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I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2022/641 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 April 2022

amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta

(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 114 and Article 168(4), point (c), 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 ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) The Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community ⁽³⁾ (the ‘Withdrawal Agreement’) was concluded on behalf of the Union by Council Decision (EU) 2020/135 ⁽⁴⁾ and entered into force on 1 February 2020. The transition period referred to in Article 126 of the Withdrawal Agreement, during which Union law continued to apply to and in the United Kingdom in accordance with Article 127 of the Withdrawal Agreement, ended on 31 December 2020. On 25 January 2021, the Commission issued a Notice ⁽⁵⁾ on the application of the Union’s pharmaceutical *acquis* in markets historically dependent on medicinal products supply from or through Great Britain, namely Cyprus, Ireland, Malta and Northern Ireland, after the end of that transition period. That Notice includes explanations of how the Commission was to apply the Union’s pharmaceutical *acquis* in those markets with regard to investigational medicinal products. That Notice ceased to apply on 31 December 2021.

⁽¹⁾ Opinion of 24 February 2022 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 7 April 2022 (not yet published in the Official Journal) and decision of the Council of 12 April 2022.

⁽³⁾ OJ L 29, 31.1.2020, p. 7.

⁽⁴⁾ Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 1).

⁽⁵⁾ Commission Notice – Application of the Union’s pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period (2021/C 27/08) (OJ C 27, 25.1.2021, p. 11).

- (2) In accordance with the Protocol on Ireland/Northern Ireland (the 'Protocol'), which forms an integral part of the Withdrawal Agreement, the provisions of Union law listed in Annex 2 to the Protocol apply, under the conditions set out in that Annex, to and in the United Kingdom in respect of Northern Ireland. That list includes Chapter IX of Regulation (EU) No 536/2014 of the European Parliament and of the Council ⁽⁶⁾ regarding the manufacturing and import of investigational medicinal products and auxiliary medicinal products. Therefore, investigational medicinal products used in clinical trials in Northern Ireland are to comply with those provisions of Union law.
- (3) Regulation (EU) No 536/2014 lays down the rules for investigational medicinal products intended to be used in clinical trials in the Union. That Regulation applies from 31 January 2022.
- (4) In accordance with Article 61(1) of Regulation (EU) No 536/2014, read in conjunction with the Protocol, the import of investigational medicinal products from third countries into the Union or Northern Ireland is subject to the holding of a manufacturing and import authorisation. Cyprus, Ireland, Malta and Northern Ireland have historically relied on the supply of medicinal products, including investigational medicinal products, from or through parts of the United Kingdom other than Northern Ireland, and the supply chains for those markets have not yet been fully adapted to comply with Union law. To ensure that clinical trial participants in Northern Ireland, as well as in Cyprus, Ireland and Malta continue to have access to new, innovative or improved treatments, it is necessary to amend Regulation (EU) No 536/2014 to provide for a derogation from the requirement of the holding of a manufacturing and import authorisation for investigational medicinal products imported into those markets from parts of the United Kingdom other than Northern Ireland. To ensure the quality of those investigational medicinal products and to avoid compromising the integrity of the internal market, certain conditions should be laid down.
- (5) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, 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 Regulation does not go beyond what is necessary in order to achieve those objectives.
- (6) Regulation (EU) No 536/2014 should therefore be amended accordingly.
- (7) To ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.
- (8) To ensure legal continuity for operators active in the pharmaceutical sector and to guarantee the continuous access of participants in clinical trials in Cyprus, Ireland, Malta and Northern Ireland to investigational medicinal products from the date of application of Regulation (EU) No 536/2014, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union* and should apply retroactively from 31 January 2022,

HAVE ADOPTED THIS REGULATION:

Article 1

In Article 61(1) of Regulation (EU) No 536/2014, the following subparagraph is added:

'However, the import of investigational medicinal products from other parts of the United Kingdom into Northern Ireland and, until 31 December 2024, into Cyprus, Ireland and Malta shall not be subject to the holding of such an authorisation provided that all of the following conditions are fulfilled:

- (a) the investigational medicinal products have undergone certification of batch release either in the Union or in parts of the United Kingdom other than Northern Ireland to verify compliance with the requirements set out in Article 63(1);

⁽⁶⁾ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

- (b) the investigational medicinal products are only made available to subjects in the Member State into which those investigational medicinal products are imported or, if imported into Northern Ireland, are only made available to subjects in Northern Ireland.'

