The attached draft text was shared by the UK negotiating team with the Task Force for Relations with the United Kingdom as a draft negotiating document, that is, to be shared among negotiating teams only, in line with the provisions of the Terms of Reference.

The text is now being made public.

ANNEXES TO THE DRAFT WORKING TEXT FOR A COMPREHENSIVE FREE TRADE AGREEMENT BETWEEN THE UNITED KINGDOM AND THE EUROPEAN UNION

ANNEX 3-A

SUPPLIER'S STATEMENT

[…]

ANNEX 3-B

PRODUCT-SPECIFIC RULES OF ORIGIN

[…]

ANNEX 3-C

TOLERANCE FOR TEXTILE AND APPAREL PRODUCTS

[…]

ANNEX 3-D

TEXT OF THE ORIGIN DECLARATION

[…]

ANNEX 5-A

THE MUTUAL ACCEPTANCE OF THE RESULTS OF CONFORMITY ASSESSMENT

ARTICLE 1

Definitions

Except as otherwise provided, the definitions contained in Annex 1 to the TBT Agreement apply to this Annex. The following additional definitions also apply:

"accreditation" means third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks;

"accreditation body" means an authoritative body that performs accreditation;[1]

"attestation" means the issuing of a statement based on a decision following review, that fulfilment of specified technical requirements has been demonstrated;

"conformity assessment" means a process to determine whether relevant requirements in technical regulations have been fulfilled. For the purpose of this Annex, conformity assessment does not include accreditation;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

"Decision 768/2008/EC" means Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC;

"European Union technical regulation" means a technical regulation of the Union listed in Appendix 1 and any measure adopted by a Member State implementing a Directive of the Union listed in Annex 1;

"in-house body" means a conformity assessment body that performs conformity assessment activities for the entity of which it forms a part, such as, in the case of the Union and its Member States, an accredited in-house body fulfilling the requirements in Article R21 of Annex I to Decision 768/2008/EC;

"Reference Article R17" means R17 of Annex I to Decision 768/2008/EC and references to its requirements shall include for the purposes of medical devices any additional requirements as set out in Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;

[1] The authority of an accreditation body is generally derived from central government

“third-party conformity assessment” means conformity assessment that is performed by a person or body that is independent of the person or organisation that provides the product, and of user interests in that product;

“third-party conformity assessment body” means a conformity assessment body that performs third-party conformity assessments;

“UK technical regulation” means a technical regulation of the United Kingdom listed in Appendix 5-A-1.

ARTICLE 2

Scope and exceptions

1. This Annex applies to those categories of goods which are regulated by technical regulations listed in Appendix 5-A-1 for which a Party recognises conformity assessment bodies for the purpose of assessing conformity of goods with that Party's technical regulations.

2. This is without prejudice to the sector specific provisions laid down in Annexes 5-B, 5-C, 5-D, 5-E and 5F to Chapter 5.

3. The Parties shall give positive consideration to making this Annex applicable to additional categories of goods which may become subject to third-party conformity assessment by recognised non-governmental bodies pursuant to technical regulations adopted by a Party after the date of entry into force of this Agreement. To that end, the Party shall promptly notify the other Party, in writing, of any such technical regulation that is adopted after the entry into force of this Agreement. If the other Party expresses an interest in including a new category of goods in Appendix 5-A-1 but the notifying Party does not agree to it, the notifying Party shall provide to the other Party, upon request, the reasons that justify its refusal to expand the scope of the Annex.

4. If the Parties decide in accordance with paragraph 3 to include additional categories of goods in Appendix 5-A-1, they shall request the Committee on Technical Barriers to Trade, pursuant to Article 17.1(c), to make recommendations to the Joint Committee to amend Appendix 5-A-1.

5. This Annex does not require the recognition or acceptance by a Party that the other Party's technical regulations are equivalent to its own.

6. This Annex does not limit the ability of a Party to prepare, adopt, apply or amend conformity assessment procedures in accordance with Article 5 of the TBT Agreement.

7. This Annex does not affect or modify the laws or obligations in the territory of a Party applicable to civil liability.

ARTICLE 3

Recognition of conformity assessment bodies

1. The United Kingdom shall recognise a third-party conformity assessment body established in the Union as competent to assess conformity with specific UK technical regulations, under conditions no less favourable than those applied for the recognition of third-party conformity assessment bodies established in the United Kingdom, provided that one of the conditions set out in sub-paragraph (a) or (b) is met and in either case the conditions set out in sub-paragraph (c) are met:

   (a) the third-party conformity assessment body:

      (i) is accredited in respect of those specified UK technical regulations, by an accreditation body appointed by the United Kingdom, as competent to assess conformity with those specific UK technical regulations; or

      (ii) is accredited, by an accreditation body established in the Union that is recognised pursuant to Article 12, as competent to assess conformity with those specific UK technical regulations; or

   (b) when appropriate accreditation is not available or when special circumstances apply, the designation is accompanied by documentary evidence which attests to the conformity assessment body's competence to assess conformity with those specific UK technical regulations and is approved by a government authority;

   and in any case:

   (c) the following conditions are satisfied:

      (i) the conformity assessment body is designated by a Member State of the Union in accordance with the procedures set out in Article 5;

      (ii) there are no unresolved objections pursuant to Article 6;

      (iii) the designation made in accordance with the procedures set out in Article 5 is not withdrawn by a Member State of the Union; and

      (iv) after the expiry of the 30 day period of time referred to in Article 6.1 or 6.2, the conformity assessment body established in the Union continues to meet all the conditions described in Article 5.5.

2. The Union shall recognise a third-party conformity assessment body established in the United Kingdom as competent to assess conformity with specific European Union technical regulations, under conditions no less favourable than those applied for the recognition of third-party conformity assessment bodies established in the Union, provided that one of the conditions set out in sub-paragraph (a) or (b) is met and in either case the conditions set out in sub-paragraph (c) are met:

(a) the third-party conformity assessment body:

(i) is accredited in respect of those specific European Union technical regulations, by an accreditation body appointed by one of the Member States of the Union; or

(ii) is accredited, by an accreditation body established in the United Kingdom that is recognised pursuant to Article 12, as competent to assess conformity with those specific European Union technical regulations; or

(b) when appropriate accreditation is not available or when special circumstances apply, the designation is accompanied by documentary evidence which attests to the conformity assessment body's competence to assess conformity with those specific European Union technical regulations and is approved by a government authority;

and in any case:

(c) the following conditions are satisfied:

(i) the third-party conformity assessment body is designated by the United Kingdom in accordance with the procedures set out in Article 5;

(ii) there are no unresolved objections pursuant to Article 6;

(iii) the designation made in accordance with the procedures set out in Article 5 is not withdrawn by the United Kingdom; and

(iv) after the expiry of the 30 day period of time referred to in Article 6.1 or 6.2, the third-party conformity assessment body continues to meet all the conditions described in Article 5.2.

3. Each Party shall maintain and publish a list of recognised conformity assessment bodies which includes the scope for which each body is recognised. The Union shall assign an identification number to conformity assessment bodies established in the United Kingdom that are recognised under this Annex, and shall list those conformity assessment bodies in the information system of the Union, namely the New Approach Notified and Designated Organisations ("NANDO"). The United Kingdom shall assign an identification number to conformity assessment bodies established in the Union that are recognised under this Annex, and shall list those conformity assessment bodies in the information system of the United Kingdom, namely the UK Market Conformity Assessment Bodies ("UKMCAB").

ARTICLE 4

Accreditation of conformity assessment bodies

1. The Parties recognise that, where relevant, a conformity assessment body should seek accreditation from an accreditation body that is in the territory of the Party in which the conformity assessment body is established, provided that that accreditation body has been recognised pursuant to Article 12 as able to grant the specific accreditation sought by the conformity assessment body. If there is no accreditation body in the territory of a Party that is recognised pursuant to Article 12 as able to grant a specific accreditation sought by a conformity assessment body established in the territory of that Party, then:

   (a) each Party shall take such reasonable measures as may be available to it to ensure that accreditation bodies in its territory accredit conformity assessment bodies established in the territory of the other Party under conditions no less favourable than those applied to conformity assessment bodies established in its territory;

   (b) a Party shall not adopt or maintain measures which limit the ability of accreditation bodies in its territory to accredit, or discourage those accreditation bodies from accrediting, on conditions no less favourable than those applied for the accreditation of conformity assessment bodies established in the recognising Party's territory, conformity assessment bodies established in the territory of the other Party;

   (c) a Party shall not adopt or maintain measures requiring or encouraging accreditation bodies in its territory to apply conditions for the accreditation of conformity assessment bodies in the territory of the other Party that are less favourable than those applied for the accreditation of conformity assessment bodies in its territory.

2. This Article is without prejudice to the provisions for recognition of conformity assessment bodies set out in Article 3.1(b) or 3.2(b).

3. Accreditation shall constitute a presumption of technical competence in relation to the requirements of the other Party when:

   (a) the accreditation process is conducted in conformity with the relevant international documentation (ISO/IEC 17000 series); and either

   (b) the accreditation body participates in mutual recognition arrangements where they are subject to peer evaluation, which involves evaluation by individuals with recognised expertise in the field of the work being evaluated, of the competence of accreditation bodies and conformity assessment bodies accredited by them; or

   (c) the accreditation bodies take part, in accordance with procedures to be agreed, in comparison programmes and exchanges of technical experience in order to ensure the continued confidence in the technical competence of the accreditation bodies and conformity assessment bodies. Such programmes may include joint assessments, special cooperation programmes or peer evaluation.

ARTICLE 5

Designation of conformity assessment bodies

1. A Party shall designate a conformity assessment body by notifying the contact point of the other Party and sending to that contact point the information described in Appendix 5-A-2. The Union shall allow the United Kingdom to use the Union's electronic notification tool for those purposes.

2. The United Kingdom shall only designate a conformity assessment body that meets the following conditions and shall take reasonable measures to ensure that the conditions continue to be met:

   (a) the conformity assessment body meets the requirements set out in Reference Article R17 , except that establishment under national law is interpreted as meaning the law of the United Kingdom for the purposes of this Annex; and

   (b) one of the following conditions are met:

      (i) the conformity assessment body is accredited, by an accreditation body appointed by a Member State of the Union, as competent to assess conformity with the European Union technical regulations for which the conformity assessment body is being designated;

      (ii) the conformity assessment body is accredited, by an accreditation body established in the United Kingdom that is recognised pursuant to Articles 12 or 15 as competent to assess conformity with the European Union technical regulations for which the conformity assessment body is being designated; or

      (iii) the designation is accompanied by documentary evidence which attests to the arrangements in place to ensure that the conformity assessment body meets the requirements of Reference Article R17 and is approved by a government authority. Documentary evidence may include:

         (1) participation in regional/international mutual recognition arrangements or certification systems;

         (2) regular peer evaluations;

         (3) proficiency testing; and

         (4) comparisons between conformity assessment bodies.

3. The Parties shall deem the applicable requirements of Reference Article R17 to be met when the conformity assessment body is designated pursuant to any procedure described in paragraph 2(b)(i), (ii) or (iii) and, where applicable, if the accreditation body requires, as a condition for granting the accreditation, that the conformity assessment body meet requirements equivalent to the applicable requirements of Reference Article R17.

4. If the Union considers revising the requirements set out in Reference Article R17, it shall consult the United Kingdom at the earliest stage of, and throughout, the review process with a view to ensuring that conformity assessment bodies in the territory of the UK continue to meet any revised requirements on no less favourable conditions than conformity assessment bodies in the territory of the Union.

5. A Member State of the Union shall only designate a conformity assessment body that meets the following conditions and shall take reasonable measures to ensure that the conditions continue to be met:

   (a) the conformity assessment body meets the requirements set out in the UK legislation in Appendix 5-A-1, except that any requirement as to establishment in the United Kingdom is met if the body is established in the Union; and

   (b) one of the following conditions are met:

      (i) the conformity assessment body is accredited, by an accreditation body established in and recognised by the United Kingdom, as competent to assess conformity with the UK technical regulations for which the conformity assessment body is being designated;

      (ii) the conformity assessment body is accredited, by an accreditation body established in the Union that has been recognised pursuant to Article 12 or 15, as competent to assess conformity with the UK technical regulations for which the conformity assessment body is being designated; or

      (iii) the designation is accompanied by documentary evidence which attests to the arrangements in place to ensure that the conformity assessment body meets the requirements set out in the UK legislation in Appendix 5-A-1. Documentary evidence may include:

         (1) participation in regional/international mutual recognition arrangements or certification systems;

         (2) regular peer evaluations;

         (3) proficiency testing; and

         (4) comparisons between conformity assessment bodies.

6. The Parties shall deem the requirements set out in the UK legislation in Appendix 5-A-1 to be met when the conformity assessment body is designated pursuant to any procedure described in paragraph 5(b)(i), (ii) or (iii) and if, where applicable, the accreditation body requires, as a condition for granting the accreditation, that the conformity assessment body meet requirements equivalent to the applicable requirements set out in the UK legislation in Appendix 5-A-1.

7. If the United Kingdom considers revising the requirements set out in the UK legislation in Appendix 5-A-1, it shall consult the Union at the earliest stage of, and throughout, the review process with a view to ensuring that conformity assessment bodies in the territory of the Union continue to meet any revised requirements on no less favourable conditions than conformity assessment bodies in the territory of the United Kingdom.

8. A Party may refuse to recognise a conformity assessment body that does not meet the conditions in paragraph 2 or 5, as the case may be.

ARTICLE 6

Objections to the designation of conformity assessment bodies

1. A Party may object to the designation of a conformity assessment body, within 30 days of the notification by the other Party pursuant to Article 5.1, if:

   (a) the Party which designated the conformity assessment body failed to provide the information described in Appendix 5-A-2; or

   (b) the Party has reasons to believe that the conformity assessment body that is designated does not meet the conditions described in Article 5.2 or 5.5.

2. Following any subsequent transmission of information by the other Party, a Party may object within 30 days of the receipt of that information, if the information remains insufficient to demonstrate that the designated conformity assessment body meets the conditions described in Article 5.2 or 5.5.

ARTICLE 7

Challenges to designations of conformity assessment bodies

1. A Party which has recognised a conformity assessment body under this Annex may challenge the competence of that conformity assessment body if:

   (a) the Party which designated the conformity assessment body failed to take the actions required by Article 11.3, following a notification by the other Party of the non-conformity with applicable technical regulations of a product that had been assessed as being in conformity with those technical regulations by that conformity assessment body; or

   (b) the Party has reasons to believe that the results of conformity assessment activities performed by that conformity assessment body do not provide sufficient assurances that the products assessed by that body as conforming with applicable technical regulations are in fact in conformity with those technical regulations.

2. A Party which challenges the competence of a recognised conformity assessment body under this Annex shall immediately notify the Party which designated the conformity assessment body of the challenge, and provide the reasons for the challenge.

3. A Party that:

   (a) has challenged the competence of a recognised conformity assessment body under this Annex; and

   (b) has well-founded reasons to believe that the products assessed to be in conformity with applicable technical regulations by that conformity assessment body may fail to conform to its technical regulations,

   may refuse to accept the results of that conformity assessment body's conformity assessment activities until the challenge is resolved or the recognising Party has ceased to recognise the conformity assessment body in accordance with paragraph 5.

4. The Parties shall cooperate and make reasonable efforts to resolve the challenge promptly.

5. Without prejudice to paragraph 3, the recognising Party may cease to recognise the conformity assessment body whose competence is challenged if:

   (a) the Parties resolve the challenge by concluding that the recognising Party has raised valid concerns as to the competence of the conformity assessment body;

   (b) the Party which designated the conformity assessment body failed to complete the actions required by Article 11.3 within 60 days after being notified pursuant to sub-paragraph 1(a); or

   (c) the recognising Party objectively demonstrates to the other Party that the results of conformity assessment activities performed by that conformity assessment body do not provide sufficient assurance that the products assessed by it as conforming with the applicable technical regulations are in fact in conformity with these technical regulations, and

   (d) the challenge has not been resolved within 120 days after the Party that had designated the conformity assessment body has been notified of the challenge pursuant to paragraph 1.

ARTICLE 8

Withdrawals of designations of conformity assessment bodies

1. A Party shall withdraw the designation, or modify the scope of the designation, as appropriate, of a conformity assessment body it has designated if the Party becomes aware that:

(a) the conformity assessment body's scope of accreditation has been reduced;

(b) the conformity assessment body's accreditation lapses;

(c) the conformity assessment body no longer meets the other conditions described in Article 5.2 or 5.5; or

(d) the conformity assessment body is no longer willing, or is otherwise no longer competent or able, to assess conformity within the scope for which it was designated.

2. A Party shall notify the other Party, in writing, of a withdrawal or modification of the scope of a designation under paragraph 1.

3. When a Party withdraws the designation or modifies the scope of the designation of a conformity assessment body owing to concerns about the competence or the continued fulfilment by that conformity assessment body of the requirements and responsibilities to which it is subject under Article 5, it shall communicate the reasons for its decision in writing to the other Party.

4. When communicating with the other Party, a Party shall indicate the date as of which it considers that any of the conditions or concerns enumerated under paragraphs 1 or 3 may have applied to the conformity assessment body.

5. Without prejudice to Article 7.5, the recognising Party may immediately cease to recognise a conformity assessment body as competent if:

(a) the conformity assessment body's accreditation lapses;

(b) the conformity assessment body voluntarily withdraws its recognition;

(c) the designation of the conformity assessment body is withdrawn pursuant to this Article;

(d) the conformity assessment body ceases to be established in the territory of the other Party; or

(e) the recognising Party ceases to recognise the accreditation body that accredited the conformity assessment body pursuant to Article 12 or 15.

ARTICLE 9

Acceptance of the results of conformity assessment by recognised conformity assessment bodies

1. A Party shall accept the results of conformity assessment activities performed by conformity assessment bodies established in the other Party's territory which the Party recognises in accordance with Article 3 under conditions no less favourable than those applied to the results

of conformity assessment activities performed by recognised conformity assessment bodies in its territory. The Party shall accept these results regardless of the nationality and location of the supplier or manufacturer, or of the country of origin of the product for which the conformity assessment activities are performed.

2. If a Party has ceased to recognise a conformity assessment body established in the territory of the other Party, it may cease to accept the results of conformity assessment activities performed by that conformity assessment body from the date when it ceased to recognise that conformity assessment body in accordance with the provisions of this Annex. Unless the Party has reason to believe that the conformity assessment body established in the territory of the other Party was not competent to assess conformity of products with the technical regulations of the Party prior to the date when the Party ceased to recognise that conformity assessment body, the Party shall continue to accept the results of conformity assessment activities performed by that conformity assessment body prior to the date when the Party ceased to recognise the conformity assessment body, even though the products may have been placed on the market of the Party after that date.

