acceptance on their markets of both Parties of industrial products which fulfil the requirements for being lawfully placed on the market in [*partner country*] and any one of the Member States of the European Union, on conditions analogous to those applying to trade in goods between the Member States of the European Union.

## **Article 2**

### *Definitions*

For the purpose of this Agreement,

(a) “Industrial products” means products, as specified in Article [...] of the [*base agreement*] [(or this definition could be omitted: the scope of the agreement is in any case defined by the sectoral Annexes)];

(b) “Union law” means any legal act and implementing practice of the European Union 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 [*partner country*] takes over Union law applicable to a particular situation, risk or category of industrial products;

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- (d) “Responsible Authority” means a body under the jurisdiction of one of the Member States of the European Union or of [*partner country*] which is responsible for the effective implementation of Union and national law in a specified industrial sector, and which where appropriate has the responsibility for notifying Notified Bodies;
- (e) “Notified Body” means a body notified, by a Responsible Authority under the respective jurisdiction of one of the Parties to this Agreement, to the other Party, as competent to assess conformity in relation to requirements of Union or national law.

The terms used in this Agreement shall have the meaning given in Union law and [*partner country's*] national law.

### Article 3

#### *Alignment of legislation*

For the purpose of this Agreement, [*partner country*] agrees to take appropriate measures, in consultation with the European Commission, to take over and maintain Union law as it applies to the placing on the market of products covered by this Agreement, in particular, in the fields of standardisation, metrology, accreditation, conformity assessment, market surveillance, general safety of products, and producers’ liability.

### Article 4

#### *Technical infrastructure*

For the purpose of this Agreement, [*partner country*] agrees to take appropriate measures, in consultation with the European Commission, to establish and maintain appropriate Responsible Authorities in accordance with Article 9.

[*partner country*] agrees to establish and maintain bodies that are capable of sustaining the functions of standardisation, metrology, accreditation, market surveillance, assessment of general safety of products, and assessment and enforcement of producer liability on its territory at a level broadly equivalent to those in place in the Member States of the Union.

### Article 5

#### *Mutual acceptance of industrial products including their conformity assessment*

5.1 The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the Annexes on Acceptance of Regulated 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.

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5.2 Where products are subject to obligatory conformity assessment procedures to be carried out in accordance with the Union and national laws listed in the Annexes, the Parties further agree to recognise the results of such procedures without requiring them to be repeated, nor with the imposition of any additional requirements for the purposes of accepting such conformity assessment. [*if appropriate*: This shall be without prejudice to the provisions of Article [...] of the [Action Plan].]

## Article 6

### *Safeguard clause*

Where a Party finds that an industrial product placed on the market on its territory by virtue of this Agreement, 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*

If [*partner country*] adopts and implements further national law taking over Union law, the Parties may amend the Annexes or conclude new ones, in accordance with the procedure laid down in Article 14.

## Article 8

### *Origin*

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

## Article 9

### *Obligations of Parties as regards their Responsible Authorities and Notified Bodies*

9.1 (a) The Parties shall ensure that Responsible Authorities under their jurisdiction which are responsible for the effective implementation of Union and national law shall continuously apply it. Further, they shall ensure that these Responsible Authorities are able to ensure the conformity of industrial products with Union or national law or to require their withdrawal from the market and, where appropriate, to notify, suspend, remove suspension and withdraw the notification of Notified Bodies.

(b) The Parties shall notify each other of the names and addresses of their Responsible Authorities, and shall maintain a list of such bodies.

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

(b) The Parties shall notify each other of the names and addresses of their Notified Bodies, and shall maintain a list of such bodies.

## **Article 10**

### *Procedures for the recognition of Responsible Authorities and the notification of Notified Bodies*

10.1 The following procedure shall apply for the recognition of Responsible Authorities which are responsible for the effective implementation of Union and national law, to ensure the conformity of industrial products with Union or national law or to require their withdrawal from the market and, where appropriate, are able to notify, suspend, remove suspension and withdraw the notification of Notified Bodies:

- (a) a Party shall forward its nomination to the other Party in writing, stating the territory and title of the Annex to this Agreement under which the Responsible Authority is competent to carry out the tasks listed in Article 9.1, including as appropriate any limitations to such competence within the territory or the scope of the Annex;
- (b) on the acknowledgement of the other Party, given in writing, the Responsible Authority shall be considered as competent to carry out the tasks listed in Article 9.1 in relation to the Annexes for which it has been recognised from that date.

10.2 The following procedure shall apply for the notification of Notified Bodies to assess conformity in relation to the requirements of Union or national law specified in the Annexes:

- (a) a Party shall forward its notification to the other Party in writing, stating the title of the Annex to this Agreement under which the Notified Body is competent to assess conformity, and as appropriate any limitations to such competence within the scope of the Annex;
- (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.