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 31 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 April 2022.

For the European Parliament

The President

R. METSOLA

For the Council

The President

C. BEAUNE

DIRECTIVES

DIRECTIVE (EU) 2022/642 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 April 2022

amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta

(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 114 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 ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) The Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community ⁽³⁾ (the 'Withdrawal Agreement') was concluded on behalf of the Union by Council Decision (EU) 2020/135 ⁽⁴⁾ and entered into force on 1 February 2020. The transition period referred to in Article 126 of the Withdrawal Agreement, during which Union law continued to apply to and in the United Kingdom in accordance with Article 127 of the Withdrawal Agreement, ended on 31 December 2020. On 25 January 2021, the Commission issued a Notice ⁽⁵⁾ on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicinal products supply from or through Great Britain, namely Cyprus, Ireland, Malta and Northern Ireland, from the end of that transition period until 31 December 2021.
- (2) In accordance with the Protocol on Ireland/Northern Ireland (the 'Protocol'), which forms an integral part of the Withdrawal Agreement, the provisions of Union law listed in Annex 2 to the Protocol apply, under the conditions set out in that Annex, to and in the United Kingdom in respect of Northern Ireland. That list includes Article 13 of Directive 2001/20/EC of the European Parliament and of the Council ⁽⁶⁾ regarding the manufacture and import of investigational medicinal products, Directive 2001/83/EC of the European Parliament and of the Council ⁽⁷⁾ and Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽⁸⁾. Therefore, medicinal products placed on the market in Northern Ireland are to comply with those provisions of Union law.

⁽¹⁾ Opinion of 24 February 2022 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 7 April 2022 (not yet published in the Official Journal) and decision of the Council of 12 April 2022.

⁽³⁾ OJ L 29, 31.1.2020, p. 7.

⁽⁴⁾ Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 1).

⁽⁵⁾ Commission Notice – Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period (2021/C 27/08) (OJ C 27, 25.1.2021, p. 11).

⁽⁶⁾ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

⁽⁷⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁽⁸⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

- (3) Directives 2001/20/EC and 2001/83/EC lay down the rules for medicinal products for human use and investigational medicinal products intended to be placed on the market in the Member States.
- (4) Cyprus, Ireland, Malta and Northern Ireland have historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland, and the supply chains for those markets have not yet been fully adapted to comply with Union law. To prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, Directives 2001/20/EC and 2001/83/EC need to be amended to provide for derogations for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland. In order to ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.
- (5) In accordance with Article 13(1) of Directive 2001/20/EC, read in conjunction with the Protocol, the import of investigational medicinal products from third countries into the Union or Northern Ireland is subject to the holding of a manufacturing and import authorisation. To ensure continued access to new, innovative or improved treatments for clinical trial participants in Northern Ireland, as well as in Cyprus, Ireland and Malta after 31 December 2021, such a manufacturing and import authorisation should not be required for investigational medicinal products imported into those markets from parts of the United Kingdom other than Northern Ireland provided that certain conditions are fulfilled. To ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.
- (6) Regulation (EC) No 726/2004 lays down Union procedures for the authorisation of medicinal products. Upon authorisation in the Union, medicinal products are available to patients in Northern Ireland. It is possible, however, that the competent authorities of the United Kingdom in respect of parts of the United Kingdom other than Northern Ireland issue a marketing authorisation for a medicinal product before a marketing authorisation has been granted for the same medicinal product in the Union. In such exceptional cases, and in order to ensure that patients in Northern Ireland have access to those medicinal products at the same time as patients in other parts of the United Kingdom, the competent authorities of the United Kingdom in respect of Northern Ireland should be able to supply those medicinal products to patients in Northern Ireland temporarily and until a marketing authorisation is granted or refused in the Union. In order to ensure the full effectiveness of the centralised procedure for granting marketing authorisations set out in Regulation (EC) No 726/2004, those temporary authorisations should be limited in time and should cease to be valid when the Commission takes a decision to grant or refuse the authorisation to market that medicinal product.
- (7) In accordance with Article 8(2) of Directive 2001/83/EC, read in conjunction with the Protocol, a marketing authorisation is only able to be granted to an applicant established in the Union or in Northern Ireland. A number of operators were not able to comply with that requirement by 31 December 2021. To ensure access to certain medicinal products in Northern Ireland, it is crucial that the holders of marketing authorisations granted by the competent authorities of the United Kingdom in respect of Northern Ireland are allowed to be established in parts of the United Kingdom other than Northern Ireland. Similarly, to ensure access to certain medicinal products in Cyprus, Ireland, Malta and Northern Ireland, it is necessary to allow the competent authorities of Cyprus, Ireland, Malta and Northern Ireland to grant marketing authorisations in the context of the mutual recognition or the decentralised procedure to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.
- (8) It follows from Articles 17 and 18 of Directive 2001/83/EC, read in conjunction with the Protocol, that applicants for a marketing authorisation wishing to obtain both a marketing authorisation for the United Kingdom in respect of Northern Ireland as well as a marketing authorisation for one or more Member States need to include the United Kingdom in respect of Northern Ireland in the scope of their marketing authorisation application in accordance with the mutual recognition or the decentralised procedure. Where medicinal products are also authorised in parts of the United Kingdom other than Northern Ireland, the requirement to comply with that obligation could hamper the continuous access to medicinal products for patients in Northern Ireland. To avoid that issue, it is necessary to allow applicants in such situations the possibility to apply for a marketing authorisation for the United Kingdom in respect of Northern Ireland either in accordance with the mutual recognition or the decentralised procedure, or in accordance with the national marketing authorisation procedure applicable in relation to the United Kingdom in respect of Northern Ireland. In the case of such a national marketing authorisation procedure, the marketing authorisation should be granted in compliance with Union law, including the requirements on quality, safety and efficacy of medicinal products.