ARTICLE 10

Acceptance of results of conformity assessment by in-house bodies

1. The Union shall accept the results of conformity assessment activities performed by an accredited in-house body established in the United Kingdom under conditions no less favourable than those applied to the results of conformity assessment activities performed by an accredited in-house body established in the territory of one of the Member States of the Union, provided that:

   (a) the in-house body established in the United Kingdom is accredited, by an accreditation body that has been appointed by one of the Member States of the Union, as competent to assess conformity with European Union technical regulations; or

   (b) the in-house body established in the United Kingdom is accredited, by an accreditation body that has been recognised pursuant to Article 12, as competent to assess conformity with European Union technical regulations.

2. The United Kingdom shall accept the results of conformity assessment activities performed by an accredited in-house body established in the Union under conditions no less favourable than those applied to the results of conformity assessment activities performed by an accredited in-house body established in the territory of the United Kingdom, provided that:

   (a) the in-house body established in the Union is accredited, by an accreditation body that has been appointed by the United Kingdom, as competent to assess conformity with UK technical regulations; or

   (b) the in-house body established in the Union is accredited, by an accreditation body that has been recognised pursuant to Article 12, as competent to assess conformity with UK technical regulations.

3. Results pursuant to paragraphs 1 and 2 shall be accepted regardless of the country of origin of the product for which the conformity assessment activities were performed.

ARTICLE 11

Market surveillance, enforcement and safeguards

1. Except for customs procedures, a Party shall ensure that activities performed by market surveillance or enforcement authorities for the inspection or verification of conformity with applicable technical regulations for products assessed by a recognised conformity assessment body established in the territory of the other Party or an in-house body which meets the conditions of Article 10, are conducted under conditions no less favourable than those conducted with respect to products assessed by conformity assessment bodies in the territory of the recognising Party. The Parties shall co-operate as necessary in the conduct of these activities.

2. If a product's placement or use on the market could compromise the fulfilment of a legitimate objective, a Party may adopt or maintain measures with respect to that product provided that they are consistent with this Agreement. These measures can include withdrawing the product from the market, prohibiting its placement or use on the market or restricting its movement on the market. A Party that adopts or maintains such measures shall promptly inform the other Party and, at the request of the other Party, provide its reasons for adopting or maintaining these measures.

3. A Party shall, upon receipt of a written complaint by the other Party, which must be supported by evidence, that products assessed by a conformity assessment body that the Party designated do not comply with applicable technical regulations:

   (a) promptly seek additional information from the designated conformity assessment body, its accreditation body and relevant operators when necessary;

   (b) investigate the complaint; and

   (c) provide the other Party with a written reply to the complaint.

4. A Party may take the actions in paragraph 3 through an accreditation body.

ARTICLE 12

Recognition of accreditation bodies

1. A Party ("recognising Party") shall, in accordance with the procedure described under paragraphs 2 and 3, recognise an accreditation body established in the territory of the other Party ("nominating Party") as competent to accredit conformity assessment bodies as,

themselves, competent to assess conformity with the relevant technical regulations of the recognising Party.

2. The nominating Party may request that the other Party recognise an accreditation body established on its territory as competent by providing a notification to the recognising Party that includes the following information regarding that accreditation body ("nominated accreditation body"):

   (a) its name, address and contact details;

   (b) evidence that its authority is derived from central government;

   (c) whether it acts on a non-commercial and non-competitive basis;

   (d) evidence of its independence from the conformity assessment bodies it assesses and from commercial pressures, in order to ensure that no conflicts of interest with conformity assessment bodies occur;

   (e) evidence that it is organised and operated so as to safeguard the objectivity and impartiality of its activities and the confidentiality of the information it obtains;

   (f) evidence that each decision relating to the attestation of competence of conformity assessment bodies is taken by a competent person different from those who carry out the assessment;

   (g) the scope for which its recognition is requested;

   (h) evidence of its competence to accredit conformity assessment bodies within the scope for which its recognition is requested, referring to applicable international standards, guides and recommendations, and applicable European Union or UK standards, technical regulations and conformity assessment procedures;

   (i) evidence of its internal procedures to ensure efficient management and appropriate internal controls, including the procedures in place for documenting the duties, responsibilities and authorities of personnel who can affect the quality of the assessment as well as the attestation of competence;

   (j) evidence of the number of competent personnel at its disposal, which should be sufficient for the proper performance of its tasks, and of the procedures in place for monitoring the performance and competence of the personnel involved in the accreditation process;

   (k) whether or not it is appointed for the scope for which its recognition is requested in the territory of the nominating Party;

   (l) evidence of its status as a signatory to the International Laboratory Accreditation Cooperation ("ILAC") or International Accreditation Forum ("IAF") multilateral recognition arrangements; and

(m) any other information that the Parties may decide is necessary.

3. The Parties recognise that differences may exist between their respective standards, technical regulations and conformity assessment procedures. When such differences exist, the recognising Party may seek to satisfy itself that the nominated accreditation body is competent to accredit conformity assessment bodies as competent to assess conformity with the relevant technical regulations of the recognising Party. The recognising Party may satisfy itself based on an arrangement establishing cooperation between the Union and the United Kingdom accreditation systems.

4. Pursuant to a request made under paragraph 2, and subject to paragraph 3, a Party shall recognise a competent accreditation body established in the territory of the other Party under conditions no less favourable than those applied to the recognition of accreditation bodies established in its territory.

5. The recognising Party shall respond in writing within 60 days to a request made under paragraph 2, and provide the following information in its response:

   (a) that it recognises the nominating Party's accreditation body as competent to accredit conformity assessment bodies for the scope proposed;

   (b) that it will recognise the nominating Party's accreditation body as competent to accredit conformity assessment bodies for the scope proposed following necessary legislative or regulatory amendments. Such a response must include an explanation of the amendments required and an estimate of the period of time required for the entry into force of the amendments;

   (c) that the nominating Party failed to provide the information described in paragraph 2. Such a response must include a statement of what information is missing; or

   (d) that it does not recognise the nominated accreditation body as competent to accredit conformity assessment bodies for the scope proposed. Such a statement must be justified in an objective and reasoned manner, and state explicitly the conditions under which recognition would be granted.

6. Each Party shall publish the names of the accreditation bodies of the other Party that it recognises, and for each accreditation body, the scope of the technical regulations for which it recognises that accreditation body.

ARTICLE 13

Cessation of the recognition of accreditation bodies

1. If an accreditation body that is recognised by a Party pursuant to Article 12 ceases to be a signatory of a multilateral arrangement referred to in sub-paragraph (l) of Article 12.2 or of a

cooperation arrangement of the type described in Article 12.3, the recognising Party may cease to recognise that accreditation body as competent, as well as any conformity assessment bodies recognised on the basis that they were accredited solely by that accreditation body.

ARTICLE 14

Challenges to the recognition of accreditation bodies

1. Without prejudice to Article 13, the recognising Party may challenge the competence of an accreditation body that it has recognised under Article 12 on the grounds that the accreditation body is no longer competent to accredit conformity assessment bodies as, themselves, competent to assess conformity with the relevant technical regulations of the recognising Party. The recognising Party shall immediately notify the nominating Party of the challenge and shall justify its reasons in an objective and reasoned manner.

2. The Parties shall cooperate and make reasonable efforts to promptly resolve the challenge. The Parties shall ensure that their respective accreditation bodies seek to resolve the challenge on behalf of the Parties.

3. The recognising Party may cease to recognise the nominated accreditation body whose competence is challenged and any conformity assessment bodies recognised on the basis that they were accredited solely by that accreditation body if:

   (a) the Parties, including through the Union and United Kingdom accreditation systems, resolve the challenge by concluding that the recognising Party has raised valid concerns as to the competence of the nominated accreditation body; or

   (b) the recognising Party objectively demonstrates to the other Party that the accreditation body is no longer competent to accredit conformity assessment bodies as, themselves, competent to assess conformity with the relevant technical regulations of the recognising Party, and the challenge has not been resolved within 120 days after the nominating Party has been notified of the challenge.

ARTICLE 15

Transition from the EU Single Market

1. The Union recognises:

   (a) the United Kingdom Accreditation Service (UKAS) in respect of accreditation services for which it was recognised by the Union immediately prior to the date of the entry into force of this Agreement, as if it had been recognised pursuant to Article 12 (and any reference to recognition of accreditation bodies under Article 12 shall include recognition of UKAS);

(b) that UKAS is competent to assess conformity assessment bodies as themselves competent to assess conformity with the relevant European Union technical regulations; and

(c) any conformity assessment body as competent to assess for the conformity assessment procedures for which it was, immediately prior to the date of entry into force of this Agreement;

(i) notified by the United Kingdom to the European Commission, the United Kingdom and the Member States of the Union using the Union's electronic notification tool; and

(ii) listed on the New Approach Notified and Designated Organisations ("NANDO").

2. The United Kingdom recognises:

(a) the accreditation bodies of the Union in respect of accreditation services for which they were recognised by the United Kingdom immediately prior to the date of the entry into force of this Agreement, as if they had been recognised pursuant to Article 12 (and any reference to recognition of accreditation bodies under Article 12 shall include recognition of those bodies);

(b) that those accreditation bodies are competent to assess conformity assessment bodies as themselves competent to assess conformity with the relevant UK technical regulations; and

(c) any conformity assessment body as competent to assess for the conformity assessment procedures for which it was, immediately prior to the date of entry into force of this Agreement and which are equivalent to the procedures required in the relevant UK technical regulations;

(i) notified to the European Commission, the United Kingdom and the Member States of the Union using the Union's electronic notification tool; and

(ii) listed on NANDO.

3. The results of conformity assessment activities performed by a body satisfying Article 15(1)(c) or Article 15(2)(c) prior to the date of entry into force of this Agreement shall continue to be recognised as if they had been recognised under Article 9 unless a Party decides otherwise based on health, safety or environmental considerations. For the avoidance of doubt, conformity assessment activities under this Annex performed after the date of entry into force of this Agreement must be performed in accordance with the technical regulations of the other Party.

ARTICLE 16

Communication

1. Each Party shall identify contact points responsible for communications with the other Party related to any matter arising under this Annex.

2. The contact points may communicate by electronic mail, video-conferencing or other means on which they decide.

ARTICLE 17

Management of this Annex

1. For the purposes of this Annex, the functions of the Committee on Technical Barriers to Trade include:

   (a) managing the implementation of this Annex;

   (b) addressing any matter that a Party may raise related to this Annex;

   (c) making recommendations to the Joint Committee to amend this Annex ;

   (d) taking any other step that the Parties consider will assist them in implementing this Annex; and

   (e) reporting to the Joint Committee on the implementation of this Annex, as appropriate.

APPENDIX 5-A-1

PRODUCT COVERAGE

The applicable laws, regulations and administrative provisions are the following, including any amendment thereto or replacement thereof, irrespective of the date of adoption, entry into force or application of the amendment:[2]

1) Electromagnetic compatibility;

Union	United Kingdom
Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79).	The Electromagnetic Compatibility Regulations 2016 (S.I. 2016/1091).

2) Radio and telecommunications terminal equipment;

Union	United Kingdom
Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).	The Radio Equipment Regulations 2017 (S.I. 2017/1206)

3) Machinery, including parts, components, including safety components, interchangeable equipment, and assemblies of machines;

[2] References in this list to Retained EU Law are deemed to be references to such legislation, as amended by the United Kingdom to apply to the United Kingdom.

Union	United Kingdom
Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (as amended by Directive 2009/127/EC of the European Parliament and of the Council amending Directive 2006/42/EC with regard to machinery for pesticide application) (OJ L 157, 9.06.2006 p. 24)	The Supply of Machinery (Safety) Regulations 2008 (S.I. 2008/1597)

4) Equipment for use outdoors as it relates to noise emission in the environment;

Union	United Kingdom
Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 03.07.2000 p1)	Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 (S.I. 2001/1701)

5) Equipment, machines, apparatus, devices, control components, protection systems, safety devices, controlling devices and regulating devices, and related instrumentation and prevention and detection systems for use in potentially explosive atmospheres (ATEX equipment);

Union	United Kingdom
Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast) (OJ L 96, 29.03.2014, p. 309)	The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (S.I. 2016/1107)

6) Medical devices;

Union	United Kingdom
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	The Medical Devices Regulations 2002 Retained Regulation 2017/745

7) In-vitro medical devices;

Union	United Kingdom
[Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	The Medical Devices Regulations 2002 Retained Regulation 2017/746

8) Pressure equipment, including vessels, piping, accessories and assemblies, transportable and simple;

Union	United Kingdom
Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast) (OJ L 189, 27.06.2014 p. 164, as corrected by OJ L 157, 23.06.2015, p. 112)	The Pressure Equipment (Safety) Regulations 2016 (S.I. 2016/1105)

9) Simple pressure vessels;

Union	United Kingdom
Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.03.2014, p. 45)	The Simple Pressure Vessels (Safety) Regulations 2016 (S.I. 2016/1092)

10) Transportable pressure equipment;

Union	United Kingdom
Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC	The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009

11) Construction products;

Union	United Kingdom
Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p 5)	The Construction Products Regulations 2013 (S.I. 2013/1387) Retained Regulation 305/2011

12) Measuring instruments;

Union	United Kingdom
Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) (OJ L 96, 29.03.2014, p. 149)	The Measuring Instruments Regulations 2016 (S.I. 2016/1153)

13) Non-automatic weighing instruments;

Union	United Kingdom
Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of nonautomatic weighing instruments (OJ L 96, 29.03.2014, p. 107)	The Non-Automatic Weighing Instruments Regulations 2016 (S.I. 2016/1152)

14) Toys;

Union	United Kingdom
Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.06.2009, p. 1)	Toy Safety Regulations 2011 (S.I. 2011/1881)

15) Rail subsystems and interoperability constituents;

Union	United Kingdom
Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union	The Railways (Interoperability) Regulations 2011

16) Personal Protective Equipment;

Union	United Kingdom
Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.03.2016, p. 51)	The Personal Protective Equipment (Enforcement) Regulations 2018 Retained Regulation 2016/425

17) Recreational craft, including their components;

Union	United Kingdom
Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013 p90).	The Recreational Craft Regulations 2017 (S.I. 2017/737)

18) Lifts and components for lifts;

Union	United Kingdom
Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (recast) (OJ L 96, 29.03.2014, p. 251)	The Lifts Regulations 2016 (S.I. 2016/1093)

19) Gas Appliances;

Union	United Kingdom
Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.03.2016, p.99).	Retained Regulation (EU) 2016/426

20) Hot-water boilers, including related appliances;

Union	United Kingdom
Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	The Ecodesign for Energy-Related Products Regulation 2010/2617

21) Cableway installations;

Union	United Kingdom
Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations became applicable as of 21 April 2018, replacing Directive 2000/9/EC	The Cableway Installations Regulations 2018 Retained Regulation 2016/424

22) Pyrotechnics;

Union	United Kingdom
Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast) (OJ L 178, 28.06.2013, p.27)	The Pyrotechnic Articles (Safety) Regulations 2015 (S.I. 2015/1553)

23) Civil Explosives;

Union	United Kingdom
Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses	The Explosives Regulations 2014

24) Fertilisers;

Union	United Kingdom
Regulation 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003	Retained Regulation 2019/1009

25) Unmanned Aircraft;

Union	United Kingdom
Regulation 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems	Retained Regulation 2019/945

APPENDIX 5-A-2

INFORMATION TO BE INCLUDED AS PART OF A DESIGNATION

[…]

ANNEX 5-B

THE MUTUAL RECOGNITION OF CERTIFICATES OF CONFORMITY FOR MARINE EQUIPMENT

ARTICLE 1

Definitions

1. For the purposes of this Annex:

"Certificate of Conformity" means the document or documents issued by a Conformity Assessment Body of a Party certifying that a product fulfils the relevant legislative, regulatory, and administrative requirements of that Party. In the United Kingdom, these are the certificates, approvals or declarations provided for by the Merchant Shipping (Marine Equipment) Regulations 2016 (S.I.2016/1025). In the Union, they are the certificates, approvals and declarations provided for by Directive 2014/90/EU.

"Conformity Assessment Body" means a legal entity, whether a Regulatory Authority or another body, public or private, that has the authority to issue Certificates of Conformity under a Party's domestic laws and regulations. For purposes of this Annex, the Parties' respective Conformity Assessment Bodies are those referred to in Article 6.

"Equivalence of technical regulations" means that the technical regulations of the Parties related to a specific product are sufficiently comparable to ensure that the objectives of each Party's respective regulations are fulfilled. Equivalence of technical regulations does not require that the respective technical regulations are identical.

"International Instrument" means the relevant international conventions, resolutions, codes and circulars of the International Maritime Organisation (IMO), and the relevant testing standards as listed in Appendix 5-B-2 to this Annex.

"Regulatory Authority" means a government agency or entity that has the authority to issue regulations regarding issues related to safety at sea and prevention of marine pollution, that exercises a legal right to control the use or sale of marine equipment within a Party's jurisdiction, and that may take enforcement action to ensure that products marketed within its jurisdiction comply with applicable legal requirements. The Parties' respective Regulatory Authorities are identified in Appendix 5-B-3 to this Annex.

"Technical regulations" comprise the mandatory product requirements, testing and performance standards and conformity assessment procedures laid down in the legislative, regulatory, and administrative provisions of the Parties related to marine equipment, as well as any applicable guidelines for their application.

2. Other terms concerning conformity assessment used in this Annex shall have the meaning given elsewhere in this Annex or in the definitions contained in Guide 2:2004 (‘Standardization and related activities – General vocabulary’) of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In the event of an inconsistency between ISO/IEC Guide 2:2004 and definitions in this Annex, the definitions in this Annex shall prevail.

ARTICLE 2

Purpose of the Annex

1. This Annex establishes the conditions under which the importing Party's Regulatory Authority shall accept the Certificates of Conformity issued by the exporting Party's Conformity Assessment Bodies in accordance with the technical regulations of the exporting Party, hereinafter referred to as "mutual recognition".

2. This Annex also lays down a framework for regulatory cooperation with the objective of maintaining and furthering mutual recognition between the Union and the United Kingdom of their respective regulatory requirements for marine equipment; of encouraging the improvement and evolution of regulatory requirements for the purpose of enhancing safety at sea and the prevention of marine pollution; and ensuring a consistent application of this Annex. This cooperation shall take place fully respecting the Parties regulatory autonomy and their evolving policies and regulations as well as their shared commitment to the evolution of the relevant International Instruments.

3. This Annex is intended to evolve as programmes and policies of the Parties evolve. The Parties shall review this Annex periodically, in order to assess progress and identify potential enhancements to this Annex as United Kingdom and Union policies evolve over time. Particular attention shall also be given to the evolution of the International Instruments.

