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THE EUROPEAN UNION**

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**LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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**Subject:** Free Trade Agreement between the European Union and its Member States,  
of the one part, and the Republic of Korea, of the other part

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KOREA

1. This Appendix applies to TRQs provided for in this Agreement and sets out modifications to the Harmonized Tariff Schedule of Korea (hereinafter referred to as the "HSK") which reflect the TRQs that Korea shall apply to certain originating goods under this Agreement. In particular, originating goods of the European Union included under this Appendix shall be subject to the rates of duty set out in this Appendix in lieu of the rates of duty specified in Chapters 1 through 97 of the HSK. Notwithstanding any other provision of the HSK, originating goods of the European Union in the quantities described in this Appendix shall be imported into the territory of Korea as provided for in this Appendix. Furthermore, any quantity of originating goods imported from the European Union under a TRQ provided for in this Appendix shall not be counted toward the in-quota amount of any TRQs provided for such goods elsewhere in the HSK.

## Auction System for Certain TRQs Provided for in this Agreement

2. Korea may use an auction system, the terms of which the Parties shall establish by mutual agreement by decision of the Committee on Trade in Goods, to administer and implement the TRQs provided for in paragraphs 6, 8, 10 and 11, provided that the conditions in subparagraph (a) are met<sup>1</sup>:
  - (a) (i) If less than 95 percent of the in-quota quantity of an auctioned TRQ is utilised in two of three consecutive years, on the written request of the European Union, the Parties shall consult in the Committee on Trade in Goods regarding the operation of the auction system with a view to identifying and addressing the causes for the incomplete utilisation. In the consultations, the Parties shall consider prevailing market conditions;
  - (ii) The Parties shall hold consultations within 30 days of the date of the request;
  - (iii) Korea shall implement any decision in the Committee on Trade in Goods that the Parties reach on the means to facilitate full utilisation of the auctioned TRQ within 60 days of the decision, or by such other date as the Parties may agree on; and

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<sup>1</sup> The terms of the auction system shall include provisions for the timely surrender and reallocation of unused licenses, as well as penalties, including forfeiture of import performance bonds, for failing to utilise or return unused licenses.

- (iv) Korea shall permit originating goods of the European Union to enter under the relevant TRQ on a first-come, first-served basis if either of the following occurs:
  - (A) Korea does not implement a decision in accordance with subparagraph (a)(iii); or
  - (B) the consultations referred to in subparagraph (a)(i) do not result in a decision within 90 days of the date of the request for consultations or by such other date as the Parties may agree on.
  
- (b) On the written request of either Party, the Parties shall consult on any matter related to the application or operation of this paragraph. The consultations shall begin within 15 business days of the date the Party receives the request for consultations, or on such other date as the Parties may agree.

## Licensing System for Certain TRQs Provided for in this Agreement

3. Korea may use a licensing system to administer and implement the TRQs provided for in paragraphs 7, 9, 11, 12, 13, 14 and 15, provided that the conditions set forth in subparagraph (a) are met. The Parties shall agree in the Committee on Trade in Goods on the policies and procedures for the licensing system, including eligibility to receive TRQ quantities, and any changes or amendments to them:
  - (a)
    - (i) If less than 95 percent of the in-quota quantity of a TRQ is utilised in two of three consecutive years, on the written request of the European Union, the Parties shall consult in the Committee on Trade in Goods regarding the operation of the allocation system with a view to identifying and addressing the causes for the incomplete utilisation of the in-quota quantity. In the consultations, the Parties shall consider prevailing market conditions;
    - (ii) The Parties shall hold consultations within 30 days of the date of the request;
    - (iii) Korea shall implement any decision in the Committee on Trade in Goods that the Parties reach in the consultations on the means to facilitate full utilisation of the TRQ within 60 days of the decision, or by such other date as the Parties may agree on; and

- (iv) Korea shall permit originating goods of the European Union to enter under the relevant TRQ on a first-come, first-served basis if either of the following occurs:
  - (A) Korea does not implement a decision in accordance with subparagraph (a)(iii); or
  - (B) the consultations referred to under subparagraph (a)(i) do not result in a decision within 90 days of the date of the request for consultations or by such other date as the Parties may agree on.
- (b) On the written request of either Party, the Parties shall consult on any matter related to the application or operation of this paragraph. The consultations shall begin within 15 business days of the date the Party receives the request for consultations, or on such other date as the Parties may agree.

#### State Trading Enterprises

4. Korea may require an originating good of the European Union to be imported, purchased or distributed in its territory by a state trading enterprise only if, and on such terms and conditions as, the Parties may agree.

Flatfish

5. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	800
2	800
3	864
4	933
5	1,008
6	1,088
7	1,175
8	1,269
9	1,371
10	1,481
11	1,599
12	1,727
13	Unlimited

The quantities shall enter on a first-come, first-served basis.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "12-A" as described in paragraph 1(o) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provision: 0303.39.0000.

Milk or cream powder less than 1.5 percent fat and buttermilk,

Milk and cream powder sweetened and unsweetened over 1.5 percent fat (whole milk powder)

Milk and cream (evaporated) sweetened or unsweetened and/or not concentrated

6. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	1,000
2	1,000
3	1,030
4	1,060
5	1,092
6	1,125
7	1,159
8	1,194
9	1,229
10	1,266
11	1,304
12	1,343
13	1,384
14	1,425
15	1,468
16	1,512



After year 16, the in-quota quantity shall remain the same as the quantity of year 16. The Korea Agro-Fisheries Trade Corporation shall administer these TRQs and allocate the in-quota quantity through quarterly auctions (December, March, June and September).

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be treated in accordance with staging category "E" as described in paragraph 1(s) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provisions: 0402.10.1010, 0402.10.1090, 0402.10.9000, 0402.21.1000, 0402.21.9000, 0402.29.0000, 0402.91.1000, 0402.91.9000, 0402.99.1000, 0402.99.9000 and 0403.90.1000.

Food whey

7. (a) The aggregate quantity of originating goods of European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	3,350
2	3,350
3	3,450
4	3,554
5	3,660
6	3,770
7	3,883
8	4,000
9	4,120
10	4,243
11	Unlimited

The Korea Dairy Industries Association shall administer these TRQs and allocate the in-quota quantity to historical and new importers using a licensing system.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "10-B" as described in paragraph 1(n) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provisions: 0404.10.1010, 0404.10.1090, 0404.10.2110, 0404.10.2120, 0404.10.2130, 0404.10.2190 and 0404.10.2900.

Butter and other fats and oils derived from milk

8. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	350
2	350
3	360
4	371
5	382
6	393
7	405
8	417
9	430
10	443
11	Unlimited

The Korea Agro-Fisheries Trade Corporation shall administer these TRQs and allocate the in-quota quantity by auction, with the entire in-quota quantity of originating goods made available during the first auction in the year, to be held in the first month of each year. Any quantity not allocated in the first auction shall be made available at a subsequent auction on or before the 15th day of the third month, and at subsequent auctions thereafter, within 45 days of the date of the previous auction.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "10" as described in paragraph 1(g) of Annex 2-A.

- (c) Subparagraphs (a) and (b) apply to the following HSK provisions: 0405.10.0000 and 0405.90.0000.

Fresh, curd grated or powdered, processed, and all other cheeses

9. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	4,560
2	4,560
3	4,696
4	4,837
5	4,982
6	5,132
7	5,286
8	5,444
9	5,608
10	5,776
11	5,949
12	6,128
13	6,312
14	6,501
15	6,696
16	Unlimited

The Korea Dairy Industries Association shall administer these TRQs and allocate the in-quota quantity to historical and new importers through a licensing system.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "15" as described in paragraph 1(j) of Annex 2-A.
  
- (c) Subparagraphs (a) and (b) apply to the following HSK provisions: 0406.10.1000, 0406.20.0000, 0406.30.0000 and 0406.90.0000 (0406.90.0000 includes cheddar cheese). Beginning in year 11, cheddar cheese will be free of customs duty and no longer be subject to TRQs.

Honey, natural

10. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	50
2	50
3	51
4	53
5	54
6	56
7	57
8	59
9	61
10	63
11	65
12	67
13	69
14	71
15	73
16	75

After year 16, the in-quota quantity shall remain the same as the quantity of year 16.

The Korea Agro-Fisheries Trade Corporation shall administer these TRQs and allocate the in-quota quantity through quarterly auctions (December, March, June and September).

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be treated in accordance with staging category "E" as described in paragraph 1(s) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provision: 0409.00.0000.

Oranges

- 11. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	20
2	20
3	20
4	20
5	20
6	20
7	40
8	40
9	40
10	40
11	40
12	60

After year 12, the in-quota quantity shall remain the same as the quantity of year 12.

The Korea Agro-Fisheries Trade Corporation shall administer these TRQs and allocate the in-quota quantity through an annual auction in years 1 through 11 and, beginning in year 12, through a licensing system based on historical shipments over the most recent three-year period. The Corporation shall conduct auctions and allocate import licenses in August of each year, and importers shall be permitted to import the duty-free quantities from September 1 through the last day of February. Any person or entity, including a producer group, registered as an importer under the Foreign Trade Act of Korea shall be eligible to apply and to be considered for the allocation of the duty-free quantities.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be treated in accordance with staging category "S-B" as described in paragraph 1(r) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provision: 0805.10.0000.



Malt and malting barley

12. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	10,000
2	10,000
3	10,800
4	11,600
5	12,400
6	12,772
7	13,155
8	13,549
9	13,956
10	14,375
11	14,806
12	15,250
13	15,707
14	16,179
15	16,664
16	Unlimited

The Korea Agro-Fisheries Trade Corporation shall administer the licenses for these TRQs starting on the first business day of the first month of each year on a first-come, first-served basis, in response to written applications that it receives. Between the first business day and the last day of the first month, if the aggregate TRQ quantity requested by the applicants exceeds the total TRQ quantity for that year, the Corporation shall allocate the TRQ quantities among applicants on a pro rata basis.

If the aggregate TRQ quantity requested during the first month is less than the aggregate TRQ quantity for the year, the Corporation shall continue to allocate the TRQ on a first-come, first-served basis through the end of the year. Each license the Corporation issues to an applicant shall be valid for 90 days from the date of issuance, unused licenses shall be surrendered to the Corporation when the 90 day period expires, and the Corporation shall reallocate unused quantities to applicants on a first-come, first-served basis within 45 days of the date the licenses are surrendered.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "15" as described in paragraph 1(j) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provisions: 1003.00.1000 and 1107.10.0000.