- (9) In accordance with Article 51(1), point (b), of Directive 2001/83/EC, medicinal products imported into the Union are to undergo quality control testing in the Union. Article 20, point (b), of that Directive allows the importers which place medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland on the market in Cyprus, Ireland, Malta or Northern Ireland, or wholesale distributors placing such medicinal products on those markets, to have, in justifiable cases, certain controls carried out in parts of the United Kingdom other than Northern Ireland. Taking into account the historical dependence of Cyprus, Ireland, Malta and Northern Ireland on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland and the related risks of shortages of medicinal products in those jurisdictions, a justifiable case within the meaning of Article 20, point (b), of Directive 2001/83/EC should be considered to occur when each batch of the medicinal product concerned is released by a qualified person on a site in the Union or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards equivalent to those laid down in Union law, thereby ensuring an equivalent level of protection of human health. Since Article 20, point (b), of Directive 2001/83/EC only provides for batch testing to be carried out in a third country on a case-by-case basis, it is necessary to lay down conditions harmonising the implementation of that provision with regard to medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland.
- (10) It follows from Article 40(3) of Directive 2001/83/EC, read in conjunction with the Protocol, that importers of medicinal products from third countries into a Member State are to hold a manufacturing authorisation granted by the Member State where the importer is established or, in the case of importers established in Northern Ireland, by the United Kingdom in respect of Northern Ireland. To avoid a situation in which operators withdraw from or significantly reduce medicinal products supply to Cyprus, Ireland, Malta and Northern Ireland, it is necessary to derogate exceptionally from that requirement under certain conditions and to allow imports of medicinal products from or through parts of the United Kingdom other than Northern Ireland into Cyprus, Ireland, Malta and Northern Ireland by wholesale distributors that do not hold the relevant manufacturing authorisation, while ensuring an equivalent level of protection of human health.
- (11) In a situation where medicinal products are exported from a Member State to parts of the United Kingdom other than Northern Ireland, and subsequently imported into Cyprus, Ireland, Malta or Northern Ireland, it should be possible to waive specific controls, namely quality control testing, intended to guarantee the quality of those medicinal products imported from third countries, provided that appropriate arrangements have been made by the Union to ensure that the necessary controls are carried out in the exporting country.
- (12) It follows from Article 48 of Directive 2001/83/EC, read in conjunction with Article 49 of that Directive and with the Protocol, that the manufacturing authorisation holder is to have at its disposal a qualified person who resides and operates in the Union or Northern Ireland. To ensure a continuous access to certain medicinal products to patients in Northern Ireland, it is appropriate to allow the qualified person to reside and operate in parts of the United Kingdom other than Northern Ireland.
- (13) It follows from Article 104(3) of Directive 2001/83/EC, read in conjunction with the Protocol, that the qualified person responsible for pharmacovigilance is to reside and operate in the Union or Northern Ireland. A number of operators were not able to comply with that requirement by 31 December 2021. To ensure that access to certain medicinal products for patients in Northern Ireland is not hampered, it is appropriate to allow the qualified person responsible for pharmacovigilance to reside and operate in parts of the United Kingdom other than Northern Ireland.
- (14) To avoid shortages of medicinal products in Cyprus and Malta, the competent authorities of Cyprus and Malta should be allowed, for public health reasons and for a certain period, to grant, maintain in force and extend marketing authorisations on the basis of Article 126a of Directive 2001/83/EC which rely on marketing authorisations granted by the competent authorities of parts of the United Kingdom other than Northern Ireland, even if the marketing authorisation holder is no longer established in the Union, provided that certain conditions are fulfilled. Since Union law no longer applies in parts of the United Kingdom other than Northern Ireland, it is necessary to provide that the competent authorities of Cyprus and Malta ensure that such authorisations comply with Union law. In order to ensure that the functioning of the Union market is not undermined, it is necessary to establish the conditions for enhanced supervision and enforcement of the rules relevant for the application of the derogations introduced by this Directive. The Commission should monitor developments in parts of the United

