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<sup>(1)</sup> Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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## I

*(Legislative acts)*

## DIRECTIVES

**DIRECTIVE (EU) 2019/692 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 17 April 2019****amending Directive 2009/73/EC concerning common rules for the internal market in natural gas****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 194(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) The internal market in natural gas, which has been progressively implemented throughout the Union since 1999, aims to deliver real choice for all final customers in the Union, be they citizens or businesses, new business opportunities, fair conditions of competition, competitive prices, efficient investment signals and a higher standard of service, and to contribute to security of supply and sustainability.
- (2) Directives 2003/55/EC <sup>(4)</sup> and 2009/73/EC <sup>(5)</sup> of the European Parliament and of the Council have made a significant contribution towards the creation of the internal market in natural gas.
- (3) This Directive seeks to address obstacles to the completion of the internal market in natural gas which result from the non-application of Union market rules to gas transmission lines to and from third countries. The amendments introduced by this Directive are intended to ensure that the rules applicable to gas transmission lines connecting two or more Member States are also applicable, within the Union, to gas transmission lines to and from third countries. This will establish consistency of the legal framework within the Union while avoiding distortion of competition in the internal energy market in the Union and negative impacts on the security of supply. It will also enhance transparency and provide legal certainty to market participants, in particular investors in gas infrastructure and system users, as regards the applicable legal regime.

<sup>(1)</sup> OJ C 262, 25.7.2018, p. 64.

<sup>(2)</sup> OJ C 361, 5.10.2018, p. 72.

<sup>(3)</sup> Position of the European Parliament of 4 April 2019 (not yet published in the Official Journal) and decision of the Council of 15 April 2019.

<sup>(4)</sup> Directive 2003/55/EC of the European Parliament and of the Council of 26 June 2003 concerning common rules for the internal market in natural gas (OJ L 176, 15.7.2003, p. 57).

<sup>(5)</sup> Directive 2009/73/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in natural gas and repealing Directive 2003/55/EC (OJ L 211, 14.8.2009, p. 94).

- (4) To take account of the lack of specific Union rules applicable to gas transmission lines to and from third countries before the date of entry into force of this Directive, Member States should be able to grant derogations from certain provisions of Directive 2009/73/EC to such gas transmission lines which are completed before the date of entry into force of this Directive. The relevant date for the application of unbundling models other than ownership unbundling should be adapted for gas transmission lines to and from third countries.
- (5) Pipelines connecting a third-country oil or gas production project to a processing plant or to a final coastal landing terminal within a Member State should be considered to be upstream pipeline networks. Pipelines connecting an oil or gas production project in a Member State to a processing plant or to a final coastal landing terminal within a third country should not be considered to be upstream pipeline networks for the purpose of this Directive, since such pipelines are unlikely to have a significant impact on the internal energy market.
- (6) Transmission system operators should be free to conclude technical agreements with transmission system operators or other entities in third countries on issues concerning the operation and interconnection of transmission systems, provided that the content of such agreements is compatible with Union law.
- (7) Technical agreements regarding the operation of transmission lines between transmission system operators or other entities should remain in force provided that they comply with Union law and the relevant decisions of the national regulatory authority.
- (8) When such technical agreements are in place, the conclusion of an international agreement between a Member State and a third country or of an agreement between the Union and a third country regarding the operation of the gas transmission line concerned is not required by this Directive.
- (9) The applicability of Directive 2009/73/EC to gas transmission lines to and from third countries remains confined to the territory of the Member States. As regards offshore gas transmission lines, Directive 2009/73/EC should be applicable in the territorial sea of the Member State where the first interconnection point with the Member States' network is located.
- (10) It should be possible for existing agreements concluded between a Member State and a third country on the operation of transmission lines to remain in force, in accordance with this Directive.
- (11) With regard to agreements or parts of agreements with third countries which may affect common rules of the Union, a coherent and transparent procedure should be established by which to authorise a Member State, upon its request, to amend, extend, adapt, renew or conclude an agreement with a third country on the operation of a transmission line or an upstream pipeline network between the Member State and a third country. The procedure should not delay the implementation of this Directive, should be without prejudice to the allocation of competence between the Union and the Member States, and should apply to existing and new agreements.
- (12) Where it is apparent that the subject matter of an agreement falls partly within the competence of the Union and partly within that of a Member State, it is essential to ensure close cooperation between that Member State and the Union institutions.
- (13) Commission Regulation (EU) 2015/703 <sup>(6)</sup>, Commission Regulation (EU) 2017/459 <sup>(7)</sup>, Commission Decision 2012/490/EU <sup>(8)</sup>, as well as Chapters III, V, VI and IX, and Article 28 of Commission Regulation (EU) 2017/460 <sup>(9)</sup> apply to entry points from and exit points to third countries, subject to the relevant decisions of the relevant national regulatory authority, whereas Commission Regulation (EU) No 312/2014 <sup>(10)</sup> applies exclusively to balancing zones within the borders of the Union.