Prepared dry milk and other

13. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	450
2	450
3	463
4	477
5	491
6	506
7	521
8	537
9	553
10	570
11	Unlimited

The Korea Dairy Industries Association shall administer these TRQs and allocate the in-quota quantity to historical and new importers through a licensing system.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "10" as described in paragraph 1(g) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provisions: 1901.10.1010 and 1901.10.1090.

Supplementary feeds, animal

14. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	5,500
2	5,500
3	5,665
4	5,834
5	6,009
6	6,190
7	6,376
8	6,567
9	6,764
10	6,967
11	7,176
12	7,391
13	Unlimited

The Korea Feed Ingredients Association and the Korea Feed Milk Replacer Association shall administer these TRQs and allocate the in-quota quantity through licensing systems. These TRQs shall be allocated based on the amount of originating goods described in subparagraph (c) imported by applicants during the 24 month period immediately preceding the year for which the license is issued and the quantity of originating goods requested by applicants for the year.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "12" as described in paragraph 1(h) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provision: 2309.90.2010, 2309.90.2020, 2309.90.2099 and 2309.90.9000.

Dextrins

- 15. (a) The aggregate quantity of originating goods of the European Union described in subparagraph (c) that shall be permitted to enter free of customs duty in a particular year is specified below:

Year	Quantity (Metric Tons)
1	28,000
2	28,000
3	30,500
4	33,000
5	35,000
6	36,050
7	37,131
8	38,245
9	39,392
10	40,574
11	41,791
12	43,045
13	Unlimited

The Korea Agro-Fisheries Trade Corporation shall administer the licenses for these TRQs starting on the first business day of the first month of each year on a first-come, first-served basis, in response to written applications that it receives. Between the first business day and the last day of the first month of each year, if the aggregate TRQ quantity requested by the applicants exceeds the total TRQ quantity for that year, the Corporation shall allocate the TRQ quantities among applicants on a pro rata basis.

If the aggregate TRQ quantity requested during the first month is less than the aggregate TRQ quantity for the year, the Corporation shall continue to allocate the TRQ on a first-come, first-served basis through the end of the year. Each license the Corporation issues to an applicant shall be valid for 90 days from the date of issuance, unused licenses shall be surrendered to the Corporation when the 90 day period expires, and the Corporation shall reallocate unused quantities to applicants on a first-come, first-served basis within 45 days of the date the licenses are surrendered.

- (b) Customs duties on goods entered in excess of the quantities listed in subparagraph (a) shall be removed in accordance with staging category "12" as described in paragraph 1(h) of Annex 2-A.
- (c) Subparagraphs (a) and (b) apply to the following HSK provision: 3505.10.4010, 3505.10.4090, 3505.10.5010 and 3505.10.5090.

THE EU PARTY

1. This Appendix sets out modifications to the entry price scheme that the EU Party applies to certain fruits and vegetables in accordance with the Common Customs Tariff provided for in Commission Regulation (EC) No 1031/2008 of 19 September 2008 (and subsequent acts) and EU's WTO Schedule CXL. In particular, originating goods of Korea included under this Appendix shall be subject to the entry price scheme set out in this Appendix in lieu of the entry price scheme specified in the Common Customs Tariff provided for in Commission Regulation (EC) No 1031/2008 of 19 September 2008 (and subsequent acts) and EU's WTO Schedule CXL.
2. For originating goods of Korea to which the European Union applies its entry price scheme in accordance with Commission Regulation (EC) No 1031/2008 of 19 September 2008 and EU's WTO Schedule CXL, the ad valorem customs duties on such goods shall be removed in accordance with the staging categories as set out in the European Union's Schedule included in Annex 2-A.
3. The specific customs duties provided for in Commission Regulation (EC) No 1549/2006 of 17 October 2006 on the goods under paragraph 2 shall not be subject to the elimination of customs duties in accordance with the staging categories as set out in the European Union's Schedule included in Annex 2-A. Instead, the duties shall:

(a) be eliminated entirely at the entry into force of this Agreement for the following goods:

CN code	Description
07070005	Cucumbers, fresh or chilled
08082050	Fresh pears (excl. perry pears, in bulk, from 1 August to 31 December)
08092005	Fresh sour cherries "Prunus cerasus"
08092095	Fresh cherries (excl. sour cherries "Prunus cerasus")
20096110	Grape juice, incl. grape must, unfermented, Brix value $\leq$ 30 at 20°C, value of $>$ 18 € per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)
20096919	Grape juice, incl. grape must, unfermented, Brix value $>$ 67 at 20°C, value of $>$ 22 € per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)
20096951	Concentrated grape juice, incl. grape must, unfermented, Brix value $>$ 30 but $\leq$ 67 at 20°C, value of $>$ 18 € per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)
20096959	Grape juice, incl. grape must, unfermented, Brix value $>$ 30 but $\leq$ 67 at 20°C, value of $>$ 18 € per 100 kg, whether or not containing added sugar or other sweetening matter (excl. concentrated or containing spirit)
22043092	Grape must, unfermented, concentrated within the meaning of Additional Note 7 to chapter 22, of a density $\leq$ 1,33 g/cm <sup>3</sup> at 20°C and of an actual alcoholic strength by volume $\leq$ 1% vol but $>$ 0,5% vol (excl. grape must whose fermentation has been arrested by the addition of alcohol)
22043094	Grape must, unfermented, non-concentrated, of a density $\leq$ 1,33 g/cm <sup>3</sup> at 20°C and of an actual alcoholic strength by volume $\leq$ 1% vol but $>$ 0,5% vol (excl. grape must whose fermentation has been arrested by the addition of alcohol)



CN code	Description
22043096	Grape must, unfermented, concentrated within the meaning of Additional Note 7 to chapter 22, of a density > 1,33 g/cm <sup>3</sup> at 20°C and of an actual alcoholic strength by volume <= 1% vol but > 0,5% vol (excl. grape must whose fermentation has been arrested by the addition of alcohol)
22043098	Grape must, unfermented, non-concentrated, of a density > 1,33 g/cm <sup>3</sup> at 20°C and of an actual alcoholic strength by volume <= 1% vol but > 0,5% vol (excl. grape must whose fermentation has been arrested by the addition of alcohol)

(b) be eliminated for the following goods in accordance with the following schedule:

CN code	Description	Elimination on
07099070	Fresh or chilled courgettes	the first day of year 5
07099080	Fresh or chilled globe artichokes	the first day of year 10
08052010	Fresh or dried clementines	the first day of year 15
08052050	Fresh or dried mandarins and wilkings	the first day of year 15
08052070	Fresh or dried tangerines	the first day of year 15
08052090	Fresh or dried tangelos, ortaniques, malaquinas and similar citrus hybrids (excl. clementines, monreales, satsumas, mandarins, wilkings and tangerines)	the first day of year 15
08055010	Fresh or dried lemons "Citrus limon, Citrus limonum"	the first day of year 2
08061010	Fresh table grapes	the first day of year 17

CN code	Description	Elimination on
08081080	Fresh apples (excl. cider apples, in bulk, from 16 September to 15 December)	the first day of year 10/20 <sup>1</sup>
08091000	Fresh apricots	the first day of year 7
08093010	Fresh nectarines	the first day of year 10
08093090	Fresh peaches (excl. nectarines)	the first day of year 10
08094005	Fresh plums	the first day of year 10

(c) be maintained for the following goods:

CN code	Description
07020000	Tomatoes, fresh or chilled
08051020	Fresh sweet oranges
08052030	Fresh or dried monreales and satsumas

4. The specific duty under paragraph 3 shall not exceed the lesser specific duty of the prevailing most-favoured-nation (MFN) applied rate, or the MFN applied rate of duty in effect on the day immediately preceding the date this Agreement enters into force.

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<sup>1</sup> The first day of year 20 for the fuji variety.

ELECTRONICS

ARTICLE 1

General Provisions

1. Recalling the obligations of the Parties under the WTO Agreement, in particular the TBT Agreement, and recognising the importance of electronics for growth, employment and trade for each Party, the Parties confirm their shared objectives and principles of:
  - (a) progressively and simultaneously eliminating tariffs and non-tariff obstacles to bilateral trade;
  - (b) establishing competitive market conditions based on principles of openness, non-discrimination, proportionality and transparency;
  - (c) gradually aligning their domestic regulations with existing international standards;
  - (d) promoting "one test" and, where practicable, a supplier's declaration of conformity through elimination of duplicative and unnecessarily burdensome conformity assessment procedures;

- (e) implementing appropriate regulatory and legal enforcement mechanisms related to product liability and market surveillance; and
- (f) enhancing cooperation to foster continued mutually beneficial development in trade, as well as to improve product quality with a view to ensuring protection of public health and safety of products.

2. This Annex shall apply to any standard, technical regulation and conformity assessment procedure that either Party may introduce or maintain with respect to the safety and electromagnetic compatibility (hereinafter referred to as "EMC") of electrical and electronic equipment, professional electrotechnical equipment, electrical household appliances and consumer electronics defined in Appendix 2-B-1 (hereinafter referred to as "covered products").

## ARTICLE 2

### International Standards and Standard-Setting Bodies

1. The Parties recognise that the International Organization for Standards (hereinafter referred to as the "ISO"), the International Electrotechnical Commission (hereinafter referred to as the "IEC") and the International Telecommunication Union (hereinafter referred to as the "ITU") are the relevant international standard-setting bodies for EMC and safety of covered products<sup>1</sup>.

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<sup>1</sup> The Parties may agree in the future by decision of the Trade Committee on any new international standard-setting bodies which they deem relevant for the purpose of implementing this Article.

2. Where relevant international standards established by the ISO, IEC and ITU exist, the Parties shall use these international standards or the relevant parts of them as a basis for any standard, technical regulation or conformity assessment procedure<sup>2</sup>.

3. The Parties shall ensure that their standard-setting bodies participate in the development of international standards in the ISO, IEC and ITU, and commit to consult with a view to establishing common approaches.

### ARTICLE 3

#### Conformity Assessment Procedure

In case a Party requires a positive assurance of conformity with technical regulations on EMC or safety of covered products, the following rules shall apply<sup>3</sup>:

- (a) conformity assessment procedures shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to trade with the other Party;

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<sup>2</sup> In case no such international standards exist, or where a Party has adopted any standard, technical regulation or conformity assessment procedure which differs from that under international standards, the Party shall limit its standard, technical regulation or conformity assessment procedure to what is necessary for the achievement of legitimate objectives on safety and other public interest requirements and, wherever appropriate, base them on products requirements in terms of performance rather than design or descriptive characteristics, in accordance with Chapter Four (Technical Barriers to Trade).