Kingdom other than Northern Ireland that could affect the level of protection regarding the regulatory functions covered by this Directive. If the Commission finds that the level of protection of public health ensured by the United Kingdom by means of rules governing the production, distribution and use of medicinal products, as well as by means of the effective enforcement of those rules, is no longer essentially equivalent to that guaranteed within the Union, or if the Commission lacks information to assess whether an essentially equivalent level of protection is guaranteed, the Commission should enter into consultation with the United Kingdom to find a mutually agreed remedy to that situation. If no such remedy is found within the prescribed period, the Commission should, as a last resort, be empowered to adopt delegated acts suspending the application of one or more provisions introduced by this Directive.

- (15) In order to ensure transparency, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland should publish a list of medicinal products to which they intend to apply or have applied the derogations set out in this Directive. In order to make that list easily searchable, it should contain the same information as that included in the package leaflet or summary of product characteristics of the medicinal products concerned.
- (16) Since the objectives of this Directive cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, 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 in order to achieve those objectives.
- (17) Directives 2001/20/EC and 2001/83/EC should therefore be amended accordingly.
- (18) In order to ensure legal continuity for operators active in the pharmaceutical sector and to guarantee the continuous access of patients in Cyprus, Ireland, Malta and Northern Ireland to medicinal products, this Directive should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union* and the measures adopted by the Member States to comply with it should apply retroactively from 1 January 2022,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Article 13(1) of Directive 2001/20/EC, the following subparagraph is added:

'By way of derogation from the first subparagraph, the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta shall allow investigational medicinal products to be imported from parts of the United Kingdom other than Northern Ireland without such an authorisation provided that all of the following conditions are fulfilled:

- (a) the investigational medicinal products imported into Cyprus, Ireland, Malta or Northern Ireland have undergone certification of batch release either in the Union, as provided for in paragraph 3, point (a), or in parts of the United Kingdom other than Northern Ireland in compliance with the requirements set out in paragraph 3, point (b);
- (b) the investigational medicinal products are only made available to subjects in the Member State into which those investigational medicinal products are imported, or, if imported into Northern Ireland, are only made available to subjects in Northern Ireland.'

Article 2

Directive 2001/83/EC is amended as follows:

- (1) the following Article is inserted:

'Article 5a

By way of derogation from Article 6, the competent authorities of the United Kingdom in respect of Northern Ireland may temporarily authorise the supply to patients in Northern Ireland of a medicinal product belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004 provided that all of the following conditions are fulfilled:

- (a) the medicinal product concerned has been granted a marketing authorisation by the competent authority of the United Kingdom for parts of the United Kingdom other than Northern Ireland;
- (b) the medicinal product concerned is only made available to patients or end-consumers in the territory of Northern Ireland and is not made available in any Member State.