ARTICLE 3

Basic Obligations

1. With respect to each product listed in Appendix 5-B-2, the United Kingdom shall accept as complying with its own legislative, regulatory, and administrative provisions as referred to in Appendix 5-B-1, without any further conformity assessment, Certificates of Conformity issued by the Union’s Conformity Assessment Bodies in accordance with the legislative, regulatory, and administrative provisions of the Union.

2. With respect to each product listed in Appendix 5-B-2, the Union and its Member States shall accept as complying with their own legislative, regulatory, and administrative provisions as referred to in Appendix 5-B-1, without any further conformity assessment, Certificates of Conformity issued by the Conformity Assessment Bodies of the United Kingdom in accordance with the legislative, regulatory, and administrative provisions of the United Kingdom.

3. The technical regulations applicable in the United Kingdom and the Union to each such product within the scope of this Annex are specified in Appendix 5-B-2.

ARTICLE 4

Equivalence of Technical Regulations

1. The mutual recognition obligations referred to in Article 3 are based on the determination by the Parties that the technical regulations applicable to each product listed in Appendix 5-B-2 are equivalent.

2. Determination of equivalence of technical regulations of the Parties shall be based on their implementation of the relevant International Instruments in their respective legislation, regulations and administrative provisions, except where a Party regards the International Instrument as being an ineffective or inappropriate means of fulfilment of its regulatory objectives. In the latter case, equivalency shall be determined on a mutually acceptable basis.

ARTICLE 5

Marking

The Parties may maintain their respective requirements with regard to the marking, numbering and identification of products. With respect to the products listed in Appendix 5-B-2, the Union Conformity Assessment Bodies shall have the right to issue the marking and numbering required by the United Kingdom legislation and regulations, as allocated to them by the United Kingdom Maritime and Coastguard Agency. The United Kingdom Conformity Assessment Bodies shall have the right to issue the marking and numbering required by Union law and shall be given the identification number(s) allocated to them by the European Commission, as provided for in Directive 2014/90/EU, which shall be affixed next to the marking required by that Directive.

ARTICLE 6

Conformity Assessment Bodies

1. For the purpose of issuing Certificates of Conformity in accordance with the provisions of this Annex, the following shall apply:

   (a) The United Kingdom recognises the Notified Bodies that have been designated by the Union Member States under Directive 2014/90/EU as Conformity Assessment Bodies;

   (b) The Union and its Member States recognise the Conformity Assessment Bodies designated by the United Kingdom in accordance with the Merchant Shipping (Marine Equipment) Regulations 2016 (S.I.2016/1025) as amended.

2. Each Party recognises that the Conformity Assessment Bodies of the other Party are authorised to perform the following procedures in relation to the legislative, regulatory, and administrative provisions referred to in Appendix 5-B-1:

(a) testing and issuing of test reports,

(b) performing quality assurance functions or system certification.

3. The Regulatory Authorities of the Parties are responsible for the following procedures, but may delegate some or all of these functions to Conformity Assessment Bodies:

(a) reviewing equipment design and test results against identified standards,

(b) issuing Certificates of Conformity.

4. Prior to the entry into force of this Annex the Parties shall exchange their respective lists of Conformity Assessment Bodies. The Parties shall inform each other promptly of any changes to their list of Conformity Assessment Bodies. The Parties shall maintain on the internet updated lists of their Conformity Assessment Bodies.

5. Each Party shall require that its Conformity Assessment Bodies record and retain details of their investigations of the competence and compliance of their sub-contractors and maintain a register of all sub-contracting. These details shall be available to the other Party on request.

6. Each Party shall require that its Conformity Assessment Bodies, upon request of a Regulatory Authority of the other Party, make available to that Regulatory Authority, copies of the Certificates of Conformity and related technical documentation they have issued.

ARTICLE 7

Committee on Marine Equipment

1. The Committee on Marine Equipment, shall consist of representatives of each Party. The Committee on Marine Equipment shall be responsible for advising the Joint Committee so as to ensure the effective functioning of this Annex.

2. Each Party shall have one vote in the Committee on Marine Equipment. The Committee on Marine Equipment shall make its decisions by unanimity. The Committee on Marine Equipment shall determine its own rules of procedure.

3. The Committee on Marine Equipment may consider any matter relating to the effective functioning of this Annex. The Committee on Marine Equipment shall have the authority to make recommendations to the Joint Committee in the cases provided for in this Annex. The Parties shall take the necessary measures to implement decisions of the Joint Committee upon the recommendation of the Committee on Marine Equipment. In particular, the Committee on Marine Equipment shall be responsible for:

(a) making recommendations to the Joint Committee to adopt decisions to develop and maintain the list in Appendix 5-B-2 of products and associated legislative, regulatory, and administrative provisions that the Parties have determined to be equivalent;

(b) resolving problems that may arise concerning the implementation of this Annex, including concerns that technical regulations of the Parties applicable to a specific product in Appendix 5-B-2 may no longer be equivalent;

(c) addressing technical, conformity assessment and technology issues in order to ensure a consistent application of this Annex, in particular in relation to the relevant International Instruments;

(d) making recommendations to the Joint Committee to amend the Annexes;

(e) providing guidance and, if necessary, developing guidelines to facilitate the successful implementation and application of this Annex;

4. The Committee on Marine Equipment may establish joint working groups comprised of appropriate Regulatory Authorities' representatives and appropriate experts deemed necessary, in order to address and advise the Committee on Marine Equipment, and, as required, the Joint Committee, on specific issues related to the functioning of this Annex.

ARTICLE 8

Preservation of Regulatory Authority

Nothing in this Annex shall be construed to limit the authority of a Party to determine, through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for enhancing safety at sea and improving the prevention of marine pollution, or otherwise act with regard to risks within the scope of this Annex.

ARTICLE 9

Exchange of Information and Contact Points

1. The Regulatory Authorities of the Parties shall establish appropriate means of exchanging information on any regulatory problems concerning products subject to this Annex.

2. Each Party shall designate at least one contact point, which may be the Regulatory Authorities, to provide answers to all reasonable inquiries from the other Party and other interested parties such as manufacturers, consumers, trade unions, regarding procedures, regulations, and other matters related to this Annex. The Parties shall exchange, and make publicly available, lists of contact points.

3. With regard to the exchange of information and notifications under this Annex a Party shall have the right to communicate in its official language or languages. If a Party deems that information it receives must be translated into its official language or languages, that Party shall undertake the necessary translation and bear the cost.

4. Each Party agrees to make available to the public on the internet the list of products for which its Conformity Assessment Bodies have issued Certificates of Conformity and to update it on a regular basis.

ARTICLE 10

Regulatory Changes

1. When a Party introduces new technical regulations related to this Annex, it shall do so on the basis of existing International Instruments, except when a Party considers the International Instrument would be an ineffective or inappropriate means for fulfilment of its regulatory objectives.

2. Each Party shall notify the other Party of changes to technical regulations related to the subject matter of this Annex at least 90 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a Party shall notify the other Party as soon as practicable.

3. The Parties and their Regulatory Authorities shall inform and consult with one another, as permitted by their respective laws and regulations, on:

   (a) proposals to amend or introduce new technical regulations as laid down in their respective legislative, regulatory, and administrative provisions referred in, or related to, provisions listed in Appendices 5-B-1 and 5-B-2;

   (b) timely incorporation of amended or new international instruments into their respective legislation, regulations and administrative provisions; and

   (c) the renewal of existing and valid Certificates of Conformity when the renewal is required by amended or new legislative, regulatory, and/or administrative provisions

4. The Parties shall provide each other the opportunity to comment on the regulatory changes referred to in paragraphs 1 to 3, as permitted by their respective laws and regulations.

5. In the event of changes to the legislation, regulations, and administrative provisions referred to in Appendices 5-B-1 and 5-B-2, the Committee on Marine Equipment shall consider whether or not the equivalence of the technical regulations with respect to products listed in Appendix 5-B-2 has been maintained, and:

   (a) if it is agreed in the Committee on Marine Equipment, that equivalence is maintained, then the product shall be retained in Appendix 5-B-2;

   (b) if it is agreed in the Committee on Marine Equipment that equivalence cannot be maintained, a recommendation shall be made to the Joint Committee that references to products and the relevant technical regulations for which equivalence cannot be maintained should be removed from Appendix 5-B-2. On receipt of the recommendation the Joint Committee shall make a decision on whether to update Appendix 5-B-2. Upon

the discontinuance of mutual recognition, the Parties are no longer bound by the obligations referred to in Article 3 of this Annex for the specific product. However, the importing Party shall continue to recognize previously issued Certificates of Conformity for products that have been placed on the market of that Party prior to the discontinuance of mutual recognition, unless a Regulatory Authority in the Party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of this Annex; or

(c) If the Parties, within the Committee on Marine Equipment, cannot agree on whether or not equivalence of their technical regulations with respect to a product listed in Appendix 5-B-2 is maintained, then mutual recognition with respect to that product shall be suspended according to the terms of Article 15.

6. The Parties shall make available on the internet an up-to-date version of Appendix 5-B-2.

ARTICLE 11

Regulatory Cooperation

1. The Parties agree to cooperate in the IMO and other relevant international organisation such as the ISO, the IEC and the International Telecommunications Union (ITU), with a view to establishing and improving international rules for enhancing the safety at sea and the prevention of marine pollution.

2. The Parties shall consider what technical work, data and information exchange, scientific and technological cooperation or other cooperative activities can be pursued between them with a view to improving the quality and level of their technical regulations applicable to marine equipment and making efficient use of resources for regulatory development.

3. For products that are not included in Appendix 5-B-2 upon entry into force of this Annex or for which equivalence of technical regulations has been discontinued or suspended, the Parties undertake to examine their respective technical regulations with a view to establishing, to the extent possible, mutual recognition. The Parties shall set out a work program and time-table for exploring equivalence of their technical regulations, including the initiation of appropriate international standards work. The Parties shall endeavour to make their technical regulations equivalent to the extent possible on the basis of existing International Instruments in pursuit of the objective of their domestic legislation to enhance safety at sea and improve the prevention of marine pollution.

4. When the Parties have determined that equivalence can be established for a product and associated legislative, regulatory, and administrative provisions, the Committee on Marine Equipment shall recommend that the Joint Committee amend Appendix 5-B-2 accordingly.

ARTICLE 12

Cooperation on Conformity Assessment

1. The Parties, including representatives of their respective Regulatory Authorities, shall consult as necessary to ensure the maintenance of confidence in conformity assessment procedures and Conformity Assessment Bodies. This can take the form of, for example, comparison of methods to verify and monitor the technical competence and ability of Conformity Assessment Bodies, and, with the consent of both Parties, joint participation in audits/inspections related to conformity assessment activities or other assessment of Conformity Assessment Bodies.

2. The Parties shall encourage their Conformity Assessment Bodies to take part in coordination and cooperation activities organised by the Parties either separately or jointly.

ARTICLE 13

Surveillance of Conformity Assessment Bodies

1. The Parties shall ensure that their Conformity Assessment Bodies are capable and remain capable of properly assessing conformity of products or processes, according to the applicable legislative, regulatory, and administrative provisions. In this regard, the Parties shall maintain, or cause to maintain, ongoing surveillance, as applicable, over their conformity assessment bodies and/or recognised laboratories, by means of regular audit or assessment.

2. In case a Party has objective reasons for contesting the technical competence of a Conformity Assessment Body of the other Party, it shall inform the other Party in writing. Such contestation shall be exercised when justified in an objective and reasoned manner. The other Party shall in a timely manner present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation. If necessary, the matter shall be discussed in the Committee on Marine Equipment. If agreement cannot be reached on the competency of the Conformity Body, the contesting Party may refuse to grant its marking and/or numbering to the contested Conformity Assessment Body and refuse to recognise the Certificates of Conformity issued by the contested Conformity Assessment Body.

ARTICLE 14

Market Surveillance

1. Nothing in this Annex shall be construed to limit the authority of a Regulatory Authority to take all appropriate and immediate measures whenever it ascertains that a product may:

   (a) although correctly installed, maintained and used for its intended purpose, compromise the health and/or safety of the crew, the passengers or, where applicable, other persons, or adversely affect the marine environment;

   (b) not meet the legislative, regulatory, or administrative provisions within the scope of the Annex; or

   (c) otherwise fail to satisfy a requirement within the scope of the Annex;

Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the Regulatory Authority takes such action, it shall inform the other Party no later than fifteen days after taking such action, providing its reasons for such action.

2. Nothing in this Annex shall prevent the Parties from removing products from the market that do not in fact conform to a Party's technical regulations.

3. The Parties agree that any applicable border inspections and checks of products which have been certified, labelled or marked as conforming with the importing Party's requirements specified in Appendix 5-B-1 shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, the Parties agree that these shall be completed in no less a favourable manner than for like domestic products.

ARTICLE 15

Suspending Mutual Recognition

1. In case a Party considers that equivalence of technical regulations with respect to one or more products listed in Appendix 5-B-2 is not being or cannot be maintained, it shall inform the other Party in writing and give the objective reasons for this. Any contestation of equivalence shall be discussed in the Committee on Marine Equipment. If no recommendation to the Joint Committee is made by the Committee on Marine Equipment within 60 days of the referral to it, the mutual recognition obligation with respect to such products shall be suspended by one or both Parties and the Joint Committee informed. The suspension shall remain in effect until the Joint Committee decides otherwise.

2. The Joint Committee shall update Appendix 5-B-2 by a decision to reflect the suspension of mutual recognition for the products in question. The Parties agree to cooperate according to the terms of Article 11 in view of establishing equivalence again, to the extent possible.

3. Upon suspension of mutual recognition of technical regulations referred to in Appendix 5-B-2 the Parties are no longer bound by the obligations referred to in Article 3 of this Annex for the specific product. However, the importing Party shall continue to recognize previously issued certificates of conformity for products that have been placed on the market of that Party prior to the suspension of mutual recognition, unless a Regulatory Authority in the Party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of this Annex.

ARTICLE 16

Alert System

The Parties shall put into place a two-way alert system between their Regulatory Authorities in order to inform each other of products that have been found not to comply with applicable technical regulations or can pose an imminent danger to health, safety or the environment.

ARTICLE 17

Confidentiality

1. Each Party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this Annex. In particular, neither Party shall disclose to the public, nor permit a Conformity Assessment Body to disclose, information exchanged under this Annex that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

2. A Party or a Conformity Assessment Body may, upon exchanging information with the other Party or with a Conformity Assessment Body of the other Party, designate the portions of the information that it wishes to be exempt from disclosure.

3. Each Party shall take all precautions reasonably necessary to protect information exchanged under this Annex from unauthorised disclosure.

ARTICLE 18

Fees

Each Party shall endeavour to ensure that fees imposed for services related to the subject matter of this Annex shall be commensurate with the services provided. Each Party shall ensure that, for conformity assessment procedures covered under this Annex, it shall charge no fees with respect to conformity assessment services provided by the other Party.

ARTICLE 19

Agreements with other Countries

1. Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by either Party with a party not a signatory to this Annex (a third party) shall have no force and effect with regard to the other Party in terms of acceptance of the results of conformity assessment procedures in the third party.

2. In view of furthering trade facilitation in marine equipment with other countries, the Union and the United Kingdom undertake to examine the possibility of establishing a multilateral agreement on the subject matter covered by this Annex with other interested countries.

APPENDIX 5-B-1

LEGISLATION, REGULATIONS AND ADMINISTRATIVE PROVISIONS

Union legislation, regulations and administrative provisions:

Council Directive 2014/90/EU of 23 July 2014 on marine equipment. The Parties recognise that the "Guide to the Implementation of Directives Based on the New Approach and Global Approach" provides useful guidelines for the implementation of in particular conformity assessment procedures falling under this Directive.

United Kingdom legislation, regulations and administrative provisions:

The Merchant Shipping Act 1995;
The Merchant Shipping (Marine Equipment) Regulations 2016, S.I. 2016/1025;
Marine Shipping Notice (MSN) 1874, Amendment 3 or later version.

APPENDIX 5-B-2

PRODUCT COVERAGE FOR MUTUAL RECOGNITION

[…]

APPENDIX 5-B-3

REGULATORY AUTHORITIES

[…]

ANNEX 5-C

MOTOR VEHICLES AND PARTS

ARTICLE 1

Definitions

1. For the purposes of this Annex:

"WP.29" means the World Forum for Harmonisation of Vehicle Regulations within the framework of the United Nations Economic Commission for Europe (hereinafter referred to as "UN ECE");

"1958 Agreement" means the Agreement Concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts which can be Fitted and/or be Used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of these Prescriptions (done at Geneva, 1958) administered by the WP.29, and all subsequent amendments and revisions thereof;

"1998 Agreement" means the Agreement concerning the Establishing of Global Technical Regulations for Wheeled Vehicles, Equipment and Parts which can be Fitted and/or be Used on Wheeled Vehicles (done at Geneva, 1998) administered by the WP.29, and all subsequent amendments and revisions thereof;

"UN Regulations" means Regulations adopted in accordance with the 1958 Agreement;

"GTRs" means the Global Technical Regulations established and placed on the Global Registry in accordance with the 1998 Agreement;

"type approval" means the procedure whereby an approval authority certifies that a type of vehicle, system, component or separate technical unit satisfies the relevant administrative provisions and technical requirements;

"type approval certificate" means the document whereby an approval authority officially certifies that a type of vehicle, system, component or separate technical unit is type-approved; and

"HS 2017" means the 2017 edition of Harmonized System Nomenclature issued by the World Custom Organisation.

2. Terms used in this Annex shall have the same meaning as defined in the 1958 Agreement or in Annex 1 to the TBT Agreement.

ARTICLE 2

Objectives

With regard to the products covered, the objectives of this Annex are to:

(a) eliminate and prevent any non-tariff barriers to bilateral trade;

(b) promote compatibility and convergence of regulations based on international standards;

(c) promote recognition of approvals based in particular on approval schemes applied under the agreements administered by WP.29 and those based on Union and United Kingdom type approvals;

(d) reinforce competitive market conditions based on principles of openness, non-discrimination and transparency;

(e) promote high levels of safety, environmental protection, energy efficiency and anti-theft performance of motor vehicles, their parts and equipment which can be fitted or used on wheeled vehicles; and

(f) maintain cooperation to foster continued mutually beneficial development in trade.

ARTICLE 3

Product scope

This Annex shall apply to trade between the Parties of all categories of motor vehicles, equipment and parts thereof, as defined under Paragraph 1.1. of UN ECE Consolidated Resolution on the Construction of Vehicles (R.E.3),[3] falling inter alia under Chapters 40, 84, 85, 87 and 94 of the HS 2017 (hereinafter referred to as "products covered").