<sup>(6)</sup> Commission Regulation (EU) 2015/703 of 30 April 2015 establishing a Network Code on interoperability and data exchange rules (OJ L 113, 1.5.2015, p. 13).

<sup>(7)</sup> Commission Regulation (EU) 2017/459 of 16 March 2017 establishing a network code on capacity allocation mechanisms in gas transmission systems and repealing Regulation (EU) No 984/2013 (OJ L 72, 17.3.2017, p. 1).

<sup>(8)</sup> Commission Decision 2012/490/EU of 24 August 2012 on amending Annex I to Regulation (EC) No 715/2009 of the European Parliament and of the Council on conditions for access to the natural gas transmission networks (OJ L 231, 28.8.2012, p. 16).

<sup>(9)</sup> Commission Regulation (EU) 2017/460 of 16 March 2017 establishing a network code on harmonised transmission tariff structures for gas (OJ L 72, 17.3.2017, p. 29).

<sup>(10)</sup> Commission Regulation (EU) No 312/2014 of 26 March 2014 establishing a Network Code on Gas Balancing of Transmission Networks (OJ L 91, 27.3.2014, p. 15).

- (14) In order to adopt decisions authorising or refusing to authorise a Member State to amend, extend, adapt, renew or conclude an agreement with a third country, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>(11)</sup>.
- (15) Since the objective of this Directive, namely to establish consistency of the legal framework within the Union while avoiding distortion of competition in the internal energy market in the Union, cannot be sufficiently achieved by the Member States, but can rather, by reasons of its scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.
- (16) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents <sup>(12)</sup>, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a Directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- (17) Directive 2009/73/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

#### Article 1

#### Amendments to Directive 2009/73/EC

Directive 2009/73/EC is amended as follows:

- (1) in Article 2, point (17) is replaced by the following:

‘(17) “interconnector” means a transmission line which crosses or spans a border between Member States for the purpose of connecting the national transmission system of those Member States or a transmission line between a Member State and a third country up to the territory of the Member States or the territorial sea of that Member State’;

- (2) Article 9 is amended as follows:

- (a) in paragraph 8, the first subparagraph is replaced by the following:

‘8. Where on 3 September 2009 the transmission system belonged to a vertically integrated undertaking, a Member State may decide not to apply paragraph 1. As regards the part of the transmission system connecting a Member State with a third country between the border of that Member State and the first connection point with that Member State’s network, where on 23 May 2019 the transmission system belongs to a vertically integrated undertaking, a Member State may decide not to apply paragraph 1.’;

- (b) paragraph 9 is replaced by the following:

‘9. Where on 3 September 2009 the transmission system belonged to a vertically integrated undertaking and arrangements are in place which guarantee more effective independence of the transmission system operator than the provisions of Chapter IV, a Member State may decide not to apply paragraph 1 of this Article.