The maximum validity of the temporary authorisation shall be six months. Notwithstanding the specified validity, the temporary authorisation shall cease to be valid if the medicinal product concerned has been granted a marketing authorisation in accordance with Article 10 of Regulation (EC) No 726/2004, or if such marketing authorisation has been refused in accordance with that Article.;

- (2) in Article 8, the following paragraphs are inserted:

'2a. By way of derogation from paragraph 2, marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland to applicants established in parts of the United Kingdom other than Northern Ireland.

2b. By way of derogation from paragraph 2, marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, by the competent authorities of Cyprus, Ireland and Malta, in accordance with the mutual recognition or the decentralised procedure laid down in Chapter 4 of this Title, to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

The competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

The marketing authorisations granted or extended by the competent authorities of Cyprus, Ireland or Malta in accordance with the first and second subparagraph shall cease to be valid at the latest on 31 December 2026.;

- (3) the following Article is inserted:

'Article 18a

1. By way of derogation from Article 17(1), second subparagraph, Article 17(2) and Article 18, if an application for marketing authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an application for marketing authorisation is submitted in the United Kingdom in respect of Northern Ireland for a medicinal product which is already being examined or has already been authorised in a Member State, the application regarding the United Kingdom in respect of Northern Ireland shall not have to be submitted in accordance with Articles 28 to 39 provided that all of the following conditions are fulfilled:

- (a) the marketing authorisation for the United Kingdom in respect of Northern Ireland is granted by the competent authority for the United Kingdom in respect of Northern Ireland in compliance with Union law, and such compliance with Union law is ensured during the period of validity of that marketing authorisation;

- (b) the medicinal products authorised by the competent authority for the United Kingdom in respect of Northern Ireland are made available to patients or end-consumers only in the territory of Northern Ireland, and they are not made available in any Member State.

2. The marketing authorisation holder of a medicinal product for which a marketing authorisation has already been granted for the United Kingdom in respect of Northern Ireland in accordance with Articles 28 to 39 before 20 April 2022 shall be allowed to withdraw the marketing authorisation for the United Kingdom in respect of Northern Ireland from the mutual recognition or the decentralised procedure and to submit an application for a marketing authorisation for that medicinal product to the competent authorities of the United Kingdom with respect to Northern Ireland in accordance with paragraph 1.;

- (4) in Article 20, the following paragraph is added:

‘With regard to quality control testing carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in Article 127d other than those authorised by the Commission, the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta may consider that there is a justifiable case within the meaning of point (b) of the first paragraph, without carrying out a case-by-case assessment provided that:

- (a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51;
- (b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;
- (c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.;

- (5) Article 40 is amended as follows:

- (a) the following paragraph is inserted:

‘1a. By way of derogation from paragraph 1 of this Article, the competent authorities of the United Kingdom in respect of Northern Ireland and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta shall allow medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by holders of a wholesale distribution authorisation as referred to in Article 77(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:

- (a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 51(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20, first paragraph, point (b);
- (b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 51(1) or, for medicinal products authorised by the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland, in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51(1);
- (c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;
- (d) medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients or end-consumers in Northern Ireland;

(e) the medicinal products bear the safety features referred to in Article 54, point (o).

Article 80, first subparagraph, point (b), shall not apply to imports that fulfil the conditions laid down in the first subparagraph of this paragraph.;

(b) the following paragraph is inserted:

‘3a. For batches of medicinal products which are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Northern Ireland or, until 31 December 2024, into Cyprus, Ireland or Malta, the controls upon importation referred to Article 51(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 51(1), third subparagraph.;

(6) in Article 48, the following paragraph is added:

‘3. Where the manufacturing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to in paragraph 1 may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the manufacturing authorisation holder already has at its disposal a qualified person who resides and operates in the Union on 20 April 2022.;

(7) in Article 104(3), the following subparagraph is added:

‘By way of derogation from the second subparagraph, where the marketing authorisation is granted by the competent authority of United Kingdom in respect of Northern Ireland, the qualified person referred to in point (a) of the first subparagraph may reside and operate in parts of the United Kingdom other than Northern Ireland. This subparagraph shall not apply where the marketing authorisation holder already has at its disposal a qualified person who resides and operates in the Union on 20 April 2022.;