ARTICLE 4

International standards

The Parties recognise that the WP.29 is the relevant international standardising body and that UN Regulations and GTRs under the 1958 and 1998 Agreements are relevant international standards for the products covered by this Annex.

ARTICLE 5

Regulatory convergence based on international standards

1. Each Party shall refrain from introducing or maintaining new domestic technical regulations, markings or conformity assessment procedures diverging from UN Regulations or GTRs, unless there are substantiated reasons, based on scientific or technical information, why a specific UN Regulation or GTR is ineffective or inappropriate for ensuring safety, or the protection of the environment or human health.

2. A Party which adopts new domestic technical regulations, markings or conformity assessment procedures in accordance with paragraph 1 shall, upon request from the other Party, identify the parts of the domestic technical regulations, markings or conformity assessment procedures which substantially deviate from the relevant UN Regulations or GTRs. That Party shall provide due justification as to the reasons for the deviation.

3. Insofar as a Party has introduced or maintains, domestic technical regulations, markings and conformity assessment procedures that diverge from UN Regulations or GTRs, as permitted by paragraph 1, that Party shall review those at regular intervals, with a view to increasing their convergence to the relevant UN Regulations or GTRs. When reviewing their domestic

[3] ECE/TRANS/WP.29/78/Rev.6 of 11 July 2017.

technical regulations, markings and conformity assessment procedures, each Party shall consider whether the reasons that justified the divergence still exist. The outcome of these reviews, including scientific and technical information used, shall be notified to the other Party upon request.

4. Each Party shall refrain from introducing or maintaining domestic technical regulations, markings, or conformity assessment procedures which have the effect of prohibiting, restricting, inconveniencing or increasing the burden for the importation and the putting into service on their domestic market of products granted approval covered by UN Regulations unless such domestic technical regulations, markings or conformity assessment procedures are explicitly foreseen by those UN Regulations.

5. When a Party intends to develop or amend a domestic technical regulation or conformity assessment procedure in areas not covered by existing UN Regulations, the regulatory authorities of the Party shall:

   (a) inform the regulatory authorities of the other Party of the regulatory objective and plan as well as transmit any regulatory justification or existing impact assessment regarding the intended domestic technical regulation or conformity assessment procedure at an early stage;

   (b) assess the possibility to develop and adopt a new UN Regulation or to amend an existing UN Regulation in the area in which that Party intends to introduce a domestic technical regulation or conformity assessment procedure; and

   (c) notify the Co-Chair of the Working Group on Motor Vehicles and Parts of the other Party when that Party decides to introduce a domestic technical regulation or conformity assessment procedure in an area not covered by a UN Regulation.

6. When a Party decides to introduce or to amend a domestic technical regulation or conformity assessment procedure in areas not covered by UN Regulations or GTRs, the other Party may request consultations with that Party, which shall accept those consultations without delay. During those consultations, the Parties shall cooperate to develop a solution to minimise negative effects on bilateral trade. In situations where the Party requires an immediate action, that Party may adopt the domestic technical regulation or conformity assessment procedure before the completion of such consultations. That Party shall communicate and substantiate the urgency and imminent risks to safety or the environment.

ARTICLE 6

Type Approval

1. Each Party shall accept type approval certificates, and products which are covered by a type approval certificate, under the 1958 Agreement, issued by an approval authority of the other Party for the UN Regulations specified in Appendix 5-C-1 to this Annex as compliant with its

domestic technical regulations and conformity assessment procedures, in the area regulated by the relevant UN Regulation, without requiring any further testing, documentation, certification or marking.

2. Each Party shall apply UN Regulation No. 0 and accept products under the 1958 Agreement for which an International Whole Vehicle Type Approval Certificate has been issued by an approval authority of the other Party as compliant with all domestic technical regulations and conformity assessment procedures in the areas covered by the International Whole Vehicle Type Approval, without requiring any further testing, documentation, certification or marking.

3. The Parties agree to promote the use of UN Regulation No. 0 internationally and to cooperate in enlarging its coverage to additional vehicle categories.

4. Where marks displaying compliance apply in the UK and the EU, and there is no equivalent in the UN Regulations, the parties agree that these items may bear both the UK and EU compliance marks.

ARTICLE 7

Independent Operators

1. The Parties recognise that to allow:

   (a) effective competition in the United Kingdom and Union markets for vehicle repair and maintenance information services, so as to ensure that the independent vehicle repair and maintenance market as a whole can compete with authorised dealers; and

   (b) the inspection of the safety- and environment- related components of vehicles, it is necessary for such independent operators to maintain access to the technical information of each individual vehicle.

2. Accordingly, both Parties agree to encourage United Kingdom and Union manufacturers to provide to independent operators in both the United Kingdom and the Union unrestricted, standardised and non-discriminatory access to vehicle on-board diagnostics information, diagnostic equipment, other equipment, tools including the complete references, and available downloads, of the applicable software and vehicle repair and maintenance information.

ARTICLE 8

Technical Services

1. The Parties agree that:

(a) UK-based bodies can be designated by approval authorities of EU Member States for EU approval activities; and

(b) EU-based bodies can be designated by the UK approval authority for UK approval activities,

to provide technical services as a testing laboratory to carry out tests, or as a conformity assessment body to carry out initial assessment, conformity of production assessments and other tests or inspections.

2. The parties agree that testing and supervision of tests can take place within the country of the body providing the technical services.

ARTICLE 9

Products with New Technologies or Features

1. The Parties shall endeavour to permit the importation and marketing of products incorporating a new technology or a new feature, that the importing Party has not yet regulated, unless it has a reasonable doubt , based on scientific or technical information, that this new technology or new feature creates a risk for human health, safety or the environment. The Party refusing the placing on the market shall notify this decision to the other Party as soon as possible.

ARTICLE 10

Joint Cooperation

1. The Parties desire to maintain cooperation and the efficient use of resources in matters that relate to motor vehicle technical regulations, in a manner that does not compromise each Party's ability to fulfil its responsibilities. The Parties recognise the right of each Party to determine its desired level of health, safety, and environmental and consumer protection.

2. In order to further facilitate trade in motor vehicles, their parts and equipment, and to address market access problems before they arise, while ensuring safety and environmental protection, the Parties agree to cooperate and consult promptly on any matters concerning products covered by this Annex. Upon request, each Party shall, in a timely manner and within a time period not exceeding 60 days, respond in writing to comments and questions of the other Party regarding any aspects covered by this Annex, and, if requested, enter into consultations with a view to seeking a mutually satisfactory solution.

3. The Parties shall endeavour to share information and cooperate on activities in areas including:

(a) the development and establishment of technical regulations or related standards;

(b) the exchange of research, information and results linked to the development of new vehicle safety regulations or related standards, and advanced emission reduction, and emerging vehicle technologies; and

(c) the exchange of available information on the identification of safety-related or emission-related defects and non-compliance with technical regulations.

4. The Parties shall endeavour to maintain an open and ongoing dialogue on matters within the scope of this Annex, at both a bilateral and international level. To this end, the Parties shall endeavour to :

(a) contribute jointly to encourage and promote greater international harmonisation of technical requirements through multilateral fora, such as the 1958 and 1998 Agreements, including through cooperation in the planning of initiatives in support of such activities;

(b) share and discuss research and development plans on motor vehicle safety and environmental technical regulations or related standards;

(c) conduct joint analyses, develop methodologies and approaches, as mutually beneficial, practical and convenient, to assist and facilitate the development of motor vehicle technical regulations or related standards and ensure efficient interaction of government technical experts and regulatory authorities at international, regional or national level; and

(d) develop additional provisions for cooperation.

ARTICLE 11

Market Surveillance

1. The Parties agree that the market surveillance authorities of the UK and EU Member States shall endeavour to cooperate with each other and regularly share the results of their market surveillance activities, in particular the regular sharing of data and intelligence to support identifying and addressing non-conformities of vehicles, systems, components or separate technical units.

2. If a product's placement or use on the market could compromise the fulfilment of a legitimate objective such as the safety of a vehicle or its environmental performance, a Party may adopt or maintain appropriate and immediate measures with respect to that product provided that they are consistent with this Annex. Such measures can include withdrawing the product from the market, initiating vehicle recalls, and prohibiting the placing on the market, the registration or the entry into service of vehicles, systems, components or separate technical units. A Party that adopts or maintains such measures shall promptly inform the other Party and, at the request of the other Party, provide its reasons for adopting or maintaining these measures.

ARTICLE 12

Working Group on Motor Vehicles and Parts

1. The Working Group on Motor Vehicles and Parts shall be responsible for the effective implementation and operation of this Annex.

2. The Working Group shall meet at least annually (including meetings held on the margins of WP.29 Sessions), by video-conference or, if directly,

   (a) on an alternating basis in the UK and in the EU; and

   (b) on the request of a Party, at such venue as is mutually determined.

3. The functions of this Working Group shall include:

   (a) discussing any matter arising under this Annex, upon a Party's request;

   (b) cooperating to eliminate barriers to trade in areas not covered by UN Regulations, including under Article 5.4 of Chapter 5;

   (c) facilitating cooperation and information sharing between relevant authorities, where provided for in this Annex;

   (d) carrying out cooperation provided for in this Annex;

   (e) considering options for undertaking additional commitments of mutual interest, in accordance with Article 2;

   (f) maintaining a list of contact points responsible for matters arising under this Annex;

   (g) carrying out consultations in accordance with paragraph 6 of Article 5;

   (h) assessing the need for amending this Annex and making recommendations to the Committee on Technical Barriers to Trade;

   (i) establishing ad hoc working groups at the request of either Party, in order to address a specific issue raised by a Party; and

   (j) carrying out other functions as may be delegated by the Committee on Technical Barriers to Trade.

4. Cooperation between the relevant authorities of the Parties shall be guided by a joint regulatory cooperation work plan, based on the programme of work established under the 1958 and 1998 Agreements. The Working Group shall agree a joint regulatory cooperation work plan, within six months of the entry into force of this Agreement, which includes short- and medium-term priorities for regulatory cooperation under this Annex. The Working Group shall regularly review the joint regulatory cooperation work plan.

APPENDIX 5-C-1

UN REGULATIONS APPLIED BY BOTH PARTIES

UN Regulation No.	Subject
0	International Whole Vehicle Type Approval
1	Headlamps for motor vehicles (R2, HS1)
3	Retro-reflecting devices for power-driven vehicles and their trailers
4	Illumination of rear-registration plates of power-driven vehicles and their trailers
5	Lighting, light-signalling devices and their light sources
6	Direction indicators for power-driven vehicles and their trailers
7	Front and rear position lamps, stop-lamps and end-outline marker lamps for motor vehicles and their trailers
8	Head lamps for motor vehicles (H1, H2, H3, HB3, HB4, H7, H8, H9, H11, HIR1, HIR2)
10	Electromagnetic compatibility
11	Door latches and door retention components
12	Protection of the driver against the steering mechanism in the event of impact
13	Braking of vehicles and trailers
13-H	Braking of passenger cars
14	Safety-belt anchorages, Isofix anchorages systems and Isofix top tether anchorages

16	Safety-belts, restraint systems, child restraint systems and Isofix child restraint systems
17	Seats, their anchorages and any head restraints
18	Protection of motor vehicles against unauthorised use
19	Power-driven vehicle front fog lamps
20	Headlamps for motor vehicles (H4)
21	Interior fittings
22	Protective helmets for drivers and passengers of motorcycles
23	Reversing lights for power-driven vehicles and their trailers
24	Diesel Smoke
25	Head restraints (headrests), whether or not incorporated in vehicle seats
26	External projections
27	Advance-warning triangles
28	Audible warning devices and signals
29	Cab strength
30	Pneumatic tyres for motor vehicles and their trailers (Class C_1)
31	Power-driven vehicle's sealed-beam headlamps (SB) emitting an European asymmetrical passing beam or a driving beam or both

34	Prevention of fire risks (liquid fuel tanks)
37	Filament lamps for use in approved lamp units of power-driven vehicles and their trailers
38	Rear fog lamps for power-driven vehicles and their trailers
39	Speedometer equipment including its installation
41	Noise emissions of motorcycles
43	Safety glazing materials and their installation on vehicles
44	Child Restraint Systems
45	Headlamp cleaners
46	Devices for indirect vision and their installation
47	Emission of gaseous engine pollutants (mopeds)
48	Installation of lighting and light-signalling devices on vehicles
49	Emissions of C.I. and P.I. (LPG and CNG) engines
50	Lighting components for vehicles of category L
51	Sound levels (M and N)
53	Installation of lighting (motorcycle)
54	Pneumatic tyres for commercial vehicles and their trailers (Classes C_2 and C_3)
55	Mechanical coupling components of combinations of vehicles

56	Headlamps for mopeds and vehicles treated as such
57	Headlamps for motorcycles and vehicles treated as such
58	Rear underrun protective devices (RUPDs) and their installation; rear underrun protection (RUP)
59	Replacement silencing systems
60	Identification of controls tell-tales and indicators
61	Commercial vehicles with regard to their external projections forward of the cab's rear panel
62	Protection against unauthorised use
64	Temporary-use spare unit, run-flat tyres/system and tyre pressure monitoring system
65	Warning lamps for power-driven vehicles and their trailers
66	Strength of the superstructure of large passenger vehicles
67	Specific components for liquefied petroleum gases (LPG) and their installation on motor vehicles
69	Rear marking plates for slow-moving vehicles
70	Rear-marking plates for heavy and long vehicles
71	Field of vision, agricultural tractors
72	Headlamps for motorcycles and vehicles treated as such (HS1)
73	Lateral protection of goods vehicles

74	Installation of lighting (moped)
75	Tyres
77	Parking lamps for power-driven vehicles
78	Braking, including anti-lock and combined brake systems
79	Steering equipment
80	Seats of large passenger vehicles
81	Rear-view mirrors
82	Headlamps for mopeds and vehicles treated as such (HS2)
83	Emissions of pollutants
85	Power – internal combustion and electric (M and N)
86	Installation of lighting and light-signalling devices for agricultural vehicles
87	Daytime running lamps for power-driven vehicles
89	Speed limitation of vehicles
90	Replacement brake lining assemblies and drum brake linings
91	Side-marker lamps for motor vehicles and their trailers
93	Front underrun protective devices (FUPDs) and their installation; front underrun protection (FUP)
94	Protection of occupants in the event of a frontal collision

95	Protection of occupants in the event of lateral collision
96	Diesel emission (agricultural tractors)
97	Vehicle alarm systems (VAS)
98	Motor vehicle headlamps equipped with gas-discharge light sources
99	Gas-discharge light sources for use in approved gas-discharge lamp units of power-driven vehicles
100	Electric safety
101	CO2 emission/fuel consumption
102	Close-coupling device (CCD); fitting of an approved type of CCD
103	Replacement catalytic converters
104	Lighting installation
105	Vehicles for the carriage of dangerous goods
106	Tyres
107	M_2 and M_3 vehicles
108	Retreaded tyres motor vehicles and their trailers
109	Retreaded tyres commercial vehicles and their trailers
110	Specific components for CNG and their installation on motor vehicles
111	Roll-over stability of tank vehicles (N and O)

112	Motor vehicle headlamps emitting an asymmetrical passing beam or a driving beam or both and equipped with filament lamps and/or LED modules
113	Lighting, light-signalling devices and their light sources
114	Replacement airbags
115	LPG and CNG retrofit systems
116	Protection of motor vehicles against unauthorised use
117	Tyre rolling sound emissions, adhesion on wet surfaces and rolling resistance (Classes C_1, C_2 and C_3)
118	Burning behaviour of materials used in the interior construction of certain categories of motor vehicles
119	Cornering lamps
120	Net power of tractors and non-road mobile machinery
121	Hand controls, tell-tales and indicators
122	Heating systems
123	Adaptive front-lighting systems (AFS) for motor vehicles
124	Replacement Wheels for passenger vehicles
125	Forward field of vision
126	Partitioning systems to protect passengers against displaced luggage
127	Pedestrian Safety

128	Light emitting diode (LED) light sources
129	Enhanced Child Restraint Systems (ECRS)
130	Lane Departure Warning Systems (LDWS)
131	Advanced emergency Braking Systems (AEBS)
132	Retrofit Emission Control Devices (REC) for heavy duty vehicles, agricultural and forestry tractors and NRMM
133	Recyclability of motor vehicles
134	Safety-related performance of hydrogen-fuelled vehicles (HFCV)
135	Pole Side Impact (PSI)
136	Electric vehicles of category L
137	Frontal impact with focus on restraint systems
138	Quiet Road Transport Vehicles (QRTV)
139	Brake Assist Systems (BAS)
140	Electronic Stability Control (ESC)
141	Tyre Pressure Monitoring Systems (TPMS)
142	Tyre installation
143	Heavy Duty Dual-Fuel Engine Retrofit Systems
144	Accident Emergency Call Systems (AECS)

145	ISOFIX anchorage systems, ISOFIX top tether anchorages and i-Size seating positions
146	Hydrogen and fuel cell vehicles of category L
147	Mechanical coupling components of combinations of agricultural vehicles

ANNEX 5-D

MEDICAL PRODUCTS

ARTICLE 1

Definitions

1. For the purposes of this Annex:

"active substance" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;

"certificate of GMP compliance" means a certificate issued by a regulatory authority attesting to the compliance of a manufacturing facility with Good Manufacturing Practice ("GMP");

"equivalent authority" means a regulatory authority of a Party that is recognised as an equivalent authority by the other Party;

"GCP inspection" means an inspection by a regulatory authority for the purpose of assessing compliance with the principles of Good Clinical Practice ("GCP") in connection with a clinical trial;

"GCP inspection report" means a document issued by a regulatory authority attesting to the inspection of an entity, by that authority, for the purpose of assessing compliance with the principles of GCP in connection with a clinical trial, and setting out the findings;

"GMP inspection" means an on-site assessment, conducted at a manufacturing facility or other premises, of compliance with GMP, other than a 'Pre-approval inspection';

"manufacturing" includes fabrication, packaging, re-packaging, labelling, testing and storage;

"medicinal product" means any product qualifying as a medicinal product, whether it is a finished, intermediate or an investigational product, under the applicable legislation of either party;

"Official Control Authority Batch Release" or "OCABR" means a requirement by a Party, under its applicable legislation, that a laboratory determines the conformity of a batch with the approved specifications as laid down in the marketing authorisation before the regulatory authority of the Party shall allow the batch to be placed on the market;

"Pre-approval inspection" means a product-specific inspection conducted in the context of a marketing application for a medicinal product at the site of manufacture to assess conformity with good manufacturing practice; such an inspection can include an assessment of:

(a) the conformity of the premises where the medicinal product is manufactured,

(b) the conformity of the process, conditions and control of manufacture with the information submitted; and

(c) any outstanding issues from the assessment of the marketing application;

"regulatory authority" means an entity in a Party that has the legal right, under the law of the Party, to supervise and control medicinal products and active substances within that Party; and

"Working group" means the Working Group on Medical Products.