<sup>3</sup> Either Party reserves its right to require in the future positive assurance of conformity for any product currently not subject to positive assurance of conformity, in which case the Party has to comply with its obligations under this Annex.

- (b) except as otherwise provided under this Annex, including the transitional arrangements set out in Article 4, each Party shall accept products on its market<sup>4</sup> on the basis of one or more of the following procedures as positive assurance of conformity to its technical regulations on EMC or safety of covered products:
- (i) a supplier's declaration of conformity without requiring the intervention of any conformity assessment body or testing of the product by recognised testing laboratories;
  - (ii) a supplier's declaration of conformity based on a test report from any testing laboratory in the other Party's territory that has been notified by the Party at the entry into force of this Agreement or in any subsequent notifications. The notifying Party shall be solely responsible for notifying any laboratory which is competent<sup>5</sup> to perform the relevant tests in its territory, without prior approval or verification by the importing Party. The importing Party may require that the declaration of conformity is submitted by the supplier before the product is placed on its market and that the declaration contains the name of the testing laboratory issuing the test report and the issuing date of the test report. The importing Party may also require a copy of the test report, including a list of critical components, demonstrating conformity to the requirements applicable to the product, and a general description of the product; or

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<sup>4</sup> The permission to place a product on the market in accordance with this subparagraph shall include permission to affix any mandatory marks that are required for placing such product on the market.

<sup>5</sup> The specific testing laboratories that are competent in the notifying Party in accordance with its legislation, that obtain accreditation (for example under ISO/IEC 17025) by the accreditation body or that are competent for post-market surveillance for conformity assessment in the notifying Party, will be considered competent for the task envisaged in this Annex.

- (iii) a supplier's declaration of conformity based on a test report issued by:
- (A) any testing laboratory in the other Party that has concluded voluntary arrangements for mutual acceptance of test reports with one or more conformity assessment bodies designated by the importing Party; or
  - (B) a CB Test Laboratory of the other Party under the IECEE CB Scheme, accompanied by a valid CB Test Certificate, in accordance with the rules and procedures of the IECEE CB Scheme and the commitments by the Parties thereunder.

The importing Party may require for review before the product is placed on its market the submission of the declaration of conformity which contains a copy of the test report, including a list of critical components, demonstrating conformity to the requirements applicable to the product, and a general description of the product.

The choice among the procedures in this subparagraph shall rest with each Party subject to the limitations set out in Appendix 2-B-2;

- (c) the Parties shall accept the supplier as solely responsible for issuing, changing or withdrawing the declaration of conformity. The Parties may require that the declaration of conformity is dated and identifies the supplier or the supplier's authorised representative in their territories, the person empowered by the manufacturer or his authorised representative to sign the declaration, the products covered by the declaration, and the applied technical regulations to which conformity is declared. When a supplier's declaration of conformity is for a batch of products, it shall cover each article of the batch. When testing is undertaken, the choice of the testing laboratory shall rest with the supplier; and
- (d) beyond what is set out in this Article, a Party shall not require any form of registration of products that may prevent or otherwise delay the placing on the market of products that comply with the Party's technical regulations. In so far as a Party reviews the supplier's declaration in line with subparagraph (b)(iii), the review shall be solely limited to verifying, on the basis of the documentation submitted, that the test has been done in accordance with the Party's relevant technical regulations and that the information contained in the documentation is complete. Any such review shall not cause undue delay for the placing of the products on the Party's market and the declaration shall be accepted, without exceptions, if the products comply with the Party's technical regulations and the documentation submitted is complete. In the event that a declaration is rejected, the Party shall communicate its decision to the supplier immediately, together with a detailed explanation of the grounds for the rejection and how these can be rectified by the supplier, as well as an explanation of possibilities to appeal the decision.



## ARTICLE 4

### Transitional Arrangements

1. The European Union shall comply with Article 3(b) of this Annex upon the entry into force of this Agreement while Korea shall comply with that subparagraph within three years of the entry into force of this Agreement.
  
2. During the transitional period set out in paragraph 1, in so far as Korea applies, upon the entry into force of this Agreement, mandatory certification to its technical regulations on EMC or safety of covered products, including third party testing, for a product falling under the scope of this Annex, Korea may require to accept such product on its market<sup>6</sup>:
  - (a) a certificate issued by a conformity assessment body in the European Union that has been designated as a "Notified Body" according to the legislation of the European Union. The European Union shall be solely responsible for choosing conformity assessment bodies in its territory, without prior approval or verification by Korea, and shall notify Korea of its list of relevant bodies upon the entry into force of this Agreement and any change thereafter; or

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<sup>6</sup> The permission to place a product on the market in accordance with this Article shall include permission to affix any mandatory marks that are required for placing the product on the market.

- (b) a certificate to its technical regulations issued by a conformity assessment body that has been designated according to the procedures of Korea. Korea shall accept such certificates based on a test report issued by:
- (i) any testing laboratory in the European Union that has concluded voluntary arrangements for mutual acceptance of test reports with one or more conformity assessment bodies designated by Korea; or
  - (ii) an EU CB Test Laboratory under the IECEE CB Scheme, accompanied by a valid CB Test Certificate, in accordance with the rules and procedures of the IECEE CB Scheme and the commitments by the European Union and Korea thereunder.

The choice between the procedures in this subparagraph shall rest with Korea subject to the limitations set out in Appendix 2-B-2.

3. For those products listed in Appendix 2-B-3, Korea may continue to require positive assurance of conformity with its technical regulations on safety of covered products on the basis of a certificate in accordance with Article 4.2(b) of this Annex after the expiry of the transitional period set out in paragraph 1. For each product listed in Appendix 2-B-3, it will be reviewed, by the end of the transitional period set out in paragraph 1, whether accepting positive assurance of the conformity of such products with its technical regulations on safety of covered products in accordance with Article 3(b) of this Annex would create risks for human health and safety. Such risk assessment will be conducted for such products on the market, on the basis of available scientific and technical information such as consumer reports on safety accidents and non-conformity rate of product inspection. It will also be considered whether the products are used for their intended end-uses and with reasonable and usual care. If the results of risk assessment demonstrate that complying with Article 3(b) of this Annex for the products concerned would create risks for human health and safety, or if the post-market surveillance system set up cannot effectively address such risks, positive assurance of conformity as set out in Article 4.2(b) of this Annex can be maintained. Every three years following the end of the transitional period, the Parties shall review in the Committee on Trade in Goods the risk assessment with the aim of further reducing products listed in Appendix 2-B-3.

## ARTICLE 5

### Consolidation and Gradual Reduction in Requirements

1. The Parties shall, for covered products, not maintain or impose any requirements that are more trade-restrictive, or otherwise have the effect of delaying access to their markets, than what is set out in this Annex regarding conformity assessment procedures covering EMC or safety of covered products or administrative procedures for approving or reviewing test reports.
2. No later than five years after the entry into force of this Agreement, Korea shall introduce a supplier's declaration of conformity in accordance with Article 3(b)(i) of this Annex for the placing on the market of some products falling within the scope of this Annex. Every five years following the introduction of a supplier's declaration of conformity, the Parties shall review the possibility of gradually eliminating technical and administrative requirements including mandatory third party testing, through expanding the introduction of a supplier's declaration of conformity in accordance with Article 3(b)(i) of this Annex and developing effective market surveillance for the proper functioning of such system.

## ARTICLE 6

### Exceptions and Emergency Measures

1. Notwithstanding Articles 3 through 5 of this Annex, either Party may introduce requirements for mandatory third party testing or certification for EMC or safety of covered products, or introduce administrative procedures for approving or reviewing test reports, for particular products falling within the scope of this Annex under the following conditions:

- (a) there exist urgent and compelling reasons related to the protection of human health and safety that justify the introduction of such requirements or procedures;
- (b) the reasons for the introduction of any such requirements or procedures are supported by substantiated technical or scientific information regarding the performance of the products in question;
- (c) any such requirements or procedures are not more trade-restrictive than necessary to fulfil the Party's legitimate objective, taking account of the risks that non-fulfilment would create; and
- (d) the Party could not have reasonably foreseen the need for introducing any such requirements or procedures at the time of entry into force of this Agreement.

Before introducing the requirements or procedures, the Party shall notify the other Party and, following consultations, take the comments of the other Party into account, to the greatest extent possible, in devising any such requirements or procedures. Any requirements introduced shall, to the greatest extent possible, be in compliance with this Annex. Once adopted, any requirement or procedure introduced shall be reviewed every third year from the date of its adoption and repealed if the reasons for its introduction no longer exist.

2. If a Party has good cause to believe that a covered product creates risk for human health and safety, notably because it does not comply with requirements applicable to it, the Party may require withdrawal of that product from its market. Any such temporary emergency measures shall be notified to the other Party with an objective and reasoned explanation of why such actions have been taken, indicating whether the need for such measures is due to:

- (a) failure to comply with applicable standards or technical regulations;
- (b) incorrect application of standards or technical regulations; or
- (c) shortcomings in the standards or technical regulations themselves.

## ARTICLE 7

### Implementation and Cooperation

1. The Parties shall closely cooperate to promote common understanding on regulatory issues, including those related to radio frequency equipment, and consider any request of the other Party regarding the implementation of this Annex.
2. The Parties shall cooperate to maintain and expand the voluntary arrangements for mutual acceptance of test reports between them.
3. Whenever Korea requires as a positive assurance of conformity the procedures set out in Article 3(b)(iii) and Article 4.2(b) of this Annex for a product falling within the scope of this Annex, it shall ensure that its certification bodies have Memoranda of Understanding (MOUs) with testing laboratories in the European Union, or are National Certification Bodies under the IECEE CB Scheme, for that product unless its technical regulations for that product substantially differ from relevant IEC standards. This paragraph shall apply as from the expiry of the transitional period set out in Article 4.1 of this Annex.

4. When amending existing technical regulations or developing any new technical regulation for EMC or safety of covered products, a Party shall notify the other Party in advance, provide, upon request, additional available information or written responses to the comments made by the other Party and, as appropriate, consider the other Party's views.
  
5. The Parties agree to consult promptly on any issue that may arise concerning the implementation of this Annex, and to cooperate for the further facilitation of trade in covered products, including, as appropriate, through the promotion of international standards.
  
6. The Parties shall protect any confidential business information obtained under the procedures referred to in this Annex.