(8) the following Article is inserted:

‘Article 111c

1. The Commission shall continuously monitor developments in the United Kingdom that could affect the level of protection regarding the regulatory functions referred to in Article 8(2a) and (2b), Article 20, second paragraph, Article 40(1a) and (3a), Article 48(3), Article 104(3) and Article 126c that are carried out in parts of the United Kingdom other than Northern Ireland taking into account, in particular, the following elements:

- (a) the rules governing the granting of marketing authorisations, the obligations of the marketing authorisation holder, the granting of manufacturing authorisations, the obligations of the manufacturing authorisation holder, the qualified persons and their obligations, quality control testing, batch release and pharmacovigilance as laid down in United Kingdom law;
- (b) whether the competent authorities of the United Kingdom ensure the effective enforcement within their territory of the rules referred to in point (a), by means of, inter alia, inspections and audits of marketing authorisation holders, manufacturing authorisation holders and wholesale distributors located in their territories, and on-the-spot checks at their premises regarding the exercise of the regulatory functions referred to in point (a).

2. Where the Commission finds that the level of protection of public health ensured by the United Kingdom through rules governing the production, distribution and use of medicinal products as well as the effective enforcement of those rules is no longer essentially equivalent to that guaranteed within the Union, or where sufficient information is not available to the Commission to enable it to establish whether an essentially equivalent level of protection of public health is ensured by the United Kingdom, the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.

For a period of six months following the written notification made pursuant to the first subparagraph, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.

3. If the situation giving rise to the written notification made pursuant to paragraph 2, first subparagraph, is not remedied within the time-limit referred to in paragraph 2, second subparagraph, the Commission shall be empowered to adopt a delegated act specifying the provisions among those referred to in paragraph 1 whose application shall be suspended.

4. Where a delegated act pursuant to paragraph 3 has been adopted, the provisions referred to in the introductory sentence of paragraph 1 as specified in the delegated act shall cease to apply on the first day of the month following the entry into force of the delegated act.

5. Where the situation giving rise to the adoption of the delegated act pursuant to paragraph 3 has been remedied, the Commission shall adopt a delegated act specifying those suspended provisions that shall apply again. In that case, the provisions specified in the delegated act adopted pursuant to this paragraph shall apply again on the first day of the month following the entry into force of the delegated act referred to in this paragraph.;

(9) Article 121a is amended as follows:

(a) in paragraph 2, the following subparagraph is added:

‘The power to adopt delegated acts referred to in Article 111c(3) and (5) shall be conferred on the Commission for an indeterminate period of time from 20 April 2022.’;

(b) paragraph 3 is replaced by the following:

‘3. The delegation of power referred to in Article 14(1), Articles 22b, 23b, 46a, 47, 52b, 54a, Article 111c(3) and (5), and Article 120 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.’;

(c) paragraph 6 is replaced by the following:

‘6. A delegated act adopted pursuant to Article 14(1), Articles 22b, 23b, 46a, 47, 52b, 54a, Article 111c(3) or (5), or Article 120 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.’;

(10) the following Article is inserted:

‘Article 126c

1. By way of derogation from Article 126a, until 31 December 2024, in the absence of a marketing authorisation or of a pending application for a marketing authorisation the competent authorities of Cyprus and Malta may authorise for justified public health reasons the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.

The competent authorities of Cyprus and Malta may also maintain in force or, until 31 December 2024, extend marketing authorisations that were granted pursuant to Article 126a before 20 April 2022 which authorise the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.

Authorisations that are granted, extended or maintained in force pursuant to the first or second subparagraph shall not be valid after 31 December 2026.

2. By way of derogation from Article 8(2), the competent authorities of Malta and Cyprus may grant marketing authorisations as referred to in paragraph 1 of this Article to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

3. Where the competent authorities of Cyprus or Malta grant or extend a marketing authorisation as referred to in paragraph 1, they shall ensure compliance with the requirements of this Directive.