As regards the part of the transmission system connecting a Member State with a third country between the border of that Member State and the first connection point with that Member State’s network, where on 23 May 2019 the transmission system belongs to a vertically integrated undertaking and arrangements are in place which guarantee more effective independence of the transmission system operator than the provisions of Chapter IV, that Member State may decide not to apply paragraph 1 of this Article.’;

- (3) in Article 14, paragraph 1 is replaced by the following:

‘1. Where on 3 September 2009 the transmission system belonged to a vertically integrated undertaking, a Member State may decide not to apply Article 9(1) and to designate an independent system operator upon a proposal from the transmission system owner.

<sup>(11)</sup> Regulation (EU) No 182/2011 of the European Parliament and the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

<sup>(12)</sup> OJ C 369, 17.12.2011, p. 14.

As regards the part of the transmission system connecting a Member State with a third country between the border of that Member State and the first connection point with that Member State's network, where on 23 May 2019 the transmission system belongs to a vertically integrated undertaking, that Member State may decide not to apply Article 9(1) and to designate an independent system operator upon a proposal from the transmission system owner.

The designation of an independent system operator shall be subject to approval by the Commission.';

(4) in Article 34, paragraph 4 is replaced by the following:

'4. In the event of cross-border disputes, the dispute-settlement arrangements for the Member State having jurisdiction over the upstream pipeline network which refuses access shall be applied. Where, in cross-border disputes, more than one Member State covers the network concerned, the Member States concerned shall consult each other with a view to ensuring that the provisions of this Directive are applied consistently. Where the upstream pipeline network originates from a third country and connects to at least one Member State, the Member States concerned shall consult each other and the Member State where the first entry point to the Member States' network is located shall consult the third country concerned where the upstream pipeline network originates, with a view to ensuring, as regards the network concerned, that this Directive is applied consistently in the territory of the Member States.';

(5) Article 36 is amended as follows:

(a) in paragraph 1, point (e) is replaced by the following:

'(e) the exemption must not be detrimental to competition in the relevant markets which are likely to be affected by the investment, to the effective functioning of the internal market in natural gas, the efficient functioning of the regulated systems concerned, or to security of supply of natural gas in the Union.';

(b) paragraph 3 is replaced by the following:

'3. The regulatory authority referred to in Chapter VIII may, on a case-by-case basis, decide on the exemption referred to in paragraphs 1 and 2.

Before the adoption of the decision on the exemption, the national regulatory authority, or where appropriate another competent authority of that Member State, shall consult:

- (a) the national regulatory authorities of the Member States the markets of which are likely to be affected by the new infrastructure; and
- (b) the relevant authorities of the third countries, where the infrastructure in question is connected with the Union network under the jurisdiction of a Member State, and originates from or ends in one or more third countries.

Where the third-country authorities consulted do not respond to the consultation within a reasonable time frame or within a set deadline not exceeding three months, the national regulatory authority concerned may adopt the necessary decision.';

(c) in paragraph 4, the second subparagraph is replaced by the following:

'Where all the regulatory authorities concerned agree on the request for exemption within six months of the date on which it was received by the last of the regulatory authorities, they shall inform the Agency of their decision. Where the infrastructure concerned is a transmission line between a Member State and a third country, before the adoption of the decision on the exemption, the national regulatory authority, or where appropriate another competent authority of the Member State where the first interconnection point with the Member States' network is located, may consult the relevant authority of that third country with a view to ensuring, as regards the infrastructure concerned, that this Directive is applied consistently in the territory and, where applicable, in the territorial sea of that Member State. Where the third country authority consulted does not respond to the consultation within a reasonable time or within a set deadline not exceeding three months, the national regulatory authority concerned may adopt the necessary decision.';

(6) in Article 41(1), point (c) is replaced by the following:

'(c) cooperating with regard to cross-border issues with the regulatory authority or authorities of the Member States concerned and with the Agency. In respect of infrastructure to and from a third country, the regulatory authority of the Member State where the first interconnection point with the Member States' network is located may cooperate with the relevant authorities of the third country, after consulting the regulatory authorities of other Member States concerned, aiming at, as regards this infrastructure, consistent application of this Directive in the territory of the Member States.';

(7) in Article 42, the following paragraph is added:

‘6. Regulatory authorities, or where appropriate other competent authorities, may consult and cooperate with the relevant authorities of third countries in relation to the operation of gas infrastructure to and from third countries with a view to ensuring, as regards the infrastructure concerned, that this Directive is applied consistently in the territory and territorial sea of a Member State.’;

(8) the following Article is inserted:

*‘Article 48a*

#### **Technical agreements regarding the operation of transmission lines**

This Directive does not affect the freedom of transmission system operators or other economic operators to maintain in force or to conclude technical agreements on issues concerning the operation of transmission lines between a Member State and a third country, insofar as those agreements are compatible with Union law and relevant decisions of the national regulatory authorities of the Member States concerned. Such agreements shall be notified to the regulatory authorities of the Member States concerned.’;

(9) the following articles are inserted:

*‘Article 49a*

#### **Derogations in relation to transmission lines to and from third countries**

1. In respect of gas transmission lines between a Member State and a third country completed before 23 May 2019, the Member State where the first connection point of such a transmission line with a Member State's network is located may decide to derogate from Articles 9, 10, 11 and 32 and Article 41(6), (8) and (10) for the sections of such gas transmission line located in its territory and territorial sea, for objective reasons such as to enable the recovery of the investment made or for reasons of security of supply, provided that the derogation would not be detrimental to competition on or the effective functioning of the internal market in natural gas, or to security of supply in the Union.

The derogation shall be limited in time up to 20 years based on objective justification, renewable if justified and may be subject to conditions which contribute to the achievement of the above conditions.

Such derogations shall not apply to transmission lines between a Member State and a third country which has the obligation to transpose this Directive and which effectively implements this Directive in its legal order under an agreement concluded with the Union.

2. Where the transmission line concerned is located in the territory of more than one Member State, the Member State in the territory of which the first connection point with the Member States' network is located shall decide whether to grant a derogation for that transmission line after consulting all the Member States concerned.

Upon request by the Member States concerned, the Commission may decide to act as an observer in the consultation between the Member State in the territory of which the first connection point is located and the third country concerning the consistent application of this Directive in the territory and territorial sea of the Member State where the first interconnection point is located, including the granting of derogations for such transmission lines.

3. Decisions pursuant to paragraphs 1 and 2 shall be adopted by 24 May 2020. Member States shall notify any such decisions to the Commission and shall publish them.

*Article 49b*

#### **Empowerment procedure**

1. Without prejudice to other obligations under Union law, and to the allocation of competence between the Union and the Member States, existing agreements between a Member State and a third country on the operation of a transmission line or an upstream pipeline network may be maintained in force until the entry into force of a subsequent agreement between the Union and the same third country or until the procedure under paragraphs 2 to 15 of this Article applies.

2. Without prejudice to the allocation of competence between the Union and the Member States, where a Member State intends to enter into negotiations with a third country in order to amend, extend, adapt, renew or conclude an agreement on the operation of a transmission line with a third country concerning matters falling, entirely or partly, within the scope of this Directive, it shall notify the Commission of its intention in writing.

Such a notification shall include the relevant documentation and an indication of the provisions to be addressed in the negotiations or to be renegotiated, the objectives of the negotiations and any other relevant information, and shall be transmitted to the Commission at least five months before the intended start of the negotiations.

3. Further to any notification pursuant to paragraph 2, the Commission shall authorise the Member State concerned to enter into formal negotiations with a third country for the part which may affect Union common rules unless it considers that the opening of such negotiations would:

- (a) be in conflict with Union law other than the incompatibilities arising from the allocation of competence between the Union and the Member States;
- (b) be detrimental to the functioning of the internal market in natural gas, competition or security of supply in a Member State or in the Union;
- (c) undermine the objectives of pending negotiations of intergovernmental agreements by the Union with a third country;
- (d) be discriminatory.

4. When carrying out the assessment under paragraph 3, the Commission shall take into account whether the intended agreement concerns a transmission line or an upstream pipeline that contributes to the diversification of natural gas supplies and suppliers by means of new natural gas sources.