1. Annex 2-B shall cover those products listed in Article 1.2 of Annex 2-B which:
  - (a) in the case of the European Union's obligations, fall, at the date of signature of this Agreement, within the scope of Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (codified version), or Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC, or of the provisions on safety or electromagnetic compatibility of Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity; and

(b) in the case of Korea's obligations, fall, at the date of signature of this Agreement, within the scope of the Radio Waves Act (Act No.8867, Feb. 29, 2008), the Framework Act on Telecommunications (Act No.8974, Mar. 21, 2008) or the Electrical Appliances Safety Control Act<sup>1</sup> (Act No.8852, Feb. 29, 2008).

2. The Parties understand that the products covered by the domestic laws listed in this Appendix, which include all the products to which Annex 2-B applies, are intended to cover the universe of electronics products. It is understood that in case a product is not covered by Annex 2-B for a Party but is covered for the other Party, or at the time of signature of this Agreement or subsequently<sup>2</sup> subject to mandatory third party certification by a Party but not by the other Party, the other Party can subject such product to a similar treatment as may be necessary for the protection of health and safety. Before such measures are implemented, the Party wishing to introduce them shall notify the other Party of its intentions and provide for a period of three months for consultations.

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<sup>1</sup> Notwithstanding this subparagraph, Korea may, when necessary, subject electrical equipment operated with direct current to conformity assessment procedures under the Electrical Appliances Safety Control Act in accordance with this Article.

<sup>2</sup> For instance, pursuant to Article 6 of Annex 2-B or in case specific instruments are introduced pursuant to Article 1 (4) of Directive 2004/108/EC on electromagnetic compatibility.

## Appendix 2-B-2

1. The European Union shall accept, for all covered products, the procedure set out in Article 3(b)(i) of Annex 2-B as positive assurance of conformity with its own technical regulations.
2. Korea shall accept as positive assurance of conformity with its own technical regulations,
  - (a) for products falling within the scope of the Radio Waves Act or the Framework Act on Telecommunications at the date of signature of this Agreement:
    - (i) during the transitional period set out in Article 4.1 of Annex 2-B the procedure defined in Article 4.2(a) of Annex 2-B; and
    - (ii) after the transitional period, the procedures defined in Article 3(b)(i) or 3(b)(ii) of Annex 2-B, where the choice between the two procedures shall rest with Korea.
  - (b) for products falling within the scope of the Electrical Appliances Safety Control Act at the date of signature of this Agreement:
    - (i) during the transitional period set out in Article 4.1 of Annex 2-B, the procedure defined in Article 4.2(b) of Annex 2-B; and

(ii) after the transitional period, the procedures defined in Article 3(b)(i), 3(b)(ii) or 3(b)(iii) of Annex 2-B, where the choice among the three procedures shall rest with Korea;

3. For products falling, at the date of signature of this Agreement, within the scope of more than one Act referred to in paragraph 2 of this Appendix, the supplier shall remain free to provide positive assurance of conformity with EMC in accordance with either of the procedures selected by Korea in accordance with subparagraph (a) or (b) of paragraph 2 of this Appendix. In case a product falls, in the future, within the scope of more than one Act referred to in paragraph 2 of this Appendix, whether EMC or safety of covered products is concerned, the same rule shall apply.

**Appendix 2-B-3**

No.	Products	HS code
1	Cables and cord sets	854442, 854449, 854459, 854460
2	Switches	853590, 853650
3	Interceptors for electrical appliances	853521, 853529, 853620, 853630, 853650
4	Magnetic switches	853650
5	Capacitors and noise filters	853210, 853221, 853222, 853223, 853224, 853225, 853229, 853230, 853540
6	Installation accessories and connection devices	853650, 853669
7	Fuses and fuse holders, thermal-links	853510, 853610, 853630
8	Power transformers and voltage regulators	850421, 850422, 850431, 850432, 850433, 850434, 850440
9	Vacuum cleaners, floor treatment machines, steam cleaners, surface-cleaning appliances	842430, 850811, 850819, 850860
10	Electric irons and press	851640, 845130
11	Dish washers and dish driers	842211, 842219, 842220, 845140, 842240
12	Heating appliances for kitchen	841989, 841990, 851410, 851650, 851660, 851672
13	Washing machines and spin extractors	842112, 845011, 845012, 845019, 845020
14	Appliances for hair care	851631, 851632
15	Warming plates and electric hot cupboards	851660, 851679, 851680
16	Motor-operated appliances for kitchen	821490, 843510, 846722, 850940, 850980
17	Electric appliances for heating liquids	841981, 841989, 851660, 851671, 851679, 851680
18	Electric blankets and mats, electric beds	630110

No.	Products	HS code
19	Cauterizing machines and foot warmers	392210, 630110, 851680
20	Storage water heaters and Instantaneous water heaters	851610, 851660, 851679, 851680
21	Electric refrigerators and ice makers	841490, 841581, 841582, 841810, 841821, 841829, 841830, 841840, 841850, 841869, 841899
22	Microwave ovens (using the frequencies of 300 MHz - 30 GHz range)	851650
23	Sewing machines for household	845210, 845229
24	Battery chargers	850440
25	Electric driers	845121, 851629, 851679, 845129, 851632, 851633
26	Heaters	851610, 851621, 851629, 851679, 851680, 940210
27	Massage appliances	901910
28	Air-conditioners and dehumidifiers	841510, 841581, 841582, 841583
29	Pumps and electric waterspouts	841350, 841360, 841370, 841381, 841810, 961610
30	Heating tools	841989, 841990, 842240, 842290, 851511, 851519, 851521, 851580
31	Electric sauna appliances	851629, 851679
32	Aquarium heaters, air bubble generators, fishbowls for display	841350, 841360, 841370, 841381, 841480, 842139, 851629, 851660
33	Electric air bubble generators	841480, 842139
34	Insect killing or repelling devices	851660, 851679, 851680
35	Electric baths	392210, 392290, 691010, 691090
36	Air-cleaning appliances	841410, 841430, 841451, 841459, 841480
37	Dispensing appliances and vending machines (equipped with heating element or cooling device or discharge lamp or accommodation)	847621, 847629, 847681, 847689

No.	Products	HS code
38	Electric fans, range hoods	630319, 841410, 841451, 841459, 841460, 841480, 841490, 841510, 854089
39	Electric appliances for toilets and electro-motive inhalers	392290, 850819
40	Humidifiers	851580
41	Spray extraction appliances	961610
42	Electric disinfectants (only equipped with sterilizer lamp)	841989
43	Food waste process machine	850980
44	Wet towel wrapping devices	820890, 842240
45	Motor-operated electric tools	820750, 843311, 843319, 843320, 846711, 846719, 846721, 846722, 846781, 846789, 850980
46	Copying machines	844331
47	DC power supplies (with the rated capacity of at most 1kVA, including those used in combination with AC power)	850440
48	Un-interruptible power supply	850440
49	Laminators	847989
50	Lamp holders	853661, 853669
51	Luminaires (general purpose luminaires)	940510, 940520, 940540, 940560, 940591, 940592, 940599
52	Ballaster (lamps, control gears)	850410, 853661, 853669
53	Self ballasted lamps	853990

For the purposes of Annex 2-B, the following definitions<sup>1</sup> shall apply:

safety of electrical equipment means that equipment, having been constructed in accordance with good engineering practice in safety matters, does not endanger the safety of persons, domestic animals or property when properly installed, maintained and used in applications for which it was made;

electromagnetic compatibility means the ability of an equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment;

declaration of conformity means the issuance of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated;

standard means a document approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method;

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<sup>1</sup> Based on ISO/IEC 17000:2004 and the TBT Agreement.



technical regulation means a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method;

supplier means a manufacturer, or his or her authorised representative in the territory of the importing Party. Where neither is present in the territory of the importing Party, the responsibility for the presentation of the supplier's declaration shall rest with the importer;

conformity assessment means a procedure demonstrating that specified requirements relating to a product, process, system, person or body are fulfilled. Conformity assessment can be performed as a first-party, second-party or third-party activity and covers activities such as testing, inspection and certification; and

testing laboratory means a conformity assessment body that performs testing services and has received attestation conveying formal demonstration of its competence to carry out these specific tasks.

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MOTOR VEHICLES AND PARTS

ARTICLE 1

General Provisions

1. Recognising the importance of motor vehicles and parts for growth, employment and trade for each Party, the Parties confirm their shared objectives and principles, for these products, of:
  - (a) ensuring full reciprocal market access by elimination of tariffs and non-tariff obstacles to bilateral trade pursuant to this Agreement;
  - (b) promoting compatibility of regulations based on international standards;
  - (c) establishing competitive market conditions based on principles of openness, non-discrimination and transparency;
  - (d) securing the protection of human health, safety and environment; and

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

2. This Annex shall apply to all forms of motor vehicles, systems and parts thereof falling under Chapters 40, 84, 85, 87 and 94 of the HS, except those products set out in Appendix 2-C-1.

## ARTICLE 2

### Regulatory Convergence

1. The Parties recognise that the World Forum for Harmonisation of Vehicle Regulations (hereinafter referred to as the "WP.29"), within the framework of the United Nations Economic Commission for Europe (hereinafter referred to as the "UN ECE"), is the relevant international standard-setting body for the products covered by this Annex.

2. The Parties agree to participate actively in the development of regulations in WP.29 and shall cooperate for the adoption, without undue delay, of new regulations by WP.29.

## ARTICLE 3

### Market Access

Each Party shall allow on its market the products originating in the other Party, in accordance with this Article:

- (a) (i) the competent approval authorities in the European Union shall accept for the purpose of EU type-approval any product that complies with the requirements listed in Table 1 of Appendix 2-C-2 as complying with the corresponding provisions of the applicable EU technical regulations<sup>1</sup>;
  
- (ii) Korea shall accept any product that complies with the requirements listed in Table 1 of Appendix 2-C-3 as complying with the corresponding provisions of the applicable Korean technical regulations<sup>1</sup>;

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<sup>1</sup> The classification of the products, for the purpose of applying Article 3(a)(i) through 3(a)(iii) and determining the applicable regulations, shall be that under the legislation of the importing Party.