2. Unless specified otherwise, where this Annex refers to GMP inspections, these references do not include pre-approval inspections.

ARTICLE 2

Objective

1. The objective of this Annex is to:

(a) eliminate and prevent any non-tariff barriers to bilateral trade;

(b) promote compatibility and convergence of regulations based on international standards;

(c) reinforce competitive market conditions based on principles of openness, non-discrimination and transparency;

(d) promote public health by safeguarding patient safety and animal health and welfare, as well as protecting high levels of consumer and environmental protection where relevant; and

(e) maintain cooperation to foster continued mutually beneficial development in trade.

ARTICLE 3

Product Scope

This Annex applies to the products set out in Appendix 5-D-1 where applicable under the relevant legislation, except Articles 7, 15 and 16, which apply to the products set out in Appendix 5-D-1 insofar as they are for human use.

ARTICLE 4

Recognition of regulatory authorities

1. The procedure for evaluating the equivalency of a new regulatory authority listed in Appendix 5-D-2 shall be conducted in accordance with Article 12.

2. Each Party shall ensure that a list of regulatory authorities that it recognises as equivalent, including any modifications, is publicly available.

ARTICLE 5

Mutual recognition of certificates of GMP compliance

1. A Party shall accept a certificate of GMP compliance issued by an equivalent authority of the other Party, in conformity with paragraph 3, as demonstrating that the manufacturing facility complies with the good manufacturing practices identified in the certificate.

2. A certificate of GMP compliance must identify:

   (a) the name and address of the manufacturing facility;

   (b) the date on which the equivalent authority that issued the certificate last inspected the manufacturing facility;

   (c) the manufacturing processes and if relevant, medicinal products, active substances and dosage forms for which the facility is in compliance with good manufacturing practices; and

   (d) the validity period of the certificate of GMP compliance.

3. If an importer, an exporter or a regulatory authority of a Party requests a certificate of GMP compliance for a manufacturing facility located in the territory of either party that is certified by an equivalent authority of the other Party, the other Party shall ensure that the equivalent authority issues a certificate of GMP compliance:

   (a) within 30 calendar days of the date on which the certifying authority received the request for the certificate, if a new inspection is not required; and

(b) within 90 calendar days of the date on which the certifying authority received the request for the certificate, if a new inspection is required, and the manufacturing facility passes the inspection.

4. If an importer, an exporter or a regulatory authority of a Party requests a certificate of GMP compliance for a manufacturing facility located outside the territory of either party that is certified by an equivalent authority of the other Party and a new inspection is not required, the other Party shall ensure that the equivalent authority issues a certificate of GMP compliance within 30 calendar days of the date on which the certifying authority received the request for the certificate.

ARTICLE 6

Acceptance of batch testing certificates

1. A Party shall accept a batch testing certificate issued by a manufacturer without re-control of that batch at import provided that:

(a) the products in the batch were manufactured in a manufacturing facility that has been certified as compliant by an equivalent authority;

(b) the batch testing certificate is consistent with the Content of the Batch Certificate for Medicinal Products of the Internationally Harmonized Requirements for Batch Certification; and

(c) the batch testing certificate is signed by the person responsible for releasing the batch for sale or supply.

2. Paragraph 1 does not affect a Party's right to conduct official control authority batch release and is without prejudice to the recognition of OCABR under Article 16.

3. The person responsible for releasing the batch:

(a) of the finished medicinal product for sale or supply for manufacturing facilities in the European Union, must be a "qualified person" as defined in Article 48 of Directive 2001/83/EC, Article 13(2) of Directive 2001/20, or Article 52 of Directive 2001/82/EC; or

(b) of the finished medicinal product for sale or supply for manufacturing facilities in the United Kingdom, must be a "qualified person" as defined in regulation 8(1) of the Human Medicines Regulations 2012 (SI 2012/1916), Regulation 2(1) of The Medicines for Human Use (Clinical Trials) Regulations (SI 2004/1031), or appointed under paragraph 9 of Schedule 2 to the Veterinary Medicines Regulations 2013 (SI 2011/2033).

ARTICLE 7

Acceptance of GCP inspection reports

1. A Party shall accept the findings in a GCP inspection report issued by an equivalent authority of the other Party, in conformity with paragraph 3.

2. A GCP inspection report must identify:

   (a) the name and address of the relevant entity;

   (b) the clinical trials covered; and

   (c) the date on which the regulatory authority that issued the report last inspected the relevant entity.

3. If a regulatory authority of a Party requests a GCP inspection report following a GCP inspection by an equivalent authority of the other Party, the other Party shall ensure that the equivalent authority issues a GCP inspection report within 30 calendar days of the date on which that authority received the request for the report.

4. A regulatory authority of a Party may request that the equivalent authority undertake a GCP inspection; following such a request:-

   (a) the equivalent authority must undertake the GCP inspection within 90 days; or

   (b) if the equivalent authority cannot undertake the GCP inspection within 90 days, the regulatory authority that made the request may undertake the inspection and the other Party has the right to join.

ARTICLE 8

Pre-approval inspection

1. A Party has the right to conduct its own pre-approval inspection of a manufacturing facility that has been certified as compliant by an equivalent authority of the other Party.

2. A Party, prior to conducting a pre-approval inspection under paragraph 1, shall notify the other Party in writing and inform that other Party of the scope of the pre-approval inspection. The Party shall endeavour to notify the other Party in writing at least 30 days before a proposed pre-approval inspection, but may provide less notice in urgent situations. The other Party has the right to join the pre-approval inspection conducted by the Party.

ARTICLE 9

Inspections and pre-approval inspections at the request of a Party

1. At the request of a Party, the other Party shall conduct a GMP inspection of a facility involved in the manufacturing process of a medicinal product that is being imported into the territory of

the requesting Party in order to verify that the facility is in compliance with good manufacturing practices.

2. At the request of a Party, the other Party may conduct a pre-approval inspection based on the assessment of data contained in a product submission dossier. The Parties may exchange relevant product information with respect to a request to conduct a pre-approval inspection in accordance with Article 17.

ARTICLE 10

Safeguards

1. A Party has the right to conduct its own GMP inspection of a manufacturing facility that has been certified as compliant by an equivalent authority of the other Party. Recourse to this right should be an exception from the normal practice of the Party.

2. A Party, prior to conducting a GMP inspection under paragraph 1, shall notify the other Party in writing and shall inform the other Party of the reasons for conducting its own inspection. The Party shall endeavour to notify the other Party in writing at least 30 days before a proposed GMP inspection, but may provide less notice in urgent situations. The other Party has the right to join the inspection conducted by the Party.

ARTICLE 11

Two-way alert programme and information sharing

1. A Party shall, pursuant to the two-way alert programme under the GMP Administrative Arrangements referred to in Article 18.3:

   (a) ensure that a restriction, suspension or withdrawal of a manufacturing authorisation that could affect the protection of public health is communicated from the relevant regulatory authority in its territory to the relevant regulatory authority in the territory of the other Party; and

   (b) if relevant, proactively notify the other Party in writing of a confirmed report of a serious problem relating to a manufacturing facility in its territory, or as identified through a GMP inspection or pre-approval inspection in the territory of the other Party, including a problem related to quality defects, batch recalls, counterfeited or falsified medicinal products or drugs, or potential serious shortages.

2. A Party shall, as part of the components of the information sharing process under the GMP Administrative Arrangement referred to in Article 18.3:

   (a) respond to a special request for information, including a reasonable request for a GMP inspection report or a pre-approval inspection report; and

(b) ensure that, at the request of the other Party or of an equivalent authority of the other Party, an equivalent authority within its territory provides relevant information.

3. A Party shall provide the other Party, through written notification, contact points for each equivalent authority in its territory.

ARTICLE 12

Equivalence of new regulatory authorities

1. A Party ("requesting Party") may request that a regulatory authority in its territory that is not recognised as equivalent to regulatory authorities in the other party ("evaluating Party"), be evaluated to determine whether it should be recognised as equivalent. Upon receiving the request, the evaluating Party shall conduct an evaluation pursuant to the procedure for evaluating new regulatory authorities under the Administrative Arrangements referred to in Article 18.3.

2. The evaluating Party shall evaluate the new regulatory authority by applying the components of a GMP, GCP and OCABR compliance programme under the Administrative Arrangements referred to in Article 18.3. The components of a compliance programme must include such elements as legislative and regulatory requirements, inspections standards, surveillance systems and a quality management system.

3. For the avoidance of doubt, equivalence does not require that the respective regulatory systems have identical procedures.

4. If, upon completion of its evaluation, the evaluating Party determines that the new regulatory authority is equivalent, it shall notify the requesting Party in writing that it recognises the new regulatory authority as equivalent.

5. If, upon completion of its evaluation, the evaluating Party determines that the new regulatory authority is not equivalent, the evaluating Party shall provide to the requesting Party a written justification demonstrating that it has well-founded reasons for not recognising that the new regulatory authority is equivalent. At the request of the requesting Party, the working group shall consider the evaluating Party's refusal to recognise the new regulatory authority as equivalent, and may provide recommendations to assist both Parties to resolve the matter.

6. If, upon completion of its evaluation, the evaluating Party determines that the new regulatory authority is only equivalent for a more limited scope than that proposed by the requesting Party, the evaluating Party shall provide to the requesting Party a written justification demonstrating that it has well-founded reasons to determine that the new regulatory authority is only equivalent for the more limited scope. At the request of the requesting Party, the working group shall consider the evaluating Party's refusal to recognise the new regulatory authority as equivalent, and may provide recommendations to assist both Parties to resolve the matter.

7. The regulatory authorities listed in Appendix 5-D-2 are recognised as equivalent under this Agreement from its entry into force.

ARTICLE 13

Equivalence maintenance programme

1. The working group shall develop an equivalence maintenance programme under the Administrative Arrangements referred to in Article 18.3 to maintain the equivalence of the regulatory authorities. The Parties shall act in accordance with this programme when deciding whether to change the equivalence status of a regulatory authority.

2. If the equivalence status of a regulatory authority changes, a Party may re-evaluate that regulatory authority. Any re-evaluation must be undertaken pursuant to the procedure set out in Article 12. The scope of re-evaluation shall be limited to the elements that caused the change of the equivalence status.

3. The Parties shall exchange all the necessary information to ensure that both Parties remain confident that equivalent authorities are in fact equivalent.

4. A Party shall inform the other Party before adopting changes to its technical guidance or regulations relating to good manufacturing practices, good clinical practices and OCABR.

5. A Party shall inform the other Party of any new technical guidance, inspection procedures or regulations relating to good manufacturing practices, good clinical practices and OCABR.

ARTICLE 14

Pharmacovigilance information sharing

1. The Parties shall, via the working group, endeavour to make every attempt to arrive at a mutually satisfactory arrangement to facilitate the sharing of documents and/or information in connection with ensuring the safety, quality and efficacy of medicinal products for human and veterinary use. The type of information that may be shared includes, but is not limited to:

   (a) Legislation and guidance documents available under the rules and regulations governing medicinal products in the Union (Eudralex) and United Kingdom, including all position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation;

   (b) Post-authorisation pharmacovigilance data, particularly data of an urgent nature or likely to have a significant public health impact;

   (c) Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and applications for agreement of paediatric investigation plans;

(d) Information Technology systems supporting regulatory processes; and

(e) Information related to implementation of international standards.

ARTICLE 15

Clinical trials information sharing

1. The Parties shall, via the working group, endeavour to make every attempt to arrive at a mutually satisfactory arrangement to facilitate the sharing of documents and/or information in connection with ensuring the safety, quality and efficacy of clinical trials. The type of information that may be shared includes, but is not limited to:

   (a) Assessments of requests for authorisation to conduct a clinical trial;

   (b) Reports of safety signals and serious breaches, including urgent safety measures;

   (c) GCP inspection reports; and

   (d) GCP inspection plans.

ARTICLE 16

Mutual recognition of OCABR

1. When OCABR applies, official batch releases carried out by a laboratory shall be recognised by the Party requiring the determination providing that laboratory is a laboratory designated or authorised by either Party, including an Official Control Batch Release Laboratory.

2. Where there is an overriding public health concern, a Party may test a product falling under the scope of this article, provided that notice and justification have been given to the other party in accordance with the Administrative Arrangements concluded under Article 18.3. The manufacturer shall provide the certificate of the official batch release.

ARTICLE 17

Confidentiality

1. A Party shall not publicly disclose non-public and confidential technical, commercial or scientific information, including trade secrets and proprietary information that it has received from the other Party.

2. A Party may disclose the information referred to in paragraph 1 if it deems such disclosure necessary to protect public health and safety. The other Party shall be consulted prior to disclosure.

ARTICLE 18

Management of the Annex

1. The working group is composed of representatives from both Parties.

2. The working group shall establish its composition and determine its rules and procedures.

3. The working group shall conclude Administrative Arrangements in relation to GMP, GCP and OCABR to facilitate the effective implementation of this Annex. The Administrative Arrangements shall include, where applicable:

   (a) the terms of reference of the working group;

   (b) the two-way alert programme;

   (c) the list of contact points responsible for matters arising under this Annex;

   (d) the components of the information sharing process;

   (e) the components of a compliance programme for good manufacturing practices and good clinical practices, and OCABR;

   (f) the procedure for evaluating new regulatory authorities;

   (g) the equivalence maintenance programme;

   (h) notification of OCABR testing where there is an overriding public health concern.

4. The working group may modify an Administrative Arrangement if it considers it necessary.

5. At the request of the Parties, the working group shall review the Appendices to this Annex and shall develop recommendations for amendments to these Appendices for consideration by the Committee on Technical Barriers to Trade.

ARTICLE 19

Fees

1. For the purposes of this Article, a fee includes a cost-recovery measure such as a user fee, a regulatory charge or an amount set under a contract.

2. A Party shall have the right to determine a fee applicable to manufacturing facilities premises or entities in its territory, including fees related to issuing certificates of GMP compliance and GCP inspection reports, and fees related to GMP and GCP inspections and pre-approval inspections.

3. The fees charged to a manufacturing facility, premises or entity in case of a GCP or GMP inspection or pre-approval inspection conducted by a Party at the request of the other Party must be consistent with paragraph 2.

APPENDIX 5-D-1

PRODUCTS

1. Subject to Article 3, this Annex applies to the following products as defined in the legislation of the Parties referred to in Appendix 5-D-3:

   (a) human pharmaceuticals including prescription and non-prescription medicinal products and medicinal gases;

   (b) human biologicals including immunologicals, stable medicinal products derived from human blood or human plasma, and biotherapeutics;

   (c) human radiopharmaceuticals;

   (d) veterinary pharmaceuticals, including prescription and non-prescription medicinal products, and pre-mixes for the preparation of veterinary medicated feeds;

   (e) veterinary biologicals;

   (f) if appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products;

   (g) active substances;

   (h) intermediate products and bulk pharmaceuticals (for example, bulk tablets);

   (i) products intended for use in clinical trials or investigational medicinal products; and

   (j) advanced therapy medicinal products.

APPENDIX 5-D-2

REGULATORY AUTHORITIES

[…]

APPENDIX 5-D-3

APPLICABLE LEGISLATION

For the Union:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products;

Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products;

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products;

Commission delegated Regulation (EU) 1252/2014 of 28 May 2014 of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use; and

Current version of the Guide to good manufacturing practices contained in volume IV of Rules governing medicinal products in the European Union and compilation of the community procedures on inspections and exchange of information.

For the United Kingdom:

The Human Medicines Regulations 2012 (SI 2012/1916);

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031); and

The Veterinary Medicines Regulations 2013 (SI 2013/2033).

ANNEX 5-E

CHEMICALS

ARTICLE 1

Definitions

For the purposes of this Annex:

“responsible authorities” means;

For the Union: the European Commission, the European Chemicals Agency (ECHA), or the competent authority of a Member State where it has lead responsibility for chemical activities;

For the United Kingdom: the Health and Safety Executive (HSE).

“UN GHS” means the United Nations Globally Harmonized System of Classification and Labelling of Chemicals.

ARTICLE 2

Scope

This Annex applies to the trade, regulation, import and export of chemicals between the Union and the United Kingdom in respect of their registration, evaluation, authorisation, restriction, approval, classification, labelling and packaging.

ARTICLE 3

Objectives

1. The objectives of this Annex are to:

   (a) facilitate the trade of chemicals and related products, between the Parties, including through the removal of technical barriers to trade relevant to these goods;

   (b) ensure high levels of protection for the environment, and human and animal health, balanced against the economic interests of the Parties; and

   (c) provide for cooperation between Union and United Kingdom regulatory authorities, including through the sharing of information on chemicals.

2. The Parties acknowledge that the commitments made under this Annex do not prevent each Party from setting its own priorities on chemicals regulation, including establishing its own levels of protection in respect of the environment, and human and animal health.

ARTICLE 4

Trade in chemicals

The Parties recognise the importance of regulated trade in chemicals between the Union and the United Kingdom in terms of economic benefits, environmental protection and the protection of human and animal health and agree to effectively implement the obligations in this Annex to facilitate that trade and those protections.

ARTICLE 5

Relevant international organisations and bodies

The Parties recognise that international organisations and bodies, in particular the OECD and the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (SCEGHS) of the United Nations Economic and Social Council (ECOSOC) are relevant for developing scientific and technical guidelines with respect to chemicals.

ARTICLE 6

Participation in relevant international organisations and bodies and regulatory development

1. The Parties shall actively contribute to the development of scientific or technical guidelines with respect to the assessment of hazards and risks of chemicals and the formats for documenting the results of such assessments.

2. The Parties shall implement the guidelines from the international organisations indicated in Article 5 unless those guidelines would be ineffective or inappropriate for the achievement of each Party's public policy objectives.

ARTICLE 7

Classification and Labelling of Chemicals

1. Each Party shall implement the UN GHS as comprehensively as considered feasible within its respective systems, including for chemicals that are not within the scope of this Annex, except where there are specific reasons to apply a different labelling system for particular chemical products in the finished state intended for the final user. Each Party shall periodically update its implementation based on the regular revisions of the UN GHS.

2. When fulfilling obligations under paragraph 1 above, the United Kingdom agrees to take account of the Union's adoption of UN GHS through legislation regulating the classification, labelling and packaging of chemicals.

3. When fulfilling obligations under paragraph 1 above, the Union agrees to take account of United Kingdom's adoption of UN GHS through legislation regulating the classification, labelling and packaging of chemicals.

4. When the responsible authorities of each Party intend to classify individual substances in accordance with respective procedures, they shall give the responsible authorities of the other Party, upon their request, the possibility to express their views with those respective procedures.