5. Within 90 days of receipt of the notification referred to in paragraph 2, the Commission shall adopt a decision authorising or refusing to authorise a Member State to enter into negotiations in order to amend, extend, adapt, renew or conclude an agreement with a third country. Where additional information is needed to adopt a decision, the 90-day period shall run from the date of receipt of such additional information.

6. In the event that the Commission adopts a decision refusing to authorise a Member State to enter into negotiations in order to amend, extend, adapt, renew or conclude an agreement with a third country, it shall inform the Member State concerned accordingly and shall give the reasons therefor.

7. Decisions authorising or refusing to authorise a Member State to enter into negotiations in order to amend, extend, adapt, renew or conclude an agreement with a third country shall be adopted, by means of implementing acts, in accordance with the procedure referred to in Article 51(2).

8. The Commission may provide guidance and may request the inclusion of particular clauses in the agreement envisaged, in order to ensure compatibility with Union law in accordance with Decision (EU) 2017/684 of the European Parliament and of the Council (\*).

9. The Commission shall be kept informed of the progress and results of the negotiations to amend, extend, adapt, renew or to conclude an agreement throughout the different stages of such negotiations and may request to participate in such negotiations between the Member State and the third country in accordance with Decision (EU) 2017/684.

10. The Commission shall inform the European Parliament and the Council of the decisions adopted pursuant to paragraph 5.

11. Before signing an agreement with a third country, the Member State concerned shall notify the Commission of the outcome of negotiations and shall transmit the text of the negotiated agreement to the Commission.

12. Upon notification pursuant to paragraph 11, the Commission shall assess the negotiated agreement pursuant to paragraph 3. Where the Commission finds that the negotiations have resulted in an agreement which complies with paragraph 3, it shall authorise the Member State to sign and conclude the agreement.

13. Within 90 days of receipt of the notification referred to in paragraph 11, the Commission shall adopt a decision authorising or refusing to authorise a Member State to sign and conclude the agreement with a third country. Where additional information is needed to adopt a decision, the 90-day period shall run from the date of receipt of such additional information.

14. Where the Commission adopts a decision pursuant to paragraph 13, authorising a Member State to sign and conclude the agreement with a third country, the Member State concerned shall notify the Commission of the conclusion and entry into force of the agreement, and of any subsequent changes to the status of that agreement.



15. In the event that the Commission adopts a decision refusing to authorise a Member State to sign and conclude the agreement with a third country pursuant to paragraph 13, it shall inform the Member State concerned accordingly and shall give the reasons therefor.

(\*) Decision (EU) 2017/684 of the European Parliament and of the Council of 5 April 2017 on establishing an information exchange mechanism with regard to intergovernmental agreements and non-binding instruments between Member States and third countries in the field of energy, and repealing Decision No 994/2012/EU (OJ L 99, 12.4.2017, p. 1).’

#### Article 2

##### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 24 February 2020, without prejudice to any derogation pursuant to Article 49a of Directive 2009/73/EC. They shall communicate to the Commission the text of those provisions forthwith.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

By way of derogation from the first subparagraph, landlocked Member States which have no geographical borders with third countries and no transmission lines with third countries, shall not be obliged to bring into force measures which are necessary to comply with this Directive.

By way of derogation from the first subparagraph, Cyprus and Malta, as a result of their geographical situation, shall not be obliged to bring into force measures which are necessary to comply with this Directive for as long as they do not have any infrastructures connecting them with third countries, including upstream pipeline networks.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 3

##### Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

#### Article 4

##### Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 17 April 2019.

*For the European Parliament*

*The President*

A. TAJANI

*For the Council*

*The President*

G. CIAMBA

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**CORRIGENDA**

**Corrigendum to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006**

*(Official Journal of the European Union L 353 of 31 December 2008)*

On page 324, Annex IV, Part 2, Table 1.5 'Precautionary statements — Disposal', third column, the entry concerning LT:

*for:* 'Turinį/talpyklą išpilti (išmesti) į ...',

*read:* 'Turinį/talpyklą šalinti ...'.