- (iii) The Parties shall harmonise the regulations listed in Table 2 of Appendix 2-C-2, in case of the European Union, and in Table 2 of Appendix 2-C-3, in case of Korea, with the corresponding UN ECE Regulations or Global Technical Regulations (hereinafter referred to as the "GTR") within a period of five years of the entry into force of this Agreement, unless exceptionally a Party demonstrates that a specific UN ECE Regulation or GTR would be ineffective or inappropriate for the fulfilment of legitimate objectives pursued on the basis of substantiated scientific or technical information<sup>1, 2</sup>; and
- (iv) If there arises any trade issue with regard to the technical regulations not covered by subparagraph (a)(i) or (a)(ii) or, with regard to the technical regulations covered by subparagraph (a)(iii) while there is no harmonisation, upon request of either Party, the Parties shall enter into consultations to seek a mutually satisfactory solution. In these consultations the Party intending to impose a measure materially affecting market access conditions shall provide the other Party with the basis of its intended decision, including a detailed explanation in terms of the relevant scientific or technical information<sup>2</sup>.
- (b) The Parties shall ensure that their respective procedures are accomplished without undue delay for the marketing of the products covered by this Annex.

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<sup>2</sup> The Parties understand that the regulations covered by subparagraph (a)(iii) and (a)(iv) existing at the time of signature of this Agreement have not caused serious market access problems and under the provisions of these subparagraphs they will not result in worsening of the market access conditions as compared with the situation prevailing at that time.

- (c) Each Party shall promptly communicate to the concerned economic operators any decision taken on applications regarding conformity assessment, as well as the basis for any such decision and information on available legal remedies.
- (d) The Parties shall review Appendices 2-C-2 and 2-C-3 of this Annex no less than every three years from the entry into force of this Agreement with a view to furthering the acceptance of products as set out in subparagraph (a) of this Article, taking into account any regulatory developments that may have occurred internationally or in the Parties. Any modifications to these Appendices shall be decided upon by the Trade Committee.

## ARTICLE 4

### Consolidation of Regulatory Convergence

1. The Parties shall:
  - (a) at any time refrain from introducing any new domestic technical regulations diverging from UN ECE Regulations or GTR in areas covered by such regulations, or where the completion of such regulations is imminent, in particular in the areas covered by Appendix 2-C-2, in the case of the European Union, and Appendix 2-C-3, in the case of Korea; and

- (b) as soon as practicable after any new UN ECE Regulations or GTR is adopted by UN ECE in areas covered by existing domestic technical regulations, provide treatment for products originating in the other Party complying with UN ECE Regulations or GTR in accordance with Article 3 of this Annex, *mutatis mutandis*,

unless there are substantiated reasons based on scientific or technical information why a specific UN ECE Regulation or GTR is ineffective or inappropriate for ensuring road safety or the protection of the environment or public health. In these cases, any such reasons shall be notified to the other Party and made public.

2. In so far as a Party introduces or maintains technical regulations that differ from existing UN ECE Regulations in areas covered by these UN ECE Regulations, that Party shall review these technical regulations no less than every three years from the entry into force of this Agreement in order to assess whether the reasons for the imposition of the relevant technical regulations remain valid. The outcome from these reviews, as well as the technical or scientific information underpinning the outcome of these reviews, shall be made public and notified to the other Party upon request.

3. In areas where there are no UN ECE Regulations or GTR and at least one Party introduces or maintains a technical regulation, the Parties shall consult on the possibility for developing international standards covering such areas. If the development of such international standards is not possible or is inappropriate, and if the Parties introduce or maintain domestic technical regulations in such areas, the Parties undertake to consult on the possibility for approximation of their respective regulations.

## ARTICLE 5

### MFN Treatment

With respect to internal taxes and emission regulations on products covered by this Annex, each Party shall accord to the products originating in the other Party no less favourable treatment than that accorded to the like products originating in any third country not party to this Agreement, including as provided in any free trade agreement with such third country.

## ARTICLE 6

### Products with New Technologies or New Features

1. Neither Party shall prevent or unduly delay the placing on its market of a product on the ground that it incorporates a new technology or a new feature which has not yet been regulated unless it can demonstrate, based on scientific or technical information, that this new technology or new feature creates a risk for human health, safety or the environment.



2. When a Party decides to refuse the placing on the market or require the withdrawal from the market of a product on the ground that it incorporates a new technology or a new feature creating a risk for human health, safety or the environment, it shall immediately notify this decision to the other Party and to the economic operators concerned. The notification shall include all relevant scientific or technical information.

## ARTICLE 7

### Other Measures Restricting Trade

Each Party shall refrain from nullifying or impairing the market access benefits accruing to the other Party under this Annex through other regulatory measures specific to the sector covered by this Annex. This is without prejudice to the right to adopt measures necessary for road safety, the protection of the environment or public health and the prevention of deceptive practices provided such measures are based on substantiated scientific or technical information.

## ARTICLE 8

### Application of Regulations

1. When a Party accepts compliance or harmonisation with UN ECE requirements in conformity with Article 3 of this Annex, UN ECE type-approval certificates issued by competent authorities shall be considered as providing a presumption of conformity. If a Party finds that a certain product covered by a type-approval certificate does not conform to the approved type, it shall inform the other Party. This paragraph is without prejudice to the Parties' right to take appropriate measures, as set out in paragraphs 2 and 3.

2. The competent administrative authorities of each Party may verify by random sampling in accordance with its domestic legislation that the products, including those self-certified by manufacturers, comply as appropriate with:

- (a) all the technical regulations of that Party; or
- (b) the domestic technical regulations and the other requirements, as set out in Article 3(a) of this Annex.

Each Party may require the supplier to withdraw a product from its market in case the product concerned does not comply with those regulations or requirements as the case may be.

3. Type-approval can be refused if the documentation is incomplete, the relevant procedures for verifying conformity of production are not complied with, or the products concerned do not comply as appropriate with:

- (a) all the technical regulations of a Party; or
- (b) a Party's technical regulations and the other requirements, as set out in Article 3(a) of this Annex.

4. Notwithstanding compliance with the technical regulations or the requirements referred to in Article 3(a) of this Annex, a Party may, in exceptional circumstances, refuse to a supplier the placing of a product on its market or require a supplier to withdraw that product from its market if there are urgent and compelling risks for road safety, public health or the environment based on substantiated scientific or technical information. Such a refusal shall not constitute a means of arbitrary or unjustifiable discrimination against the products of the other Party or a disguised restriction on trade. Before it is implemented, any such temporary emergency measure shall be notified to the other Party and to the supplier with an objective, reasoned and sufficiently detailed explanation of the motivation for the measure.

## ARTICLE 9

### Working Group on Motor Vehicles and Parts

1. In order to further facilitate trade in motor vehicles and parts and to address market access problems before they arise, the Parties agree to cooperate and to consult promptly on any matters concerning the application of this Annex. They agree to inform each other of any measure that may affect trade in products falling under the scope of this Annex, in accordance with Chapter Four (Technical Barriers to Trade). Upon request, each Party shall in a timely manner respond in writing to comments and questions regarding any problems arising with respect to any such measure, and be ready to enter into consultations on such measure with a view to seeking a mutually satisfactory outcome.
  
2. The Working Group on Motor Vehicles and Parts established pursuant to Article 15.3.1 (Working Groups) shall be responsible for the effective implementation of, and may consider any matter relating to, this Annex. In particular, the Working Group shall be responsible for:
  - (a) preparing the Parties' cooperation with respect to the works of WP.29, in line with Article 2 of this Annex;

- (b) supervising the full implementation of the commitments set out in Article 3 of this Annex, including:
  - (i) discussing progress in the implementation of the harmonisation process set out in Article 3(a)(iii);
  - (ii) providing a forum for the consultations envisaged in Article 3(a)(iv); and
  - (iii) preparing decisions of the Trade Committee set out in Article 3(d);
- (c) discussing the reviews described in Article 4.2 of this Annex and holding the consultations set out in Article 4.3 of this Annex;
- (d) discussing, as appropriate, the notifications envisaged in Articles 6 and 8 of this Annex;
- (e) considering the application of technical regulations to motor vehicles imported under different channels and making recommendations where appropriate; and
- (f) any matters, as appropriate, regarding the practical implementation of transitional arrangements on on-board diagnostic (hereinafter referred to as the "OBD") and emissions set out in Table 1 of Appendix 2-C-3.

3. The Working Group shall meet at least once a year, unless agreed otherwise. Its meetings shall normally be held in conjunction with meetings of WP.29 or any other forum addressing automotive issues. The Working Group may also carry out its works by e-mail, teleconference or videoconference or any other appropriate means of communications.

## ARTICLE 10

### Compliance

1. Chapter Fourteen (Dispute Settlement) shall apply to this Annex subject to the following modifications:
  - (a) Dispute concerning the interpretation or application of this Annex shall be considered a matter of urgency;
  - (b) The period foreseen for consultations under Article 14.3 (Consultations) shall be reduced from 30 days to 15 days;
  - (c) The period foreseen for the issuance of the interim panel report under Article 14.6 (Interim Panel Report) shall be reduced from 90 days to 60 days;
  - (d) The period foreseen for the issuance of the arbitration panel ruling under Article 14.7 (Arbitration Panel Ruling) shall be reduced from 120 days to 75 days; and

- (e) The following sentence shall be deemed to be added to Article 14.9 (The Reasonable Period of Time for Compliance): "The Party complained against shall comply with the arbitration panel ruling without delay. If immediate compliance is not possible, the reasonable period of time should normally not exceed 90 days and in no case it shall exceed 150 days from the issuance of the arbitration panel ruling in cases where the adoption of a measure of general application that does not require legislative action is necessary for the Party complained against in order to bring itself into compliance."
2. The Parties may agree not to apply specific provisions of this Article.

Annex 2-C shall not cover:

- (a) Tractors (in HS 8701.10, 8701.20, 8709.11, 8709.19 and 8709.90);
- (b) Snow mobiles and Golf carts (in HS 8703.10); and
- (c) Construction machinery: (HS: 84134000, 84251100, 84251920, 84251980, 84253100, 84253930, 84253990, 84254100, 84254200, 84254900, 84261100, 84261200, 84261900, 84262000, 84263000, 84264100, 84264900, 84269110, 84269190, 84269900, 84272010, 84272090, 84281020, 84281080, 84282030, 84282091, 84282098, 84283100, 84283200, 84283300, 84283920, 84283990, 84284000, 84286000, 84289030, 84289071, 84289079, 84289091, 84289095, 84291100, 84291900, 84292000, 84293000, 84294010, 84294030, 84294090, 84295110, 84295191, 84295199, 84295210, 84295290, 84295900, 84301000, 84302000, 84303100, 84303900, 84304100, 84304900, 84305000, 84306100, 84306900, 84311000, 84313100, 84313910, 84313970, 84314100, 84314200, 84314300, 84314920, 84314980, 84741000, 84742010, 84742090, 84743100, 84743200, 84743910, 84743990, 84748010, 84748090, 84749010, 84749090, 84791000, 87013010, 87013090, 87041010, 87041090, 87051000, 87052000, 87054000 and 87059030).