4. Before granting a marketing authorisation pursuant to paragraph 1, the competent authorities of Cyprus or Malta:

- (a) shall notify the marketing authorisation holder in parts of the United Kingdom other than Northern Ireland of the proposal to grant a marketing authorisation or to extend a marketing authorisation under this Article in respect of the medicinal product concerned;
- (b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.;

(11) the following Articles are inserted:

'Article 127c

The derogations set out in Article 8(2a) and(2b), Article 18a, Article 20, second paragraph, Article 40(1a) and (3a), Article 48(3), Article 104(3a) and Article 126c shall not affect the obligations of the marketing authorisation holder to ensure the quality, safety and efficacy of the medicinal product placed on the markets of Cyprus, Ireland, Malta or Northern Ireland laid down in this Directive.

Article 127d

1. By 20 May 2022, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland shall establish, notify to the Commission and publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Directive.

2. The competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland shall ensure that the list referred to in paragraph 1 is updated and managed in an independent manner, at least on a six-monthly basis.‘.

Article 3

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive within a period of four months as from the date of its entry into force. They shall immediately inform the Commission thereof.

They shall apply those measures from 1 January 2022.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 12 April 2022.

For the European Parliament
The President
R. METSOLA

For the Council
The President
C. BEAUNE

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/643**of 10 February 2022****amending Regulation (EU) No 649/2012 of the European Parliament and of the Council as regards the listing of pesticides, industrial chemicals, persistent organic pollutants and mercury and an update of customs codes****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals ⁽¹⁾, and in particular Article 23(4), points (a), (b), (c) and (d) thereof,

Whereas:

- (1) Regulation (EU) No 649/2012 implements the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade ⁽²⁾ ('the Rotterdam Convention').

⁽¹⁾ OJ L 201, 27.7.2012, p. 60.

⁽²⁾ OJ L 63, 6.3.2003, p. 29.

- (2) By Implementing Regulations (EU) 2020/1280 ⁽³⁾, (EU) 2020/892 ⁽⁴⁾, (EU) 2020/1276 ⁽⁵⁾, (EU) 2020/18 ⁽⁶⁾, (EU) 2020/17 ⁽⁷⁾, (EU) 2020/1246 ⁽⁸⁾, (EU) 2020/2087 ⁽⁹⁾, (EU) 2019/1606 ⁽¹⁰⁾, (EU) 2020/23 ⁽¹¹⁾, and (EU) 2020/1498 ⁽¹²⁾, the Commission decided not to renew the approval of the substances benalaxyl, beta-cyfluthrin, bromoxynil, chlorpyrifos, chlorpyrifos-methyl, fenamiphos, mancozeb, methiocarb, thiacloprid and thiophanate-methyl, respectively, as active substances under Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽¹³⁾. The effect of those final regulatory actions is that those substances are banned from all use in the category 'pesticides', due to the fact that they have not been approved for any other use in that category. Therefore, those substances should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

⁽³⁾ Commission Implementing Regulation (EU) 2020/1280 of 14 September 2020 concerning the non-renewal of the approval of the active substance benalaxyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 301, 15.9.2020, p. 4).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/892 of 29 June 2020 concerning the non-renewal of the approval of the active substance beta-cyfluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 206, 30.6.2020, p. 5).

⁽⁵⁾ Commission Implementing Regulation (EU) 2020/1276 of 11 September 2020 concerning the non-renewal of the approval of the active substance bromoxynil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 300, 14.9.2020, p. 32).

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 7, 13.1.2020, p. 14).

⁽⁷⁾ Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 7, 13.1.2020, p. 11).

⁽⁸⁾ Commission Implementing Regulation (EU) 2020/1246 of 2 September 2020 concerning the non-renewal of the approval of the active substance fenamiphos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 288, 3.9.2020, p. 18).

⁽⁹⁾ Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 423, 15.12.2020, p. 50).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2019/1606 of 27 September 2019 concerning the non-renewal of the approval of the active substance methiocarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 250, 30.9.2019, p. 53).

⁽¹¹⁾ Commission Implementing Regulation (EU) 2020/23 of 13 January 2020 concerning the non-renewal of the approval of the active substance thiacloprid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 8, 14.1.2020, p. 8).

⁽¹²⁾ Commission Implementing Regulation (EU) 2020/1498 of 15 October 2020 concerning the non-renewal of approval of the active substance thiophanate-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 342, 16.10.2020, p. 5).