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**Corrigendum to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC**

*(Official Journal of the European Union L 117 of 5 May 2017)*

1. On page 17, point 30 of Article 2:

*for:* '(30) "manufacturer" means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;'

*read:* '(30) "manufacturer" means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark;'

2. On page 22, Article 7, introductory phrase:

*for:* 'In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and ...',

*read:* 'In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and ...'.

3. On page 25, Article 10(15):

*for:* '15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1).',

*read:* '15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4).',

4. On page 66, Article 74(1):

*for:* '... of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) and the relevant provisions ...',

*read:* '... of Article 62(4), Articles 75, 76 and 77, and Article 80(5) and (6), and the relevant provisions ...'.

5. On page 69, Article 78(14):

*for:* '14. The procedure set out in this Article shall, until 27 May 2027, be applied only by those of the Member States in which the clinical investigation is to be conducted which have agreed to apply it. After 27 May 2027, all Member States shall be required to apply that procedure.',

*read:* '14. The procedure set out in this Article shall, until 25 May 2027, be applied only by those of the Member States in which the clinical investigation is to be conducted which have agreed to apply it. From 26 May 2027, all Member States shall be required to apply that procedure.'.

6. On page 89, Article 120(6), second line:

*for:* '... and notified prior 26 May 2020. Notified bodies ...',

*read:* '... and notified prior to 26 May 2020. Notified bodies ...'.

7. On page 90, Article 120(10):

*for:* 'Devices falling within the scope of this Regulation in accordance with points (f) and (g) of Article 1(6) which ...',

*read:* 'Devices falling within the scope of this Regulation in accordance with point (g) of Article 1(6) which ...'.

8. On page 132, Annex VII, Section 4.5.2, point (a), fourth indent:

*for:* '...That plan shall ensure that all devices covered by the certificate are sampled over ...',

*read:* '...That plan shall ensure that the entire range of devices covered by the certificate is sampled over ...'.

9. On page 140, Annex VIII, Section 3.2:

*for:* '... Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right ...',

*read:* '... Accessories for a medical device shall be classified in their own right ...'.

10. On page 148, Annex IX, Section 2.3, third paragraph, first sentence:

*for:* 'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with Sections 4.4 to 4.8. In choosing ...',

*read:* 'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis as specified in Section 4. In choosing ...'.

11. On page 148, Annex IX, Section 3:

*for:* '3. Surveillance assessment applicable to class IIa, class IIb and class III devices',

*read:* '3. Surveillance assessment'.

12. On page 149, Annex IX, Section 3.5, first paragraph:

*for:* 'In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the second paragraph of Section 2.3.',

*read:* 'In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3.'.

13. On page 149, Annex IX, Section 4.3:

*for:* 'The notified body shall examine the application by using staff, employed by it, with proven knowledge ...',

*read:* 'The notified body shall assess the technical documentation using staff with proven knowledge ...'.

14. On page 169, Annex XV, Chapter II, Section 2.5:

*for:* '2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contraindications and warnings.',

*read:* '2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable side-effects, contraindications and warnings.'.

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**Corrigendum to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU**

*(Official Journal of the European Union L 117 of 5 May 2017)*

1. On page 183, Recital (66)

*for:* '(66) The rules on performance studies should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of performance studies ...',

*read:* '(66) The rules on performance studies should be in line with well-established international guidance in this field, such as the international standard ISO 20916 on clinical performance studies using specimens from human subjects, currently under development, so as to make it easier for the results of performance studies ...'.

2. On page 198, Article 10(14)

*for:* '14. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 27(1).',

*read:* '14. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 26(3).',

3. On page 207, Article 28(1)

*for:* '... in Article 30 the information ...',

*read:* '... in Article 27 the information ...'.

4. On page 220, Article 48(7), first subparagraph

*for:* '... of Annex IX, including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex of at least one ...',

*read:* '... of Annex IX, and, in addition, to an assessment of the technical documentation as specified in Section 4 of that Annex for at least one ...'.

5. On page 221, Article 48(9), first subparagraph:

*for:* '... of Annex IX, and including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex for at least one representative ...',

*read:* '... of Annex IX, and, in addition, to an assessment of the technical documentation as specified in Section 4 of that Annex for at least one representative ...'.