Table 1

List referred to in Article 3(a)(i) of Annex 2-C

Subject	Requirements	Corresponding EU Technical Regulation
Permissible sound level	UNECE Reg. 51	Directive 70/157/EEC
Replacement silencing systems	UNECE Reg. 59	Directive 70/157/EEC
Emissions	UNECE Reg. 83	Directive 70/220/EEC
Replacement catalytic converters	UNECE Reg. 103	Directive 70/220/EEC
Fuel tanks	UNECE Reg. 34	Directive 70/221/EEC
LPG tanks	UNECE Reg. 67	Directive 70/221/EEC
CNG tanks	UNECE Reg. 110	Directive 70/221/EEC
Rear protective device	UNECE Reg. 58	Directive 70/221/EEC
Steering effort	UNECE Reg. 79	Directive 70/311/EEC
Door latches and hinges	UNECE Reg. 11	Directive 70/387/EEC
Audible warning	UNECE Reg. 28	Directive 70/388/EEC
Indirect vision devices	UNECE Reg. 46	Directive 2003/97/EC
Braking	UNECE Reg. 13	Directive 71/320/EEC
Braking	UNECE Reg. 13H	Directive 71/320/EEC
Brake linings	UNECE Reg. 90	Directive 71/320/EEC
Radio interference (electromagnetic compatibility)	UNECE Reg. 10	Directive 72/245/EEC
Diesel smoke	UNECE Reg. 24	Directive 72/306/EEC

Subject	Requirements	Corresponding EU Technical Regulation
Interior fittings	UNECE Reg. 21	Directive 74/60/EEC
Anti-theft	UNECE Reg. 18	Directive 74/61/EEC
Anti-theft and immobiliser	UNECE Reg. 116	Directive 74/61/EEC
Vehicle Alarm Systems	UNECE Reg. 97 UNECE Reg. 116	Directive 74/61/EEC
Behaviour of steering device under impact	UNECE Reg. 12	Directive 74/297/EEC
Seat strength	UNECE Reg. 17	Directive 74/408/EEC
Seat strength (buses and coaches)	UNECE Reg. 80	Directive 74/408/EEC
Exterior projections	UNECE Reg. 26	Directive 74/483/EEC
Speedometer	UNECE Reg. 39	Directive 75/443/EEC
Seat belt anchorages	UNECE Reg. 14	Directive 76/115/EEC
Installation of lighting and light signalling devices	UNECE Reg. 48	Directive 76/756/EEC
Retro reflectors	UNECE Reg. 3	Directive 76/757/EEC
End-outline/front-position (side)/rear-position (side)/stop lamps	UNECE Reg. 7	Directive 76/758/EEC
Daytime running lamps	UNECE Reg. 87	Directive 76/758/EEC
Side marker lamps	UNECE Reg. 91	Directive 76/758/EEC
Direction indicators	UNECE Reg. 6	Directive 76/759/EEC
Rear registration plate lamp	UNECE Reg. 4	Directive 76/760/EEC
Headlamps (R <sub>2</sub> and HS <sub>1</sub> )	UNECE Reg. 1	Directive 76/761/EEC
Headlamps (sealed beam)	UNECE Reg. 5	Directive 76/761/EEC
Headlamps (H <sub>1</sub> , H <sub>2</sub> , H <sub>3</sub> , HB <sub>3</sub> , HB <sub>4</sub> , H <sub>7</sub> , and/or H <sub>8</sub> , H <sub>9</sub> , HIR1, HIR2 and/or H <sub>11</sub> )	UNECE Reg. 8	Directive 76/761/EEC
Headlamps (H <sub>4</sub> )	UNECE Reg. 20	Directive 76/761/EEC
Headlamps (halogen sealed beam)	UNECE Reg. 31	Directive 76/761/EEC

Subject	Requirements	Corresponding EU Technical Regulation
Filament lamps for use in approved lamp units	UNECE Reg. 37	Directive 76/761/EEC
Headlamps with gas-discharge light sources	UNECE Reg. 98	Directive 76/761/EEC
Gas-discharge light sources for use in approved gas-discharge lamp units	UNECE Reg. 99	Directive 76/761/EEC
Headlamps (asymmetrical passing beam)	UNECE Reg. 112	Directive 76/761/EEC
Adaptative front-lighting systems	UNECE Reg. 123	Directive 76/761/EEC
Front fog lamps	UNECE Reg. 19	Directive 76/762/EEC
Rear fog lamps	UNECE Reg. 38	Directive 77/538/EEC
Reversing lamps	UNECE Reg. 23	Directive 77/539/EEC
Parking lamps	UNECE Reg. 77	Directive 77/540/EEC
Seat belts and restraint systems	UNECE Reg. 16	Directive 77/541/EEC
Child restraints	UNECE Reg. 44	Directive 77/541/EEC
Front forward field of vision	UNECE Reg. 125	Directive 77/649/EEC
Identification of controls, tell-tales and indicators	UNECE Reg. 121	Directive 78/316/EEC
Heating systems	UNECE Reg. 122	Directive 2001/56/EC
Head restraints (combined with seats)	UNECE Reg. 17	Directive 78/932/EEC
Head restraints	UNECE Reg. 25	Directive 78/932/EEC
CO <sub>2</sub> emissions – Fuel consumption	UNECE Reg. 101	Directive 80/1268/EEC
Engine power	UNECE Reg. 85	Directive 80/1269/EEC
Emissions (Euro IV and V) heavy duty vehicles	UNECE Reg. 49	Directive 2005/55/EC
Lateral protection	UNECE Reg. 73	Directive 89/297/EEC
Safety glazing	UNECE Reg. 43	Directive 92/22/EEC
Tyres, motor vehicles and their trailers	UNECE Reg. 30	Directive 92/23/EEC

Subject	Requirements	Corresponding EU Technical Regulation
Tyres, commercial vehicles and their trailers	UNECE Reg. 54	Directive 92/23/EEC
Temporary-use spare wheels/tyres	UNECE Reg. 64	Directive 92/23/EEC
Rolling sound	UNECE Reg. 117	Directive 92/23/EEC
Speed limitation devices	UNECE Reg. 89	Directive 92/24/EEC
Couplings	UNECE Reg. 55	Directive 94/20/EC
Close-coupling device	UNECE Reg. 102	Directive 94/20/EC
Flammability	UNECE Reg. 118	Directive 95/28/EC
Buses and coaches	UNECE Reg. 107	Directive 2001/85/EC
Strength of superstructure (buses and coaches)	UNECE Reg. 66	Directive 2001/85/EC
Frontal impact	UNECE Reg. 94	Directive 96/79/EC
Side impact	UNECE Reg. 95	Directive 96/27/EC
Vehicles intended for the transport of dangerous goods	UNECE Reg. 105	Directive 98/91/EC
Front underrun protection	UNECE Reg. 93	Directive 2000/40/EC

Table 2

List referred to in Article 3(a)(iii) of Annex 2-C

Subject	EU Technical Regulations	Corresponding UNECE Regulations
External projections of cabs	Directive 92/114/EEC	61

Table 1

List referred to in Article 3(a)(ii) of Annex 2-C

Subject		Requirements	Corresponding Korean Technical Regulations
Occupant crash protection	Frontal	UNECE Reg. 94	KMVSS <sup>1</sup> Article 102
	Side	UNECE Reg. 95	KMVSS Article 102
Steering control rearward displacement		UNECE Reg. 12	KMVSS Article 89 paragraph 1 Item 2
Impact protection for the driver from the steering control system		UNECE Reg. 12	KMVSS Article 89 paragraph 1 Item 1
Seating systems		UNECE Reg. 17	KMVSS Article 97
Head restraints		UNECE Reg. 17, UNECE Reg. 25, GTR 7	KMVSS Articles 26, 99
Door locks and door retention components		UNECE Reg. 11, GTR 1	KMVSS Article 104 Paragraph 2
Instrument panel impact		UNECE Reg. 21	KMVSS Article 88
Seat back impact		UNECE Reg. 21	KMVSS Article 98
Armrest impact		UNECE Reg. 21	KMVSS Article 100
Sun visor impact		UNECE Reg. 21	KMVSS Article 101
Inside rear view mirror impact		UNECE Reg. 46	KMVSS Article 108
Towing hook		77/389/EEC	KMVSS Article 20 Items 1, 2, 4
Rear under-run protection		UNECE Reg. 58	KMVSS Article 19 Paragraph 4 and Article 96

<sup>1</sup> Korea Motor Vehicle Safety Standards.

Subject	Requirements	Corresponding Korean Technical Regulations	
Lighting and signalling system	Installation	UNECE Reg. 48	KMVSS Articles 38, 39, 40, 41, 42, 43, 44, 45 and 47
	Head lamp	UNECE Reg. 1, 2, 5, 8, 20, 31, 37, UNECE Reg. 98, 99, 112, 113, 123	KMVSS Article 38, Article 48 Paragraph 3, Article 106 Item 1
	Front fog lamp	UNECE Reg. 19	KMVSS Article 38-2 Paragraph 1, Article 106 Item 2
	Backup lamp	UNECE Reg. 23	KMVSS Article 39, Article 106 Item 3
	Clearance lamp	UNECE Reg. 7	KMVSS Article 40, Article 106 Item 4
	Registration plate lamp	UNECE Reg. 4	KMVSS Article 41, Article 106 Item 5
	Tail lamp	UNECE Reg. 7	KMVSS Article 42, Article 106 Item 6
	Stop lamp	UNECE Reg. 7	KMVSS Article 43 Paragraph 1, Article 106 Item 7
	Centre high mounted stop lamp	UNECE Reg. 7	KMVSS Article 43 Paragraphs 2, 3, Article 106 Item 8
	Turn signal	UNECE Reg. 6	KMVSS Article 44, Article 106 Item 9
	Auxiliary turn signal	UNECE Reg. 7	KMVSS Article 44, Article 106 Item 10
	Rear fog lamp	UNECE Reg. 38	KMVSS Article 38-2 Paragraph 2, Article 106 Item 2
	Retro-reflection devices	UNECE Reg. 70, UNECE Reg. 3	KMVSS Article 49 paragraphs 1, 2, Article 107