10.3 If a Party decides to withdraw the notification of a Notified Body under its jurisdiction, it shall inform the other Party in writing. The Notified 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 *[joint committee or similar body set up under the base agreement]* .

## **Article 11**

### *Verification of notified bodies*

11.1 Each Party may request the other Party to verify the technical competence and compliance of a notified body, or a candidate notified body, under its jurisdiction. Such request shall be justified, in an objective and reasoned manner, 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.

11.2 If the problems cannot be resolved to the satisfaction of both Parties, they may notify the *[joint committee or similar body set up under the base agreement]* of their disagreement, giving (a) the reasons for the request to verify the technical competence and compliance of the notified body; and (b) the reasons why the problems cannot be resolved to the satisfaction of both Parties. The *[joint committee or similar body set up under the base agreement]* may decide on appropriate action.

11.3 Unless and until decided otherwise by the *[joint committee or similar body set up under the base agreement]*, the notification of the body and the recognition of its competence to assess conformity in relation to the requirements of Union 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 *[joint committee or similar body set up under the base agreement]*.

## **Article 12**

### *Exchange of information and cooperation*

In order to ensure a correct and uniform application and interpretation of this Agreement, and to encourage trade in industrial goods between them, the Parties, shall:

- (a) notify each other of relevant proposed and actual legislative amendments, and exchange information concerning the implementation of law and practice, including in particular on procedures to ensure the compliance of Notified Bodies on their territory with the rules applicable to them;
- (b) invite each other to take part, as appropriate, in their relevant mechanisms of information exchange, coordination and other related activities;

- (c) encourage their Notified 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 Agreement 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 Agreement.

### **Article 14**

#### *Management of the Agreement*

Responsibility for the effective functioning of this Agreement shall be borne by the [*joint committee or similar body set up under the base agreement*]. In particular, it shall have the power to take decisions regarding:

- (a) amending and withdrawing Annexes;
- (b) adding new Annexes;
- (c) appointing experts to verify the technical competence of a notified body and its compliance with the requirements applicable to them, in accordance with Article 11.1;
- (d) exchanging information on proposed and actual amendments to the Union law 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 Agreement;
- (g) referring questions for decision to the [*disputes settlement mechanism*]

The [*joint committee or similar body set up under the base agreement*] may delegate the above responsibilities set out under this Agreement, in accordance with Article [...] of the [*base agreement*].

### **Article 15**

#### *Technical cooperation*

The Parties shall cooperate where necessary in order to support the effective implementation and application of this Agreement.



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## **Article 16**

### *Agreements with other countries*

1. This Agreement may, by explicit agreement between the Parties, for example in the [*joint committee or similar body set up under the base agreement*], be extended to cover the acceptance of industrial products from third countries with which the Union has concluded an Agreement similar to this Agreement in corresponding sectors.
2. Where the European Union notifies (*partner country*) that it has made an Agreement similar to this Agreement with another country, that covers the acceptance of industrial products in corresponding sectors, (*partner country*) shall consider making an Agreement with the other country that provides for such an extension.

## **Article 17**

### *Entry into force*

This Agreement 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 Agreement.

## **Article 18**

### *Status of the Agreement*

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

Done at

**ANNEX ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS**  
[(*Sample annex for a New Approach sector*)]

[*sector*]

SECTION I

UNION AND NATIONAL LAW

Union law: Directive of the Parliament and the Council on the approximation of the laws of the Member States relating to [...](OJ L..., ..., p. ), as amended

National law:

SECTION II

RESPONSIBLE AUTHORITIES [AND NOTIFIED BODIES (*The references to Notified Bodies may be omitted for sectors that do not have them*)]

*1. Lists of Responsible Authorities [and of Notified Bodies.]*

*European Union*

Bodies which have been designated by the Member States of the Union in accordance with the Union law of Section I and notified to [*partner country*] in accordance with Article 10 of this Agreement.

[*partner country*]

Bodies which have been designated by [*partner country*] in accordance with the [*partner country's*] national law of Section I and notified to the Union in accordance with Article 10 of this Agreement.

SECTION III  
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 bearing the CE marking, subject to this Annex, 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 *[joint committee or similar body set up under the base agreement]* which may decide to have an expert appraisal carried out.
5. Where the *[joint committee or similar body set up under the base agreement]* 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 *[partner country]* 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 *[joint committee or similar body set up under the base agreement]* .
2. The *[joint committee or similar body set up under the base agreement]* shall consider the matter and may request the Union to proceed in accordance with the procedure provided for in the Union legislation identified in this Annex.
3. The Union shall keep the *[joint committee or similar body set up under the base agreement]* and the other Party informed of the proceedings.
4. The outcome of the procedure shall be notified to the other Party.