5. In order to give the other Party the possibility to request such participation, the responsible authorities shall inform each other promptly when launching procedures related to the classification of substances, including for the assessment of scientific evidence. Before taking a final decision on the classification of substances, each Party shall respond to comments received from the other Party during such procedures.

ARTICLE 8

Cooperation

1. The Parties agree to continue and strengthen their cooperation on chemicals regulation, to facilitate trade in a way that benefits consumers, businesses and the environment and provides for the protection of human and animal health. This may include promoting and encouraging cooperation between the Parties' respective public or private organisations responsible for the manufacture, distribution, sale or regulation of chemicals.

2. The Parties further agree to share data, risk assessments, scientific information, priority substance information and assessment methodologies where this is appropriate and necessary to support their commitments on cooperation under this Annex.

3. The Parties shall cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines, including, where feasible, through the presentation of joint initiatives, proposals and approaches in the relevant international organisations and bodies, in particular those referred to in Article 5.

4. The Parties agree to cooperate on the dissemination of data related to chemicals safety, which shall be made available to the public with the objective to foster easy access and comprehensibility of the information by different target groups. Upon request of either Party, the other Party shall provide available non-confidential information on chemicals to the requesting Party.

5. The Parties shall enter into consultations, if so requested by either Party, on scientific information and data in the context of new and emerging issues related to the hazards or risks posed by chemicals to human health or the environment with a view to creating a common pool of knowledge and promoting, if feasible and to the extent possible, a common understanding of the science related to such issues.

6. The Parties shall develop a memorandum of understanding to enhance cooperation between the European Chemicals Agency and the United Kingdom authorities. The Parties shall endeavour to adopt this by 31 December 2021.

7. The Parties shall agree to the sharing and protection of information on chemicals within the scope of this Annex in accordance with the mechanism set out in Appendix 5-E-1 to this Annex.

APPENDIX 5-E-1

SHARING AND PROTECTION OF INFORMATION

[…]

ANNEX 5-F

ORGANIC PRODUCTS

ARTICLE 1

Objective and scope

1. The objective of this Annex is to set out the provisions and procedures for fostering trade in organic products in accordance with the principles of non-discrimination and reciprocity, by means of recognition of equivalence by the Parties of their respective laws.

2. This Annex shall apply to specified organic products which comply with the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4.

ARTICLE 2

Definitions

For the purposes of this Annex:

“competent authority” means an official agency that has jurisdiction over the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4 and is responsible for the implementation of this Annex;

“control authority” means an authority on which the competent authority has conferred, in whole or in part, its competence for inspection and certification in the field of organic production in accordance with the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4;

“control body” means an entity recognised by the competent authority to carry out inspection and certification in the field of organic production in accordance with the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4; and

"equivalence" means the capability of different laws, regulations and requirements, as well as inspection and certification systems, to meet the same objectives.

ARTICLE 3

Recognition of equivalence

1. With respect to products listed in Appendix 5-F-1 to this Annex, the Union recognises the laws and regulations of the United Kingdom listed in Appendix 5-F-3 as equivalent to its laws and regulations listed in Appendix 5-F-4.

2. With respect to products listed in Appendix 5-F-2 to this Annex, the United Kingdom recognises the laws and regulations of the Union listed in Appendix 5-F-4 as equivalent to its laws and regulations listed in Appendix 5-F-3.

3. In the event of the modification, revocation or replacement of, or addition to, the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4, the new rules shall be considered equivalent to the other Party’s rules unless the other Party objects in accordance with the procedure set out in paragraphs 4 and 5.

4. If a Party considers, following the receipt of further information from the other Party that it has requested, that the laws, regulations or administrative procedures and practices of the other Party no longer meet the requirements for equivalence, it shall issue a reasoned request to

the other Party to amend the relevant law, regulation or administrative procedure or practice and provide an adequate time-frame, which shall not be less than three months, for ensuring equivalence.

5. If, following the expiry of the period in paragraph 4, the Party concerned still considers that the requirements for equivalence are not met, it may unilaterally suspend the recognition of equivalence of the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4 as regards the relevant organic products listed in Appendix 5-F-1 or Appendix 5-F-2.

6. A decision to unilaterally suspend the recognition of equivalence of the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4 as regards the relevant products listed in Appendix 5-F-1 or Appendix 5-F-2 may also be taken, following the expiry of a notice period of three months, when one Party has not provided the information required under Article 6 or does not agree to a peer review under Article 7.

7. Where recognition of equivalence is suspended in accordance with this Article, the matter shall be referred to the Committee on Organics which shall make every effort to agree measures that would enable recognition of equivalence to be restored.

8. With respect to products not listed in Appendix 5-F-1 or Appendix 5-F-2, equivalence shall be examined at the request of one Party by the Committee on Organics.

ARTICLE 4

Import and placing on the market

1. The Union shall accept the import into its territory, and the placing on the market as organic products, of the products listed in Appendix 5-F-1, provided that those products comply with the laws and regulations of the United Kingdom listed in Appendix 5-F-3 and are accompanied by a certificate of inspection issued by a control body recognised by the United Kingdom and indicated to the Union in accordance with paragraph 3.

2. The United Kingdom shall accept the import into its territory, and the placing on the market as organic products, of the products listed in Appendix 5-F-2, provided that those products comply with the laws and regulations of the Union listed in Appendix 5-F-4 and are accompanied by a certificate of inspection issued by a control body recognised by the Union and indicated to the United Kingdom in accordance with paragraph 3.

3. Each Party recognises the control authorities or control bodies indicated by the other Party as responsible for performing the relevant controls as regards organic products covered by the recognition of equivalence as referred to in Article 3 and for issuing the certificate of inspection as referred to in paragraphs 1 and 2 with a view to their import into and placing on the market in the territory of the other Party.

4. The importing Party, in cooperation with the other Party, shall assign code numbers to each relevant control authority and control body indicated by the other Party.

ARTICLE 5

Labelling

1. Products imported from one Party by the other Party in accordance with this Annex shall meet the requirements on labelling set out in the laws and regulations of the other Party listed in Appendix 5-F-3 and Appendix 5-F-4. These products may bear the Union's organic logo, any United Kingdom organic logo or both logos, as set out in the relevant laws and regulations, provided that they comply with the labelling requirements for the respective logo or both logos.

2. The Parties undertake to avoid any misuse of the terms referring to organic production in relation to organic products that are covered by the recognition of equivalence under this Annex.

3. The Parties undertake to protect the Union's organic logo and any United Kingdom organic logo set out in the relevant laws and regulations against any misuse or imitation. The Parties shall ensure that the Union's organic logo and any United Kingdom organic logo are used only for the labelling, advertising or commercial documents of organic products complying with the laws and regulations listed in Appendix 5-F-3 and Appendix 5-F-4.

ARTICLE 6

Exchange of information

1. The Parties shall exchange all relevant information with respect to the implementation and application of this Annex. In particular, by 31 March of the second year following the entry into force of this Agreement, and subsequently by 31 March of each year, each Party shall send to the other:

   (a) a report that contains information with respect to the types and quantities of organic products exported under this Annex, covering the period from January to December of the previous year;

   (b) a report on the monitoring and supervisory activities carried out by its competent authorities, the results obtained and the corrective measures taken, covering the period from January to December of the previous year; and

   (c) details of observed irregularities and infringements of the laws and regulations listed in Appendix 5-F-3 or Appendix 5-F-4, as relevant.

2. At any time, each Party shall without delay inform the other Party of:

   (a) any update to the list of its competent authorities, control authorities and control bodies, including the relevant contact details (in particular the address and the internet address);

   (b) any changes or repeals it intends to make in respect of laws or regulations listed in Appendix 5-F-3 and Appendix 5-F-4, any proposals for new laws or regulations or any

relevant proposed changes to administrative procedures and practices related to organic products covered by this Annex; and

(c) any changes or repeals it has adopted in respect of laws or regulations listed in Appendix 5-F-3 and Appendix 5-F-4, any new legislation or relevant changes to administrative procedures and practices related to organic products covered by this Annex.

ARTICLE 7

Peer reviews

1. Following advance notice of at least six months, each Party shall permit officials or experts designated by the other Party to conduct peer reviews in its territory to verify that the relevant control authorities and control bodies are carrying out the controls required to implement this Annex.

2. Each Party shall cooperate with and assist the other Party, to the extent permitted under the applicable law, in carrying out the peer reviews referred to in paragraph 1, which may include visits to offices of relevant control authorities and control bodies, processing facilities and certified operators.

ARTICLE 8

Committee on Organics

1. The Committee on Organics shall consider all matters which may arise in connection with the implementation of this Annex.

2. The functions of the Committee on Organics shall be to:

(a) manage this Annex, taking the decisions necessary for its implementation and good functioning;

(b) make recommendations to the Joint Committee to modify this Annex or any of its appendices in order to reflect the agreed position of the Parties on equivalence or to give effect to any of its decisions;

(c) enhance cooperation on laws, regulations, standards and procedures concerning the organic products covered by this Annex, including discussions on any technical or regulatory issue related to the rules and control systems; and

(d) consider any other issue with respect to the implementation of this Annex.

APPENDIX 5-F-1

ORGANIC PRODUCTS FROM THE UNITED KINGDOM FOR WHICH THE UNION RECOGNISES EQUIVALENCE

Description	Comments
Unprocessed plant products	
Live animals or unprocessed animal products	Includes Honey/Beeswax
Aquaculture products and seaweeds	
Processed agricultural products for use as food	
Processed agricultural products for use as feed	
Seeds and propagating material	

APPENDIX 5-F-2

ORGANIC PRODUCTS FROM THE UNION FOR WHICH THE UNITED KINGDOM RECOGNISES EQUIVALENCE

Description	Comments
Unprocessed plant products	
Live animals or unprocessed animal products	Includes Honey/Beeswax
Aquaculture products and seaweeds	
Processed agricultural products for use as food	
Processed agricultural products for use as feed	
Seeds and propagating material	

APPENDIX 5-F-3

ORGANIC PRODUCTS LEGISLATION APPLICABLE IN THE UNITED KINGDOM

The following legislation applicable in the UK:[4]

Retained REGULATION (EC) No 834/2007

[4] References in this list to Retained EU Law are deemed to be references to such legislation, as amended by the United Kingdom to apply to the United Kingdom.

Retained REGULATION (EC) No 889/2008

Retained REGULATION (EC) No 1235/2008

The Organic Products Regulations 2009

APPENDIX 5-F-4

ORGANIC PRODUCTS LEGISLATION APPLICABLE IN THE UNION

The following legislation applicable in the Union:

REGULATION (EU) 2018/848 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 30 May 2018, on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

ANNEX 6-A

CONDITIONS AND PROCEDURES FOR ESTABLISHING TRADE CONDITIONS

The conditions and procedures for the purpose of Article 6.5(b) are as follows:

(a) the import of the product has been authorised, if so required, by the competent authority of the importing Party;

(b) the establishment or facility concerned has been approved by the competent authority of the exporting Party;

(c) the competent authority of the exporting Party has the authority to suspend or withdraw the approval of the establishment or facility; and

(d) the exporting Party has provided relevant information requested by the importing Party.

ANNEX 6-B

IMPORT CHECKS AND FEES

[…]

ANNEX 6-C

CERTIFICATION

[…]

ANNEX 6-D

RECOGNITION OF ANIMAL HEALTH AND PLANT PEST STATUS AND REGIONAL CONDITIONS

Part A. Procedure for recognition of zones, compartments and pest status in respect of animal health

1. In accordance with the provisions of Article 6.9, the exporting Party, seeking recognition by the importing Party of its zones and compartments, including pests or disease-free areas and low pests or disease prevalence areas or a protected zone if applicable, shall notify its measures to the importing Party.

2. The Parties shall notify each other of any change in the measures specified in paragraph 1 which relate to the disease or pest. The additional guarantees may, in the light of such notification, be amended or withdrawn.

3. Notification shall include explanation and supporting data setting out in particular:

   (a) the nature of the disease and the history of its occurrence in its territory

   (b) the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation. It shall also be considered if the disease must be notified by law to the competent authorities;

   (c) the period over which the surveillance was carried out;

   (d) where applicable, the period during which vaccination against the disease was prohibited and the geographical area concerned by the prohibition; and

   (e) the measures to verify the absence of the disease.

Part B. Procedure for recognition of zones, compartments and pest status in respect of plant health

Each Party commits to following international standards, including, but not limited to:

   (a) ISPM 29 – Recognition of pest free areas and areas of low pest prevalence;

   (b) ISPM 04 – Requirements for the establishment of pest free areas;

   (c) ISPM 10 – Requirements for the establishment of pest free places of production and pest free production sites;

   (d) ISPM 22 – Requirements for the establishment of areas of low pest prevalence; and

   (e) Article 6 of the SPS Agreement – Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence.

ANNEX 6-E

ANIMAL DISEASES FOR WHICH REGIONALISATION AND COMPARTMENTALISATION DECISIONS WILL BE MUTUALLY RECOGNISED

[…]

ANNEX 6-F

EQUIVALENCE

Part A. Guidelines to determine and recognise equivalence

1. In reaching a determination of whether an SPS measure applied by an exporting Party achieves the importing Party's appropriate level of protection, the Parties shall follow a process that includes the following steps:

   (a) the identification of the SPS measure(s) for which recognition of equivalence is sought;

   (b) the explanation by the importing Party of the objective of its SPS measure(s), including an assessment, as appropriate to the circumstances, of the risk, or risks, that the SPS measure(s) is intended to address, and identification by the importing Party of its appropriate level of protection;

   (c) the demonstration by the exporting Party that its SPS measure(s) achieves the importing Party's appropriate level of protection;

   (d) the determination by the importing Party of whether the exporting Party's SPS measure(s) achieves its appropriate level of protection; and

   (e) the importing Party shall accept the SPS measure(s) of the exporting Party as equivalent if the exporting Party objectively demonstrates that its measure(s) achieves the importing Party's appropriate level of protection.

2. Where equivalence has not been recognised, trade may take place under the conditions required by the importing Party to meet its appropriate level of protection. The exporting Party may agree to meet the importing Party's conditions, without prejudice to the result of the process set out in paragraph 1.

Part B. Guidelines on maintenance of equivalence

1. If a Party intends to adopt, modify, or repeal an SPS measure in an area for which it has made a recognition of equivalence as set out in Article 6.12 or a recognition described in Article 6.12, that Party should:

   (a) evaluate whether the adoption, modification or repeal of that SPS measure may affect the recognition; and

(b) notify the other Party of its intention to adopt, modify, or repeal that SPS measure, and of the evaluation under sub-paragraph (a). The notification should take place at an early and appropriate stage, when amendments can still be introduced and comments taken into account.

2. If a Party adopts, modifies, or repeals an SPS measure listed in Part B of Annex 6-G or which is in an area for which it has made a recognition of equivalence under Article 6.12, or a recognition described in Article 6.12, the importing Party shall continue to accept the recognition until it has communicated to the exporting Party whether special conditions must be met, and if so, provided the special conditions to the exporting Party. The importing Party shall consult with the exporting Party to develop these special conditions.

ANNEX 6-G

RECOGNITION OF SANITARY MEASURES

Part A. General

1. If a Party modifies an SPS measure listed in this Annex, the modified SPS measure applies to imports from the other Party, taking into account paragraph 2 of Part B to Annex 6-F. For updated SPS measures, refer to the legislative publications of each Party.

2. If an importing Party determines that a special condition listed in this Annex is no longer necessary, that Party shall notify the other Party in accordance with Part B of Annex 6-F that it will no longer apply that special condition to imports from the other Party.

3. For greater certainty, an SPS measure of an importing Party that is not otherwise referenced in this Annex or a measure of an importing Party that is not an SPS measure applies, as appropriate, to imports from the other Party.

Part B. Sanitary measures

[Table included for illustrative purposes only. Full content to be agreed at a later stage.]

SPS Area	Exports from the Union to the United Kingdom			Exports from the United Kingdom to the Union		
	SPS measure(s) of the Union	SPS measure(s) of the United Kingdom	Special condition(s)	SPS measure(s) of the United Kingdom	SPS measure(s) of the Union	Special condition(s)

ANNEX 6-H

PRINCIPLES AND GUIDELINES FOR AUDIT, INSPECTION AND VERIFICATION

1. The importing Party may determine that it is necessary to carry out an audit or inspection as one of the tools to assess the exporting Party's official inspection and certification systems. These audits and inspections shall follow a systems-based approach which relies on the

examination of a sample of system procedures, documents or records and, where required, on-site inspections of facilities within the scope of the audit or inspection.

2. Audits and inspections shall concentrate primarily on evaluating the effectiveness of the official inspection and certification systems as well as the capacity of the exporting Party to comply with the sanitary and phytosanitary import requirements and related control measures rather than on specific establishments in order to determine the ability of the exporting Party's competent authorities to have and maintain control and deliver the required assurances to the importing country.

3. Prior to the commencement of an audit or inspection, the Parties shall discuss the objectives and scope of the audit or inspection, the criteria or requirements against which the exporting Party will be assessed, and the itinerary and procedures for conducting the audit or inspection which shall be laid down in an audit or inspection plan. Unless otherwise agreed by the Parties, the importing Party shall provide the exporting Party an audit plan at least 30 days prior to the commencement of the audit or inspection.

4. The importing Party shall set forth its findings, conclusions and recommendations (if any) from the audit or inspection in writing in a draft audit or inspection report.

5. The importing Party shall provide the draft audit or inspection report to the exporting Party, normally within 30 days of the conclusion of the audit or inspection.

6. The exporting Party shall inform the importing Party of any corrective actions based on the findings and conclusions in the draft audit or inspection report.

7. The importing Party shall provide the exporting Party the opportunity to comment on the draft audit or inspection report. The importing Party shall provide a final report in writing to the exporting Party normally within two months from the date of receipt of those comments.

8. Each Party shall ensure that procedures are in place to prevent the disclosure of confidential information that is acquired during an audit or inspection of the exporting Party’s competent authorities, including procedures to remove any confidential information from a final audit or inspection report that is made publicly available.

ANNEX 6-I

ANIMAL DISEASES FOR WHICH REGIONALISATION AND COMPARTMENTALISATION DECISIONS WILL BE MUTUALLY RECOGNISED

[…]

ANNEX 7-A

MUTUAL RECOGNITION OF AUTHORISED ECONOMIC OPERATORS

ARTICLE 1

Scope

1. The Parties mutually recognise the following Programmes:

   (a) Her Majesty's Revenue and Customs Authorised Economic Operator (Safety and Security) Programme; and

   (b) The European Union Authorised Economic Operator (Safety and Security) Programme as set out in Regulation (EU) No 952/2013, together with Regulation (EU) 2015/2446 and Regulation (EU) 2015/2447; hereinafter referred to as the "Programmes".