Subject		Requirements	Corresponding Korean Technical Regulations
Driver's visibility		UNECE Reg. 46	KMVSS Article 50 Article 94
Engine power		UNECE Reg. 85	KMVSS Article 11 Paragraph 1 Item 2, Article 111
Device for securing driver's visibility	Windshield wiping system	78/318/ EEC	KMVSS Article 51 Paragraph 2, Article 109 Item 1
	Defrosting system	78/317/ EEC	KMVSS Article 109 Item 2
	Defogging system	78/317/ EEC	KMVSS Article 109 Item 3
	Windshield washing system	78/318/ EEC	KMVSS Article 109 Item 4
Passenger car brake		UNECE Reg. 13H	KMVSS Article 15, Article 90 Item 1
Brake system except passenger car and trailer		UNECE Reg. 13	KMVSS Article 15, Article 90 Item 2
Trailer brake system		UNECE Reg. 13	KMVSS Article 15, Article 90 Item 3
Anti-lock brake system, except trailer		UNECE Reg. 13	KMVSS Article 15, Article 90 Item 4
Trailer anti-lock brake system		UNECE Reg. 13	KMVSS Article 15, Article 90 Item 5
Steering effort		UNECE Reg. 79	KMVSS Article 14, Article 89 paragraph 2
Speed limiter		UNECE Reg. 89	KMVSS Article 110-2
Speedometer		UNECE Reg. 39	KMVSS Article 110
Electro-magnetic compatibility		UNECE Reg. 10	KMVSS Article 111-2
Fuel leakage in collision		UNECE Reg. 34, UNECE Reg. 94, UNECE Reg. 95	KMVSS Article 91

Subject	Requirements	Corresponding Korean Technical Regulations
Bumper impact	UNECE Reg. 42	KMVSS Article 93
Seat belt assembly anchorages	UNECE Reg. 14, UNECE Reg. 16	KMVSS Article 27 Paragraphs 1, 2, 3, 4, 5; Article 103 Paragraphs 1, 2, 3
Child seat anchorage	UNECE Reg. 14	KMVSS Article 27-2, Article 103-2
Horn noise, stationary noise and silencer for vehicles (4 wheels)	UNECE Reg. 28 UNECE Reg. 51	KMVSS Articles 35, 53, NVCA Article 30 and its Ordinance of MOE Article 29
Emission and noise (except the passer-by noise of 3 or 4 wheels) for motor cycles	UNECE Reg. 40, UNECE Reg. 41, UNECE Reg. 47 Directives 2002/51/EC, 2003/77/EC, 97/24/EC Chapters 5 and 9	CACA Article 46 and its Ordinance of MOE Article 62, NVCA Article 30 and its Ordinance of MOE Article 29
Emission Diesel (incl. OBD)	Below 3.5t vehicle	CACA Article 46 and its Ordinance of MOE Article 62
	Over 3.5t vehicle	
Tyres	UNECE Reg. 30, 54, 75, 106, 117, 108, 109	Quality management Safety and Control of Industrial Products Act (QMSCIPA) (Articles. 19, 20, 21); Enforcement Rules of QMSCIPA Article 2 paragraph 2, Article 19.



## On-Board Diagnostic Systems for Gasoline-Powered Vehicles

Gasoline-powered vehicles complying with Euro 6 OBD shall be considered as complying with Korea LEV and ULEV OBD.

## Transitional Arrangements on OBD and Emissions for Gasoline-Powered Motor Vehicles

### 1. OBD

Until the end of 2013 or the introduction of Euro 6 OBD, if the latter is earlier:

- (a) each EU car manufacturer<sup>2</sup> whose sales of vehicles with Euro OBD in Korea during the year 2008 exceeded 800 vehicles will be allowed to sell in Korea the following number of vehicles with Euro 5 OBD per year and brand:

the year 2010: 1,200, the year 2011: 1,500, the year 2012: 1,800 and the year 2013: 1,800;

- (b) each EU car manufacturer whose total sales of vehicles with Euro OBD in Korea during the years 2005 to 2008 exceeded an average of 750 vehicles per year will be allowed to sell in Korea 1,000 vehicles with Euro 5 OBD per year and brand; and

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<sup>2</sup> The Parties note that the Korean practice on the concept of manufacturer at the time of signature of this Agreement will provide guidance in the implementation of this paragraph.

- (c) other EU car manufacturers not covered under subparagraphs (a) or (b) above will be allowed to sell vehicles with Euro 5 OBD in Korea within an overall limit of 1,500 such vehicles per year. This quantity will be distributed among those manufacturers in accordance with principles to be determined by the Working Group on Motor Vehicles and Parts.

## 2. Emissions

Until the application of a new arrangement<sup>3</sup> for manufacturers that sell no more than 10,000 gasoline-powered vehicles per year in the territory of Korea, Korea shall provide that:

- (a) a gasoline-powered motor vehicle produced by a manufacturer that sells no more than 250 of these vehicles per year in the territory of Korea complies with the Korean emission requirements if the annual fleet average Non-Methane Organic Gases (hereinafter referred to as the "NMOG") value of the manufacturer's fleet sold in the territory of Korea does not exceed 0.047 g/km;
- (b) a gasoline-powered motor vehicle produced by a manufacturer that sells no more than 4,000 of these vehicles per year in the territory of Korea complies with the Korean emission requirements if the annual fleet average NMOG value of the manufacturer's fleet sold in the territory of Korea does not exceed 0.039 g/km; and

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<sup>3</sup> The Parties understand that a new arrangement will be introduced upon the entry into force of the Free Trade Agreement between the Republic of Korea and the United States of America.

- (c) a gasoline-powered motor vehicle produced by a manufacturer that sells no more than 10,000 of these vehicles per year in the territory of Korea complies with the Korean emission requirements if the annual fleet average NMOG value of the manufacturer's fleet sold in the territory of Korea does not exceed 0.030 g/km.

3. Application of Transitional Arrangements<sup>4</sup>

The Parties shall provide for the application of these transitional arrangements on OBD and emissions from the calendar year in which this Agreement enters into force.

Table 2

List referred to in Article 3(a)(iii) of Annex 2-C

Subject	Korean Technical Regulations	Corresponding UNECE Regulations
Maximum Stable Inclination Angle	KMVSS Art. 8	107
Minimum Turning Radius	KMVSS Art. 9	107
Running Gear	KMVSS Art. 12	30, 54
Controls and Displays	KMVSS Art. 13	121
Frame and Body	KMVSS Art. 19	58, 73
Coupling Device	KMVSS Art. 20 Items 3, 5	55
Theft Protection	KMVSS Art. 22	18

<sup>4</sup> With a mutual understanding that this Agreement will enter into effect in 2010, Korea will make the necessary measures effective as from 1 January 2010 with regard to marketing motor vehicles with Euro 5 OBD.

Subject	Korean Technical Regulations	Corresponding UNECE Regulations
Riding Accommodation	KMVSS Art. 23	107
Driver's Seat	KMVSS Art. 24	107
Passenger Seat	KMVSS Art. 25	107
Seat Belt	KMVSS Art. 27	16
Standing Space	KMVSS Art. 28	107
Entrance	KMVSS Art. 29	107
Emergency Exit	KMVSS Art. 30	107
Aisle	KMVSS Art. 31	107
Safety Glazing	KMVSS Art. 34	43, GTR 6
Hazard Warning Signal Lamp	KMVSS Art. 45	48
Speedometer & Odometer	KMVSS Art. 54	39
Fire Extinguisher	KMVSS Art. 57	36
Running Gear	KMVSS Art. 64	75
Service Brake System	KMVSS Art. 67	78, GTR 3
Headlamp	KMVSS Art. 75	53, 56, 57, 72, 74, 76, 82
Registration Plate Lamp	KMVSS Art. 76	50, 53
Tail Lamp	KMVSS Art. 77	50, 53
Stop Lamp	KMVSS Art. 78	50, 53
Turn Signal Lamp	KMVSS Art. 79	50, 53
Rear Reflex Reflector	KMVSS Art. 80	3, 53
Rear view Mirror	KMVSS Art. 84	81
Speedometer	KMVSS Art. 85	39

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

ARTICLE 1

General Provisions

Recognising that while there are differences between each Party's health care system, the Parties share a commitment to promoting the development of and facilitating access to high-quality patented and generic pharmaceutical products and medical devices, as a means of continuing to improve the health of their populations. In pursuing these objectives, the Parties confirm their shared principles with respect to the importance of:

- (a) adequate access to pharmaceutical products and medical devices while providing high-quality health care;
- (b) sound economic incentives and competitive markets for the efficient development of and access to pharmaceutical products and medical devices;
- (c) appropriate government support of academic and commercial research and development, intellectual property protection and other incentives for innovation in the research and development of pharmaceutical products and medical devices;

- (d) promotion of innovation of, and timely and affordable access to, safe and effective pharmaceutical products and medical devices through transparent and accountable procedures, without impeding a Party's ability to apply high standards of safety, efficacy and quality;
- (e) ethical practices by manufacturers and suppliers of pharmaceutical products and medical devices and by health care providers on a global basis in order to achieve open, transparent, accountable and non-discriminatory health care decision-making; and
- (f) cooperation between the Parties in regulatory affairs and in the development of international practices in international organisations such as the World Health Organisation (hereinafter referred to as the "WHO"), the Organisation for Economic Co-operation Development (hereinafter referred to as the "OECD"), the International Conference on Harmonization (hereinafter referred to as the "ICH") for pharmaceutical products and the Global Harmonization Task Force (hereinafter referred to as the "GHTF") for medical devices, with a view to improving the safety, efficacy and quality of pharmaceutical products and medical devices.

## ARTICLE 2

### Access to Innovation

To the extent that health care authorities in a Party operate or maintain procedures for listing pharmaceutical products or medical devices, for indications entitled to reimbursement, or for setting the amount of reimbursement or any measures related to pricing<sup>1</sup> for pharmaceutical products or medical devices under health care programmes they operate, that Party shall:

- (a) ensure that the procedures, rules, criteria and implementing guidelines that apply to the listing of pharmaceutical products or medical devices, indications for reimbursement, setting the amount of reimbursement, or any measures related to listing, pricing and/or reimbursement for pharmaceutical products or medical devices are fair, transparent, reasonable and non-discriminatory<sup>2</sup>; and

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<sup>1</sup> References to pricing in this Annex are only relevant if applicable under the legislation of either Party.