6. On page 234, Article 70(1)

*for:* '... of Article 58(5), and Articles 71, 72 and 73 Article 76(5) and the relevant provisions ...',

*read:* '... of Article 58(5), Articles 71, 72 and 73, and Article 76(5) and (6), and the relevant provisions ...'.

7. On page 238, Article 74(14)

*for:* '14. The procedure set out in this Article shall, until 27 May 2029, be applied only by those of the Member States in which the performance studies are to be conducted which have agreed to apply it. After 27 May 2029, all Member States shall be required to apply that procedure.',

*read:* ‘14. The procedure set out in this Article shall, until 25 May 2029, be applied only by those of the Member States in which the performance studies are to be conducted which have agreed to apply it. From 26 May 2029, all Member States shall be required to apply that procedure.’.

8. On page 256, Article 110(4)

*for:* ‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market 26 May 2022 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.’.

*read:* ‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market from 26 May 2022 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.’.

9. On page 258, point (g) of Article 113(3)

*for:* ‘(g) The procedure set out in Article 74 shall, apply from 26 May 2027 without prejudice to Article 74(14).’.

*read:* ‘(g) the procedure set out in Article 74 shall apply from 26 May 2029 without prejudice to Article 74(14).’.

10. On page 296, Annex VII, Section 4.5.2, Point (a), fourth indent

*for:* ‘That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate.’.

*read:* ‘That plan shall ensure that the entire range of devices covered by the certificate is sampled over the period of validity of the certificate, and’.

11. On page 306, Annex IX, Section 2.1, sixth indent

*for:* ‘... procedures in place to fulfil the obligations arising from by the quality management system ...’.

*read:* ‘... procedures in place to fulfil the obligations arising from the quality management system ...’.

12. On page 308, Annex IX, Section 2.3, first subparagraph

*for:* ‘... unless it duly substantiate not doing so.’.

*read:* ‘... unless it duly substantiates not doing so.’.

13. On page 308, Annex IX, Section 2.3, third subparagraph

*for:* ‘Moreover, in the case of class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 4.4 to 4.8. In choosing ...’.

*read:* ‘Moreover, in the case of class B and C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis as specified in Section 4. In choosing ...’.

14. On page 308, Annex IX, Section 2.3, fourth subparagraph, second sentence

*for:* ‘The notified body shall notify the manufacturer of its decision to issue the certificate.’.

*read:* ‘The notified body shall notify the manufacturer of its decision to issue the certificate.’.

15. On page 308, Annex IX, Section 3

*for:* ‘3. Surveillance assessment applicable to class C and class D devices’.

*read:* ‘3. Surveillance assessment’.

16. On page 309, Annex IX, Section 3.5

*for:* 'In the case of class C devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 of for the device or devices concerned on the basis of further representative ...',

*read:* 'In the case of class B and C devices, the surveillance assessment shall also include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further representative ...'.

17. On page 310, Annex IX, Section 4.3

*for:* 'The notified body shall examine the application by using staff, employed by it, with proven knowledge ...',

*read:* 'The notified body shall assess the technical documentation using staff with proven knowledge ...'.

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**Corrigendum to Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011**

*(Official Journal of the European Union L 327 of 9 December 2017)*

On page 70, Article 61, point (6), new Article 18(4) of Regulation (EC) No 767/2008, first subparagraph, point (a):

*for:* ‘... referred to in Article 9(2) and (4);’,

*read:* ‘... referred to in points (2) and (4) of Article 9;’.

On page 70, Article 61, point (6), new Article 18(5) of Regulation (EC) No 767/2008, point (a):

*for:* ‘... referred to in Article 9(2) and (4);’,

*read:* ‘... referred to in points (2) and (4) of Article 9;’.

On page 71, Article 61, point (8), new Article 19a(5) of Regulation (EC) No 767/2008, point (a):

*for:* ‘... referred to in Article 9(2) and (4);’,

*read:* ‘... referred to in points (2) and (4) of Article 9;’.

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