ARTICLE 2

Responsible entities

The customs authorities are the entities responsible for implementation of the arrangements set out in this Annex.

ARTICLE 3

Compatibility and granting of AEO status

1. For purposes of consistency, the Parties intend to maintain comparable standards for each Programme with respect to the following matters:

   (a) application process for membership;

   (b) assessment of membership applications; and

   (c) approval of membership and monitoring of membership status.

2. The Parties agree to operate each Programme within the context of the Customs-to-Customs Pillar of the SAFE Framework, as it may be amended with the concurrence of the customs authorities.

3. The Parties agree that the criteria for granting the status of AEO shall include:

   (a) a satisfactory record of compliance with customs requirements;

(b) an efficient system of managing commercial and, where appropriate, transport records, which makes it possible to carry out appropriate customs controls for security purposes;

(c) proven financial solvency; and

(d) appropriate security and safety standards.

4. Each Party shall, with respect to its Programme, determine the procedures for requesting and granting the status of AEO, and the legal effects of this status.

5. The Parties shall ensure that their customs authorities monitor AEOs′ compliance with the relevant conditions and criteria and that they re-examine these conditions and criteria, notably if there is evidence making it reasonable to think that an economic operator no longer meets the applicable requirements.

ARTICLE 4

Mutual recognition

1. Each Party shall accept the validation and approval status granted to members of the other Party's Programme.

2. Each Party shall treat members of the other Party's Programme in a manner comparable to the way it treats members in its own Programme and shall provide comparable benefits, to the extent practicable and possible and consistent with applicable law and policy. The benefits shall include, but are not limited to:

(a) taking AEO status into account favourably in its risk assessment to reduce inspections or controls and in other security and safety-related measures;

(b) notifying the AEO before the arrival of goods into the customs territory or departure of goods from it that, as a result of security and safety risk analysis, the consignment has been selected for further physical inspection, as long as this does not adversely affect the inspection to be carried out;

(c) giving priority to the inspection of consignments covered by exit or entry summary declarations lodged by an AEO, if the customs authority decides to proceed with an inspection; and

(d) offering AEOs the option of carrying out inspection of consignments covered by exit or entry summary declarations in a place other than that in which the authority normally carries out its inspections, at the request of the AEO and in agreement with the customs authority.

3. Each Party shall provide the other Party with sufficient information regarding its members to support the other Party's risk assessments.

4. Each Party may suspend treatment consistent with Article 4(2) to members of the other Party's Programme. Such suspension of treatment is to be promptly communicated to the other Party, along with additional information regarding the basis for suspension, as appropriate.

5. The Parties shall maintain the ability to revoke membership in their respective Programme procedures. The fact of the revocation by one Party of a member whose status has been accepted by the other Party should be promptly communicated to the other Party.

ARTICLE 5

Information exchange and party communication

1. The Parties shall endeavour to achieve greater communication by:

   (a) providing updates on their respective Programme's operation and development in a timely manner;

   (b) engaging in mutually beneficial information exchanges regarding supply chain security;

   (c) sharing information regarding members of the Programmes, as appropriate in connection to mutual recognition efforts; and

   (d) designating and providing the contact points of their respective Programmes to the other Party.

2. Information sharing activities are to be conducted in a format consistent with the terms of this Agreement and each Party's domestic law and policy.

3. Her Majesty's Revenue and Customs may share information obtained under this Annex with any other authority responsible for customs matters within the customs territory of the United Kingdom, provided that such entities have an official need to know such information. The competent services of the Commission of the Union and the customs authorities of the Member States of the Union may share information obtained under this Annex with other competent customs authorities within the Member States of the Union, provided that such entities have an official need to know such information.

4. Information and related data shall be exchanged by electronic means and where appropriate in a systematic manner.

ARTICLE 6

Mutual cooperation and future endeavours

1. The Parties agree to engage in actions to strengthen end-to-end supply chain security, including through periodic joint site validations.

2. The Parties agree to focus their efforts on the achievement of the following mutual objectives:

(a) development and maintenance of an automated system of data exchange to facilitate the prompt provision of benefits to new AEOs and increase cooperation between the Parties; and

(b) expansion of Programme membership through the reciprocal promotion of trade facilitation achieved through the mutual recognition of the Programmes.

ARTICLE 7

Modification and consultation

1. The Parties agree that the Customs Committee shall regularly review this Annex, and when instructed to do so by either Party shall recommend the Joint Committee adopt a decision amending this Annex as appropriate.

2. All issues related to the interpretation or implementation of this Annex shall, in the first instance, be the subject of discussion in the Customs Committee.

ARTICLE 8

Costs

The Parties shall be responsible for their own costs incurred as a result of implementing the arrangements in this Annex.

ARTICLE 9

Suspension

1. At the request of either Party, the Customs Committee may recommend the Joint Committee issue a decision suspending the operation of this Annex. For the avoidance of doubt, where the operation of this Annex is suspended, the customs authorities shall cease to provide members of the other Party's Programme the benefits previously afforded to them by virtue of this Annex.

2. Where the operation of this Annex has been suspended in accordance with paragraph 1, at the request of either Party, the Customs Committee may recommend the Joint Committee issue a decision reinstating the operation of this Annex.

ANNEX 7-B

COOPERATION AND MUTUAL ADMINISTRATIVE ASSISTANCE IN CUSTOMS MATTERS

Title I

ARTICLE 1

Definitions

For the purpose of this Annex:

“customs legislation” means any laws and regulations of the Union or the United Kingdom governing the import, export and transit of goods and their placing under any other customs regime or procedure, including measures of prohibition, restriction and control, and administered, applied or enforced by the customs authorities of the Parties in their respective territories;

“laws and regulations of the Party”, “laws and regulations of that Party” and “laws and regulations of each Party” means the laws and regulations applicable in the Union in the circumstances, or the laws and regulations applicable in the United Kingdom, as the context requires;

“applicant authority” means a competent administrative authority which has been designated in a Party for this purpose and which makes a request for assistance on the basis of this Annex;

“requested authority” means a competent administrative authority which has been designated in a Party for this purpose and which receives a request for assistance on the basis of this Annex;

“person” means any natural person, any legal person, or any other entity without legal personality constituted or organised under the laws and regulations of each Party, carrying out operations covered by the customs legislation of the Parties;

“information” means data, including personal data, documents, reports, and other communications in any format, including electronic copies thereof;

“personal data” means any information relating to an identified or identifiable natural person; and

“operations in breach of customs legislation” means any violation or attempted violation of the customs legislation.

ARTICLE 2

Implementation

1. This Annex shall be implemented in accordance with the laws and regulations applicable in the Union and in the United Kingdom, including in the field of data protection, and within the available resources of their respective customs authorities.

2. Customs authorities of the Union and of the United Kingdom shall decide on all practical measures and arrangements necessary for the implementation of this Annex.

3. In respect of questions relating to the applicability of this Annex, the Parties shall consult each other to resolve the matter in the framework of the Customs Committee.

ARTICLE 3

Relation to other international agreements

1. The provisions of this Annex shall not affect the rights and obligations of the Parties under any other international agreement to which either Party is a party.

2. Notwithstanding paragraph 1, the provisions of this Annex shall take precedence over the provisions of any bilateral agreement on customs cooperation and mutual administrative assistance which has been or may be concluded between individual Member States of the Union and the United Kingdom, insofar as the provisions of those bilateral agreements are incompatible with those of this Annex.

3. The provisions of this Annex shall not affect the Union provisions governing the communication between the customs authorities in the Union of any information obtained under this Annex which could be of interest to the Union.

Title II

ARTICLE 4

Scope of cooperation

1. Under this Annex, customs cooperation shall cover all matters relating to the application of customs legislation.

2. The Parties shall undertake to develop customs cooperation. In particular, the Parties shall seek to cooperate in:

   (a) establishing and maintaining channels of communication between their customs authorities to facilitate and secure the rapid exchange of information;

   (b) facilitating effective coordination between their customs authorities;

   (c) any other administrative matters related to this Annex that may from time to time require their joint action; and

   (d) developing joint initiatives relating to import, export and other customs procedures, as well as towards ensuring an effective service to the business community.

3. The Parties also undertake to make cooperative efforts through their customs authorities in order to develop trade facilitation action in the field of customs in accordance with international standards.

ARTICLE 5

Cooperation in customs procedures

For the purpose of facilitating the legitimate movement of goods, the customs authorities shall exchange information and expertise on measures to improve customs techniques and procedures and on computerised systems in accordance with the provisions of this Annex.

ARTICLE 6

Technical cooperation

The customs authorities may provide technical cooperation to each other and exchange personnel and expertise on measures to improve customs techniques and procedures and on computerised systems with a view towards achieving these objectives in accordance with the provisions of this Annex.

ARTICLE 7

Coordination with international organisations

The customs authorities shall seek to develop and strengthen their cooperation on topics of common interest with a view to facilitating discussions on customs matters in the framework of relevant international organisations such as the WCO and the WTO.

Title III

ARTICLE 8

Scope of assistance

1. The customs authorities of the Parties shall assist each other in the prevention, identification, investigation and suppression of breaches of their customs legislation.

2. Assistance under this Title shall not prejudice the rights and obligations of either Party in relation to mutual assistance in criminal matters under international agreements or the laws and regulations of each Party. Nor shall it cover information obtained under powers exercised at the request of a judicial authority.

3. Assistance to recover duties, taxes or fines is not covered by this Annex.

ARTICLE 9

Assistance on request

1. At the request of the applicant authority, the requested authority shall provide it with all relevant information which may enable it to ensure that customs legislation is correctly applied, including information regarding activities detected or planned which are or could be operations in breach of customs legislation.

2. At the request of the applicant authority, the requested authority shall inform it of:

   (a) whether goods exported from a Party have been properly imported into the other Party, specifying where appropriate the customs procedure applied to the goods; and

   (b) whether goods imported into a Party have been properly exported from the other Party, specifying where appropriate the customs procedure applied to the goods.

3. At the request of the applicant authority, the requested authority shall, within the framework of laws and regulations applicable to the latter, take the necessary steps to ensure special surveillance of:

   (a) persons in respect of whom there are reasonable grounds for believing that they are or have been involved in operations in breach of customs legislation;

   (b) places where stocks of goods have been or may be stored or assembled in such a way that there are reasonable grounds for believing that those goods are intended to be used in operations in breach of customs legislation;

   (c) goods that are or may be transported in such a way that there are reasonable grounds for believing that they are intended to be used in operations in breach of customs legislation;

   (d) means of transport that are or may be used in such a way that there are reasonable grounds for believing that they are intended to be used in operations in breach of customs legislation; and

   (e) premises suspected by the applicant authority of being used to commit breaches of customs legislation.

ARTICLE 10

Spontaneous assistance

The Parties shall assist each other, at their own initiative and in accordance with the laws and regulations of each Party, if they consider that to be necessary for the correct application of customs legislation, particularly by providing information obtained pertaining to:

   (a) activities which are or appear to be operations in breach of customs legislation and which may be of interest to the other Party

   (b) new means or methods employed in carrying out operations in breach of customs legislation

(c) goods known to be subject to operations in breach of customs legislation;

(d) persons in respect of whom there are reasonable grounds for believing they are or have been involved in operations in breach of customs legislation; and

(e) means of transport in respect of which there are reasonable grounds for believing that they have been, are, or may be used in operations in breach of customs legislation.

ARTICLE 11

Delivery and notification

At the request of the applicant authority, the requested authority shall, in accordance with the laws and regulations applicable to the latter, take all necessary measures in order to:

(a) deliver any documents; or

(b) notify any decisions, emanating from the applicant authority and falling within the scope of this Annex, to an addressee residing or established in the jurisdiction of the requested Party.

ARTICLE 12

Form and substance of requests for assistance

1. Requests pursuant to this Annex shall be made in writing. They shall be accompanied by the documents necessary to enable compliance with the request. When required because of the urgency of the situation, an oral request may be accepted, but shall be confirmed promptly in writing.

2. Requests pursuant to paragraph 1 shall include the following information:

(a) the applicant authority;

(b) the measure requested;

(c) the object of and the reason for the request;

(d) the relevant laws and regulations;

(e) indications as exact and comprehensive as possible on the goods or persons who are the target of the investigations; and

(f) a summary of the relevant facts of the enquiries already carried out.

3. Requests shall be submitted in an official language of the requested Party or in a language that is acceptable to that Party. That requirement shall not apply to any documents that accompany the request under paragraph 1.

4. If a request does not meet the formal requirement set out above, its correction or completion may be requested; precautionary measures may be taken in the meantime.

ARTICLE 13

Execution of requests

1. In order to comply with a request for assistance, the requested authority shall proceed promptly, as though it were acting on its own account or at the request of other authorities of that same Party, by supplying information already possessed, by carrying out appropriate enquiries or by arranging for them to be carried out. This paragraph shall also apply to any other authority to which the request has been addressed in accordance with this Annex by the requested authority when the latter cannot act on its own.

2. Requests for assistance shall be executed in accordance with the laws and regulations of the Party which receives the request.

3. Duly authorised officials of a Party may, with the agreement of the other Party and subject to the conditions laid down by the latter, be present to obtain in the offices of the requested authority or any other concerned authority in accordance with paragraph 1, information relating to activities that are or may be operations in breach of customs legislation which the applicant authority needs for the purpose of this Annex.

4. Duly authorised officials of a Party may, with the agreement of the other Party and subject to the conditions laid down by the latter, be present at enquiries carried out in the latter's territory.

5. In the event that the request cannot be complied with, the applicant authority shall be notified promptly of that fact with a statement of the reasons. The statement may be accompanied by the relevant information that the requested authority considers may be of assistance to the applicant authority.

ARTICLE 14

Form in which information is to be communicated

1. The requested authority shall communicate results of enquiries conducted pursuant to a request made under this Annex to the applicant authority in writing together with relevant documents, certified copies of documents or other items.

2. The information communicated under paragraph 1 may be in computerised form.

3. Original files and documents shall be transmitted only upon request in cases where certified copies would be insufficient. Those originals shall be returned to the requested authority at the earliest opportunity.

ARTICLE 15

Exceptions to the obligation to provide assistance

1. Any form of assistance within the scope of this Title may be refused, or may be subject to certain conditions or requirements, if the requested Party considers that execution of the request would:

   (a) be likely to prejudice the sovereignty, security, public order or other essential interests of the requested Party;

   (b) violate a trade secret or prejudice legitimate commercial interests; or

   (c) be incompatible with applicable laws and regulations including, but not limited to, those protecting personal privacy or the financial affairs and accounts of individuals.

2. Where the applicant authority seeks assistance which it would itself be unable to provide if so requested, it shall draw attention to that fact in its request. It shall then be for the requested authority to decide how to respond to such a request.

3. For the cases referred to paragraph 1, the decision of the requested authority and the reasons thereof shall be communicated to the applicant authority without delay.

ARTICLE 16

Experts and witnesses

An official of a requested authority may be authorised to appear, within the limitations of the authorisation granted, as an expert or witness before an authority in the other Party regarding the matters covered by this Annex, and produce such objects, documents or confidential or certified copies thereof as may be needed for this purpose. The request for appearance shall indicate specifically before which authority the official will have to appear, on what matters and by virtue of what title or qualification the official will be questioned.

ARTICLE 17

Assistance expenses

1. The Parties shall waive all claims on each other for the reimbursement of expenses incurred pursuant to this Annex, except, as appropriate, for expenses payable in respect of the appearance of experts and witnesses pursuant to Article 16, and expenses payable to interpreters and translators who are not public service employees.

2. If expenses of a substantial or extraordinary nature are, or will be, required to execute the request, the Parties shall consult to determine the terms and conditions under which the request will be executed as well as the manner in which the costs shall be borne.

Title IV

ARTICLE 18

Confidentiality and protection of information

1. Any information communicated in whatsoever form pursuant to this Annex shall be treated as of a confidential nature, depending on the laws and regulations of each Party and shall enjoy the protection extended to similar information under the relevant laws and regulations of the Party of the customs authority that received it and the corresponding provisions applying to the Union authorities, unless the Party which provided the information gives a prior consent to the disclosure of such information.

2. Where personal data is exchanged pursuant to this Annex, each Party will protect the data received in accordance with its own rules and measures regarding the protection of personal data.

3. Information obtained shall be used solely for the purposes of this Annex. Where one of the Parties wishes to use such information for other purposes, it shall obtain the prior written consent of the customs authority which provided the information. Such use shall then be subject to any restrictions laid down by that authority.

4. Paragraph 3 shall not impede the use of information obtained in accordance with this Annex as evidence in court or tribunal proceedings subsequently instituted in respect of operations in breach of customs legislation. Therefore, the Parties may in their records of evidence, reports and testimonies and in court or tribunal proceedings use as evidence information obtained in accordance with the provisions of this Annex. The customs authority which supplied that information shall be notified of such use.

5. Notwithstanding paragraph 3 of this Article, unless otherwise notified by the customs authority providing the information, the customs authority receiving the information may provide the information received pursuant to this Annex to the relevant law enforcement agencies of its Party. These agencies may only use this information for the correct application of customs legislation and shall be subject to the conditions set out in this Article.

6. This Article shall not preclude the use or disclosure of information to the extent that there is an obligation to do so under the laws and regulations of the Party of the customs authority that received it. Such customs authority shall, wherever possible, give advance notice of any such disclosure to the customs authority which provided the information.

   The receiving Party shall, unless otherwise agreed by the Party which provided the information, wherever appropriate, use all available measures under the applicable laws and regulations of the former Party to maintain the confidentiality of information and to protect

personal data as regards applications by a third party or other authorities for disclosure of the information concerned.

Title V

ARTICLE 19

Future developments

The Parties may, by mutual agreement through a decision of the Joint Committee, expand this Annex with a view to supplementing the levels of customs cooperation and supplementing them, in accordance with their respective customs legislations, by means of agreements or arrangements on specific sectors or matters.

ARTICLE 20

Customs Committee

1. The Customs Committee shall be responsible for the effective implementation and operation of this Annex.

2. In addition to any other responsibilities specified in this Agreement, the Customs Committee shall:

   (a) see to the proper functioning of this Annex;

   (b) take measures necessary for customs cooperation in accordance with the objectives of this Annex;

   (c) exchange views on any points of common interest regarding customs cooperation, including future measures and the resources for them;

   (d) recommend solutions aimed at attaining the objectives of this Annex; and

   (e) be empowered to recommend decisions for adoption by the Joint Committee to expand or amend this Annex.