<sup>2</sup> The Parties understand that under this subparagraph, which does not establish any obligation to reimburse products at any given price or prejudge the specific outcome of price negotiations, the criteria (which may take forms such as guidelines, public notices or "matters to be considered", etc.) on which the decisions on reimbursement and pricing will be based are expected to be objective and clear so as to allow understanding of the basis of such decisions.

- (b) ensure that the health authorities' determination of pricing and reimbursement for a pharmaceutical product or medical device, once approved by the appropriate regulatory authority as safe, efficacious and of good quality, and if based on public bodies' or quasi-public bodies' involvement, shall:
- (i) appropriately recognise the value of the patented pharmaceutical product or medical device in the amount of pricing and reimbursement it provides;
  - (ii) permit a manufacturer of the pharmaceutical product or medical device to apply, based on scientific evidence of safety, efficacy, quality and benefits, for an increased amount of pricing and reimbursement over those provided for comparator products, if any, used to determine the amount of reimbursement;
  - (iii) permit a manufacturer of the pharmaceutical product or medical device, after a decision on the pricing/reimbursement is made, to apply for an increased amount of reimbursement for the product based on scientific evidence the manufacturer provides on the product's safety, efficacy, quality and benefits;
  - (iv) permit a manufacturer of the pharmaceutical product or medical device to apply for the amount of pricing and reimbursement and price adjustment for additional medical indications for the product, based on scientific evidence the manufacturer provides on the product's safety, efficacy, quality and benefits; and



- (v) in case a Party adjusts ex officio the amount of pricing/reimbursement of the pharmaceutical products or medical devices for external causes in specific circumstances, including drastic changes in economic indicators, permit a manufacturer of the pharmaceutical product or medical device to submit opinions regarding the adjustment before the adjustment is adopted.

## ARTICLE 3

### Transparency

1. Each Party shall ensure that its laws, regulations, procedures, administrative rulings and implementing guidelines of general application (hereinafter referred to as the "rules"), regarding any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices are promptly published or otherwise made available at an early appropriate stage, in such a manner as to enable interested persons and the other Party to become acquainted with them.
2. To the extent possible, each Party shall:
  - (a) publish in advance in relevant publicly accessible sites any such rules that it proposes to adopt or to significantly amend, including an explanation of the purpose of such rules;
  - (b) provide reasonable opportunities for interested persons and the other Party to comment on any such proposed rules allowing, in particular, a reasonable period of time for consultation; and

- (c) address in writing significant and substantive issues raised in comments received from interested persons and the other Party during the comment period and explain any substantive revisions made with respect to such proposed rules, no later than the time the Party adopts them.
3. To the extent possible, each Party should allow a reasonable interval between the publication of any such rules on any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices and their effective date.
4. To the extent that each Party's health care authorities operate or maintain procedures for listing pharmaceutical products or medical devices, for indications entitled to reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices, including any measures related to the revision of pricing and reimbursement under health care programmes, the Party shall:
- (a) ensure that decisions on all formal requests and applications for the pricing or approval of pharmaceutical products or medical devices for reimbursement are adopted and communicated within a reasonable and specified period from the date of their receipt. If the information submitted by the applicant is deemed inadequate or insufficient and the procedure is suspended as a result, the Party's competent authorities shall notify the applicant of what detailed additional information is required and resume the original decision-making process upon receipt of this additional information;

- (b) disclose to applicants within a reasonable and specified period of time, all procedures, methodologies, principles, criteria, including those used, if any, to determine comparator products, and guidelines used to determine pricing and reimbursement for pharmaceutical products or medical devices;
- (c) afford applicants timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes for pharmaceutical products or medical devices;
- (d) provide, within a reasonable and specified period of time, applicants with meaningful and detailed written information regarding the basis for recommendations or determinations of the pricing and reimbursement of pharmaceutical products or medical devices, including citations to any expert opinions or academic studies relied upon in making such recommendations or determinations. Specifically, in case of a negative decision on listing, prices and/or reimbursement, or should the decision-making body decide not to permit in whole or in part the price increase requested, the decision-making body shall provide a statement of reasons that is sufficiently detailed to understand the basis of the decision, including the criteria applied and, if appropriate, any expert opinions or recommendations on which the decision is based;

- (e) make available judicial, quasi-judicial or administrative tribunals, or independent review process<sup>3</sup> that may be invoked at the request of an applicant directly affected by a recommendation or determination and at the point of communication of decision on price and reimbursement inform the applicant of his or her rights under the laws of the Party and the procedures and time-lines for seeking such remedies;
  - (f) make all reimbursement decision-making bodies open to stakeholders, including innovative and generic companies;
  - (g) make publicly available a list of central bodies relevant to the pricing or reimbursement of pharmaceutical products or medical devices; and
  - (h) provide access to each Party's national pricing and reimbursement arrangements including a positive list of products covered by the respective public health insurance schemes to be published on an annual basis for stakeholders with legitimate commercial interests. The negative list, if any, shall be published every six months.
5. Each Party shall ensure that all measures of general application respecting any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices are administered in a consistent, objective and impartial manner.

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<sup>3</sup> In addition to what is set out in this subparagraph, applicants must be able to avail themselves of remedies ensuring effective legal protection. They must be able to appeal decisions before genuine judicial bodies.

## ARTICLE 4

### Ethical Business Practices

1. Each Party shall adopt or maintain appropriate measures to prohibit improper inducements by manufacturers and suppliers of pharmaceutical products or medical devices to health care professionals or institutions for the listing, purchasing or prescribing of pharmaceutical products and medical devices eligible for reimbursement under health care programmes.
2. Each Party shall adopt or maintain appropriate penalties and procedures to enforce the measures that it adopts or maintains in conformity with paragraph 1.
3. Each Party shall bring to the other Party's attention any improper inducements conducted by its manufacturers of pharmaceutical products or medical devices. The Parties recall their obligations under the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions which entered into force on 15 February 1999.

## ARTICLE 5

### Regulatory Cooperation

1. The Parties will take into account, as appropriate, international provisions, practices and guidelines for pharmaceutical products or medical devices, including those developed by the WHO, the OECD, the ICH, the GHTF and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The Parties recognise that their full participation in those relevant international bodies will facilitate regulatory cooperation between them.
2. The Parties will consider the requests by either Party to accept conformity assessments<sup>4</sup> of that Party when performed in accordance with the Good Laboratory Practices and Good Manufacturing Practices of pharmaceutical products and medical devices and when both Parties' corresponding practices are in accordance with international practices.
3. For the Working Group on Pharmaceutical Products and Medical Devices established pursuant to Article 15.3.1 (Working Groups), the Parties shall provide for adequate participation of officials of agencies or departments responsible for health care or other matters and regulations covered by this Annex.
4. The Working Group shall:
  - (a) monitor and support the implementation of this Annex;

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<sup>4</sup> For the purposes of pharmaceutical products, conformity assessment means marketing authorisation of products, and the supervision/enforcement of manufacturers' or importers' compliance with technical standards/practices.

- (b) promote discussion and mutual understanding of issues related to this Annex; and
- (c) promote cooperation between the Parties to achieve the objectives set out in this Annex.

5. The Working Group shall meet at least once a year, unless agreed otherwise. The Working Group may also carry out its work by e-mail, teleconference or videoconference or any other appropriate means of communications.

## ARTICLE 6

### Definitions

1. For the purposes of this Annex:

pharmaceutical products means any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis, to treating or preventing diseases or to restoring, correcting or modifying physiological functions or structures.

Pharmaceutical products include, for example, chemical drugs, biologics/biologicals (vaccines, (anti)toxins, blood, blood components, blood-derived products), herbal drugs, radiopharmaceuticals, recombinant products, gene therapy products, cell therapy products and tissue engineered products;

medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for medical purposes such as diagnosis, prevention, monitoring, treatment or alleviation of diseases<sup>5</sup>. Medical device includes software incorporated into the device by its manufacturer and necessary for the proper functioning of the device;

a Party's health care authorities means entities that are part of or have been established by a Party to operate or administer its health care programmes, unless otherwise specified;

health care programmes operated by a Party means health care programmes in which the health care authorities of a Party make decisions regarding matters to which this Annex applies;

manufacturer refers to the legal right holder of the product in the respective Party's territory;

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<sup>5</sup> For greater clarity, medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.



a negative list is defined as a compilation of pharmaceutical products and medical devices that have been excluded from being prescribed and/or reimbursed under a Party's public health care programme(s); and

a positive list is defined as an exhaustive compilation of pharmaceutical products and medical devices that can be prescribed and/or reimbursed under a Party's public health care programme(s).

2. The definitions for pharmaceutical products and medical devices stated in paragraph 1 are without prejudice to each Party's right to classify products as either pharmaceutical products or medical devices in its legislation.

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CHEMICALS

1. Recalling the obligations of the Parties under the WTO Agreement, in particular the TBT Agreement, and recognising the importance of sustainable development and trade for each Party, the Parties confirm their shared objectives and principles of:
  - (a) establishing competitive market conditions based on principles of openness, non-discrimination and transparency;
  - (b) enhancing cooperation to foster continued mutually beneficial development in trade;
  - (c) ensuring a high level of protection of public health and the environment;
  - (d) promoting alternative methods for assessment of hazards of substances and reducing animal testing;
  - (e) implementing appropriate regulatory mechanisms and protecting confidential information;

- (f) contributing to the fulfilment of the Strategic Approach to International Chemicals Management; and
  - (g) developing and promoting best practices on chemicals assessment and management internationally.
2. Based on the objectives and principles in paragraph 1 and with a view to facilitating and promoting trade, the Parties recognise the importance of:
- (a) ensuring transparency regarding the content of their laws, regulations and other measures of general application in the area of chemicals;
  - (b) providing transparency and due process when regulating and operating their chemical management regimes;
  - (c) applying, whenever possible, best practices with respect to the adoption and implementation of legislation, risk assessments and registration, authorisation, notification and treatment of confidential business information; and

- (d) cooperating in the area of Good Laboratory Practices and Test Guidelines, in order to seek a more harmonised approach to chemical assessment and management for the purpose of seeking international harmonisation of approaches thereto.
3. The Parties agree to discuss in good faith any problems arising from the application of a Party's regulations on chemicals that have a substantial effect on trade of the other Party.
4. With a view to promoting cooperation in the areas covered by this Annex and providing a forum for the discussions envisaged in paragraph 3, a Working Group on Chemicals is established pursuant to Article 15.3.1 (Working Groups). It shall meet at least once every two years, unless agreed otherwise or the problems referred to in paragraph 3 arise.
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