ANNEX 9A

EXISTING NON-CONFORMING MEASURES

[…]

ANNEX 9B

FURURE NON-CONFORMING MEASURES

[…]

ANNEX 9C

PROFESSIONAL BUSINESS SERVICES

[…]

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LIST OF CONTACT POINTS OF THE MEMBER STATES OF THE EUROPEAN UNION

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MODEL OF A COMMUNITY LICENCE

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MODEL OF UK STANDARD INTERNATIONAL LICENCE

[…]

ANNEX 20-C

TYPES OF CARRIAGE AND UNLADEN JOURNEYS IN CONNECTION WITH SUCH CARRIAGE EXEMPT FROM ANY SYSTEM OF LICENCES AND FROM ANY CARRIAGE AUTHORISATION

1. Carriage of mail as a universal service.

2. Carriage of vehicles which have suffered damage or breakdown.

3. Carriage of goods in motor vehicles the permissible laden mass of which, including that of trailers, does not exceed 3.5 tonnes.

4. Carriage of goods on an occasional basis, to or from airports, in cases where services are diverted.

5. Unladen runs by goods vehicles sent to replace a vehicle, which has broken down in another country, and the return run, after repair, of the vehicle that had broken down.

6. Carriage of livestock in vehicles purpose-built or permanently converted for the transport of livestock and recognised as such by the competent authority of the country where the operator is established.

7. Carriage of spare parts and provisions for ocean-going ships and for aircraft.

8. Carriage of goods in motor vehicles provided the following conditions are fulfilled:

    (a) the goods carried are the property of the undertaking or have been sold, bought, let out on hire or hired, produced, extracted, processed or repaired by the undertaking;

    (b) the purpose of the journey is to carry goods to or from the undertaking or to move them, either inside or outside the undertaking for its own requirements;

(c) the motor vehicle used for such carriage is driven by personnel employed by, or put at the disposal of, the undertaking under a contractual obligation;

(d) the vehicle carrying the goods is owned by the undertaking, has been bought by it on deferred terms or has been hired. This sub-paragraph shall not apply to the use of a replacement vehicle during a short breakdown of the vehicle normally used; and

(e) such carriage is no more than ancillary to the overall activities of the undertaking.

9. Carriage of medicinal products, appliances, equipment and other articles required for medical care in emergency relief, in particular for natural disasters and humanitarian needs.

10. Carriage for non-commercial purposes of works and objects of art for fairs and exhibitions.

11. Carriage for non-commercial purposes of properties, accessories and animals to or from theatrical, musical, film, sports or circus performances, fairs or fetes, and those intended for radio recordings, or for film or television production.

12. Funereal transport.

13. Transfer of newly acquired vehicles without cargo to the place of their destination.

ANNEX 20-D

LIST OF THE PROVISIONS CONTAINED IN THE BILATERAL ROAD TRANSPORT AGREEMENTS CONCLUDED BY THE UNITED KINGDOM WITH THE DIFFERENT MEMBER STATES OF THE UNION RELATING TO THE CARRIAGE OF GOODS IN CROSS-TRADE TRANSPORT OPERATIONS

[…]

ANNEX 20-E

INTERNATIONAL CARRIAGE OF PASSENGERS BY COACH AND BUS

ARTICLE 1

Definitions

For the purposes of Chapter 20, the following definitions shall apply:

Scheduled services

1. Regular services are services which provide for the carriage of passengers at specified intervals along specified routes, passengers being taken up and set down at predetermined stopping points. Regular services shall be open to all, subject, where appropriate, to compulsory reservation.

2. The regular nature of the service is not affected by any adjustment to the service operating conditions.

3. Services, by whomsoever organised, which provide for the carriage of specified categories of passengers to the exclusion of other passengers, in so far as such services are operated under the conditions specified in paragraph 1, shall be deemed to be regular services. Such services are hereinafter called ‘special regular services’.

4. Special regular services shall include:

   (a) carriage of workers between home and work;

   (b) carriage of school pupils and students to and from their educational institution; and

   (c) carriage of soldiers and their families between their State of origin and the area of their barracks.

5. The fact that a special service may be varied according to the needs of users shall not affect its classification as a regular service.

6. The organisation of parallel or temporary services, serving the same public as existing regular services, the non-serving of certain stops and the serving of additional stops on existing regular services shall be governed by the same rules as existing regular services.

Occasional services

7. Occasional services are services which do not meet the definition of regular services, including special regular services, and which are characterised above all by the fact that they carry groups of passengers assembled at the initiative of the customer or the carrier.

8. The organisation of parallel or temporary services comparable to existing regular services and serving the same public as the latter shall be subject to authorisation in accordance with the procedure laid down for existing regular services.

9. The services referred to in paragraph 7 shall not cease to be occasional services solely because they are provided at certain intervals.

10. Occasional services may be provided by a group of carriers acting on behalf of the same contractor.

11. The names of carriers referred to in paragraph 10 and, where appropriate, the connection points en route shall be communicated to the competent authorities of the Member States of the Union concerned and of the United Kingdom, in accordance with procedures determined by the Committee on Road Transport.

Own-account transport operations

12. Own-account transport operations means operations carried out for non- commercial and non-profit-making purposes by a person, whereby:

    (a) the transport activity is only an ancillary activity for that person,

    (b) the vehicles used are the property of that person or have been obtained by that person on deferred terms or have been the subject of a long-term leasing contract and are driven by a member of the staff of the person or by the person, or by personnel employed by, or put at the disposal of, the person under a contractual obligation.

Authorising authority

13. The authorising authority means:

    (a) for Union operators, the competent authority of the Member State in whose territory the operator is established, and
    (b) for United Kingdom operators, the competent authority in the United Kingdom.

REGULAR SERVICES SUBJECT TO AUTHORISATION

ARTICLE 2

Type of authorisation

1. Authorisations shall be issued in the name of the transport undertaking and may not be transferred by the latter to a third party. However, the carrier who has received the authorisation may, with the consent of the authorising authority, operate the service through a subcontractor. In this case, the name of the latter undertaking and its role as subcontractor

shall be indicated in the authorisation. The subcontractor must fulfil the conditions laid down in Article 20.7 of Part 2 of this Agreement.

2. In the case of undertakings associated for the purpose of operating a regular service, the authorisation shall be issued in the names of all the undertakings. It shall be given to the undertaking that manages the operation and copies shall be given to the others. The authorisation shall state the names of all the operators.

3. The maximum period of validity of the authorisation is five years.

   Authorisations shall specify the following:

   (a) the type of service;

   (b) the route of the service, giving in particular the point of departure and the point of arrival;

   (c) the period of validity of the authorisation;

   (d) the stops and the timetable.

4. Authorisations shall conform to the model agreed by the Parties through the Committee on Road Transport.

5. Authorisations shall entitle their holder(s) to operate regular services in the territories of the Parties.

6. The operator of a regular service may use additional vehicles to deal with temporary and exceptional situations. In this event, the carrier must ensure that the following documents are on board the vehicle:

   (a) a copy of the authorisation of the regular service;

   (b) a copy of the contract between the operator of the regular service and the undertaking providing the additional vehicles or an equivalent document;

   (c) a certified copy of the Community licence in the case of Union carriers, or of a standard UK international operator licence in the case of United Kingdom carriers, issued to the operator providing the additional vehicles for the service.

ARTICLE 3

Submission of application for authorisation

1. Operators applying for authorisation shall submit to their authorising authority in the format and including the information required by that authority and agreed by the Parties through the Committee on Road Transport.

2. Applications shall conform to the model agreed by the Parties through the Committee on Road Transport.

3. Persons applying for authorisation shall provide any additional information they consider relevant or which is requested by the authorising authority. In particular, applicants shall provide a driving schedule which makes it possible to check whether the service complies with legislation on driving and rest periods. Union carriers shall also submit a copy of the Community licence for the international carriage of passengers by road for hire or reward, and United Kingdom carriers a copy of a standard UK international operator licence, issued to the operator of the regular service.

ARTICLE 4

Authorisation procedure

1. Authorisations shall be issued in agreement with the competent authorities of the United Kingdom and the Member States of the Union on whose territories passengers are picked up or set down. The authorising authority shall forward to such authorities, as well as to the competent authorities of Member States of the Union whose territories are crossed without passengers being picked up or set down, a copy of the application, together with copies of any other relevant documentation, and its assessment.

2. The competent authorities of the United Kingdom and of the Member States of the Union whose agreement has been requested shall notify the authorising authority of their decision within two months. This time limit shall be calculated from the date of receipt of the request for agreement which is shown in the acknowledgement of receipt. If, within this period, the authorising authority has received no reply, the authorities consulted shall be deemed to have given their agreement, and the authorising authority shall issue the authorisation. If the decision received from the competent authorities of the Parties whose agreement has been requested is negative, it shall contain a proper statement of reasons.

3. Subject to paragraphs 7 and 8, the authorising authority shall take a decision within four months of the date on which the carrier submits the application.

4. Authorisation shall be granted unless:
   (a) the applicant is unable to provide the service which is the subject of the application with equipment directly available to him;

   (b) in the past, the applicant has failed to comply with national or international legislation on road transport, and in particular the conditions and requirements relating to authorisations for international road passenger services, or has committed serious breaches of legislation in regard to road transport, in particular the rules applicable to vehicles and driving and rest periods for drivers;

(c) in the case of an application for renewal of authorisation, the conditions of authorisation have not been complied with;

(d) the competent authority of a Party decides on the basis of a detailed analysis that the service concerned would seriously affect the viability of a comparable service covered by one or more public service contracts conforming to the Party's applicable law on the direct sections concerned. In such a case, the competent authority shall set up criteria, on a non-discriminatory basis, for determining whether the service applied for would seriously affect the viability of the abovementioned comparable service and shall communicate them to the Committee on Road Transport, upon its request.

(e) the competent authority of a Party decides on the basis of a detailed analysis that the principal purpose of the service is not to carry passengers between stops located in the Parties.

5. In the event that an existing international coach and bus service is seriously affecting the viability of a comparable service covered by one or more public service contracts conforming to a Party's applicable law on the direct sections concerned, due to exceptional reasons which could not have been foreseen at the time of granting the authorisation, the competent authority of a Party may, with the agreement of the Committee on Road Transport, suspend or withdraw the authorisation to run the international coach and bus service after having given 6 months' notice to the carrier.

6. The fact that a carrier offers lower prices than are offered by other road carriers, or that the route in question is already being operated by other road carriers, may not in itself constitute justification for refusing the application.

7. If the procedure for reaching the agreement referred to in paragraph 1 does not result in an agreement being reached, the matter may be referred to the Committee on Road Transport.

8. The Committee on Road Transport shall, as swiftly as possible, take a decision which shall take effect within 30 days of its being notified to the United Kingdom and the Member States of the Union concerned.

9. Once the procedure laid down in this Article has been completed, the authorising authority shall inform all the authorities referred to in paragraph 1 and shall, where appropriate, send them a copy of the authorisation.

ARTICLE 5

Issuing and renewing authorisations

1. Once the procedure laid down in Article 4 has been completed, the authorising authority shall either grant the authorisation or shall formally refuse the application.

2. A decision refusing an application must state the reasons for that refusal. The Parties shall ensure that carriers have the opportunity to invoke their rights if their application is refused.

3. Article 4 of this Annex shall apply, *mutatis mutandis*, to applications for the renewal of authorisations or for alteration of the conditions under which the services subject to authorisation must be operated. In the event of a minor alteration to the operating conditions, in particular the adjustment of fares or timetables, the issuing authority need only inform the competent authorities of the other Party of the changes in question.

ARTICLE 6

Lapse of an authorisation

1. An authorisation for a regular service shall lapse at the end of its period of validity or 3 months after the authorising authority has received notice from its holder of their intention to withdraw the service. Such notice shall contain a proper statement of reasons.

2. Where demand for a service has ceased to exist, the period of notice provided for in paragraph 1 shall be one month.

3. The authorising authority shall inform the competent authorities of the Member States of the Union concerned or competent authority of the United Kingdom that the authorisation has lapsed.

4. The holder of the authorisation shall notify users of the service concerned of its withdrawal 1 month in advance by means of appropriate publicity.

ARTICLE 7

Obligations of carriers

1. Save in the event of force majeure, the operator of a regular service shall, until the authorisation expires, take all measures to guarantee a transport service that meets the required standards of continuity, regularity and capacity and complies with the other conditions laid down by the competent authority in accordance with Article 2.3 of this Annex.

2. The carrier shall display the route of the service, the bus stops, the timetable, the fares and the conditions of carriage in such a way as to ensure that such information is readily available to all users.

3. It shall be possible for the United Kingdom and the Member States of the Union concerned, by common agreement and in agreement with the holder of the authorisation, to make changes to the operating conditions governing a regular service.

OCCASIONAL SERVICES AND OTHER SERVICES EXEMPT FROM AUTHORISATION

Article 8

Control document

1. The services referred to in Article 20.8.1 of Part 2 of the Agreement shall be carried out under cover of a control document ("journey form").

2. A carrier operating occasional services must fill out a journey form before each journey.

3. The books of journey forms shall be supplied by the competent authorities of the United Kingdom or the Member State of the Union where the carrier is established or by bodies appointed by those authorities.

4. The model for the control document and the way in which it is to be used shall be agreed by the Parties through the Committee on Road Transport.

5. In the case of the services covered by Article 20.8.2 of Part 2 of the Agreement, the contract, or a certified true copy of it, shall serve as a control document.

Article 9

Certification

1. The certificate referred to in Article 20.8.6 of Part 2 of the Agreement shall be issued by the competent authority of the United Kingdom or the Member State of the Union where the vehicle is registered.

2. The certificate shall conform to the model agreed by the Parties through the Committee on Road Transport.

CONTROLS AND PENALTIES

ARTICLE 10

Transport tickets

1. Carriers operating a regular service, excluding special regular services, shall issue either individual or collective transport tickets indicating:

   (a) the points of departure and arrival and, where appropriate, the return journey;

   (b) the period of validity of the ticket, and

   (c) the fare of transport.

2. The transport ticket provided for in paragraph 1 shall be presented at the request of any authorised inspecting officer.

ARTICLE 11

Inspections on the road and in undertakings

1. In the case of carriage for hire or reward, the following documents must be carried on board the vehicle and must be presented at the request of any authorised inspecting officer: a certified true copy of the Community licence for Union carriers or of the standard UK international operator licence for United Kingdom carriers and, depending on the type of service, either the authorisation (or a certified copy thereof) or the journey form.

2. In the case of own-account transport operations, the certificate required in Article 20.8.6 of Part 2 of this Agreement (or a certified copy thereof) must be carried on board the vehicle and must be presented at the request of any authorised inspecting officer.

3. Carriers operating international carriage of passengers by coach and bus shall allow all inspections intended to ensure that operations are being conducted correctly, in particular as regards driving and rest periods.

ARTICLE 12

Mutual assistance and penalties

1. The competent authorities of the Parties shall assist one another in ensuring the application and monitoring of the provisions laid down in this Annex. They shall exchange information via the national contact points as provided for at Article 30.8 of Part 4 of this Agreement.

2. The competent authority of the country in which a carrier is established shall withdraw the Community licence for Union carriers or the standard UK international operator licence for United Kingdom carriers if the holder:

   (a) no longer meets the conditions laid down in Article 20.7.1 of Part 2 of the Agreement; or

   (b) has provided inaccurate information on the data needed for issuing the Community licence for Union carriers or the standard UK international operator licence for United Kingdom carriers.

3. The authorising authority shall withdraw an authorisation if the holder no longer meets the conditions for issuing that authorisation under Article 20.7 of Part 2 of the Agreement, in particular if the competent authority of the country in which the carrier is established requests such withdrawal. The authorising authority shall immediately inform the competent authorities of the other Party.

4. If a carrier commits a serious breach of transport regulations and road safety rules, the competent authority of the country in which that carrier is established may withdraw their Community licence for Union carriers or the standard UK international operator licence for

United Kingdom carriers, or may temporarily and/or partially withdraw the certified copies of their Community licence for Union carriers or standard UK international operator licence for United Kingdom carriers.

5. These penalties shall be determined according to the seriousness of the offence committed by the holder of the Community licence for Union carriers or the standard UK international operator licence for United Kingdom carriers, and according to the total number of certified copies of the licence they possess in connection with their international transport operations.

6. The competent authority of the country in which the carrier is established shall communicate to the competent authority of the country in which the infringements were ascertained, as soon as possible and at the latest within six weeks of their final decision on the matter, which, if any, of the penalties provided for above have been imposed. If such penalties are not imposed, the competent authority of the country in which the carrier is established shall state the reasons.

7. Where a competent authority is aware of a serious infringement of this Annex or of road transport legislation attributable to a non-resident carrier, the competent authority of the territory in which the infringement is ascertained shall transmit to the competent authority in which the carrier is established, as soon as possible and at the latest within six weeks of their final decision, the following information:

   (a) a description of the infringement and the date and time when it was committed;

   (b) the category, type and seriousness of the infringement; and

   (c) the penalties imposed and the penalties executed.

   The competent authority of the host country may request that the competent authority of the country in which the carrier is established impose administrative penalties in accordance with paragraph 4.

8. The Parties shall ensure that carriers have the right to appeal against any administrative penalty imposed on them under this Article.

ARTICLE 13

Entry in the national electronic registers

The Parties shall ensure that serious infringements of road transport legislation attributable to carriers established in their territory, which have led to the imposition of a penalty by the competent authorities of a Member State of the Union or the United Kingdom, as well as any temporary or permanent withdrawal of the Community licence for Union carriers or the standard UK international operator licence for United Kingdom carriers, or of the certified true copy of the Community licence or the standard UK international operator licence, are recorded in the national electronic register of road transport undertakings. Entries in the register which concern a temporary or permanent withdrawal of a Community licence for Union carriers or of a standard

UK international operator licence for United Kingdom carriers shall remain in the database for at least two years from the time of the expiry of the period of withdrawal, in the case of temporary withdrawal, or from the date of withdrawal, in the case of permanent withdrawal.

ANNEX 20-F

LIST OF THE PROVISIONS CONTAINED IN THE BILATERAL ROAD TRANSPORT AGREEMENTS CONCLUDED BY THE UNITED KINGDOM WITH THE DIFFERENT MEMBER STATES OF THE UNION RELATING TO THE GRANTING OF AUTHORISATIONS FOR THE CARRIAGE OF PASSENGERS IN CROSS-TRADE TRANSPORT OPERATIONS

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ANNEX 25-A

ADDITIONAL PROVISIONS CONCERNING THE SCOPE OF “REGULATORY MEASURES”

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ANNEX 30-A

RULES OF PROCEDURE OF THE JOINT COMMITTEE AND SPECIALISED COMMITTEES

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ANNEX 33-A

RULES OF PROCEDURE OF A PANEL

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ANNEX 33-B

CODE OF CONDUCT FOR ARBITRATORS

[…]

ANNEX 33-C

MEDIATION PROCEDURE

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