⁽¹³⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

- (3) The active substances epoxiconazole and mecoprop have been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that those substances are banned from all use in the category 'pesticides', due to the fact that they have not been approved for any other use in that category. In addition, the harmonised classification of epoxiconazole and mecoprop under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁴⁾ is sufficient evidence that the substances raise concerns for human health and the environment. Therefore, epoxiconazole and mecoprop should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (4) The active substance bifenthrin has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that bifenthrin is banned from use in the subcategory 'pesticide in the group of plant protection products'. That ban amounts to a severe restriction of the use of that substance at the level of the category 'pesticides', considering that bifenthrin is only approved for use in biocidal products under Regulation (EU) No 528/2012 of the European Parliament and of the Council ⁽¹⁵⁾ for product-type 8 in the subcategory 'other pesticide including biocides', and that there are no national authorisations for use of biocidal products containing bifenthrin under that Regulation. In addition, the harmonised classification of bifenthrin under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health and the environment. Therefore, bifenthrin should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (5) By Implementing Decision (EU) 2018/1251 ⁽¹⁶⁾, the Commission decided not to approve empenithrin as an active substance under Regulation (EU) No 528/2012. The effect of that final regulatory action was that empenithrin is banned from all use in the category 'pesticides', due to the fact that it has not been approved for any other use in that category. Therefore, empenithrin should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (6) The active substances azinphos-ethyl, ferbam and hexazinone have been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that those substances are banned from all use in the category 'pesticides', due to the fact that they have not been approved for any other use in that category. Therefore, azinphos-ethyl, ferbam and hexazinone should be added to the list of chemicals in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (7) The active substance methomyl has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that methomyl is banned from use in the subcategory 'pesticide in the group of plant protection products'. That ban amounts to a ban of the use of the substance at the level of the category 'pesticides', considering that methomyl has not been approved for any other use in that category. Therefore, methomyl should be added to the list of chemicals in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (8) The substances 2,4-dinitrotoluene (2,4-DNT) and 4,4'-diaminodiphenylmethane (MDA) are listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽¹⁷⁾ since they have been previously identified as substances of very high concern. Consequently, those substances are subject to authorisation in accordance with Title VII of Regulation (EC) No 1907/2006. Since no authorisations have been granted, 2,4-dinitrotoluene (2,4-DNT) and 4,4'-diaminodiphenylmethane (MDA) are severely restricted for industrial use. Therefore, those substances should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

⁽¹⁴⁾ 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 (OJ L 353, 31.12.2008, p. 1).

⁽¹⁵⁾ Regulation (EC) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

⁽¹⁶⁾ Commission Implementing Decision (EU) 2018/1251 of 18 September 2018 not approving empenithrin as an existing active substance for use in biocidal products of product-type 18 (OJ L 235, 19.9.2018, p. 24).

⁽¹⁷⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (9) The use of the substance mercury is restricted by Regulation (EU) 2017/852 of the European Parliament and of the Council ⁽¹⁸⁾, Regulation (EC) No 1907/2006, Directive 2011/65/EU of the European Parliament and of the Council ⁽¹⁹⁾ and Directive 2006/66/EC of the European Parliament and of the Council ⁽²⁰⁾, with the effect that the use of mercury is severely restricted for all industrial use. Therefore, mercury should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (10) The use of the substance cadmium and of its compounds is severely restricted by Regulation (EC) No 1907/2006 in the subcategory 'industrial chemical for public use'. That restriction amounts to a severe restriction of the use of the substance at the level of the category 'industrial chemicals', considering that cadmium and its compounds are also severely restricted in the subcategory 'industrial chemical for professional use'. Therefore, cadmium and its compounds should be added to the list of chemicals in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (11) The use of the substance lead is severely restricted by Regulation (EC) No 1907/2006 in the subcategory 'industrial chemical for public use'. Therefore, lead should be added to the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012 for that subcategory.
- (12) The use of benzene as a constituent of other substances is severely restricted by Regulation (EC) No 1907/2006 in the subcategory 'industrial chemical for public use'. Therefore, benzene as a constituent of other substances should be added to the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012 for that subcategory.
- (13) The use of the substances bis(pentabromophenyl) ether (decaBDE) and perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds is severely restricted by Regulation (EU) 2019/1021 of the European Parliament and of the Council ⁽²¹⁾ for all industrial use. Therefore, those substances should be added to the list of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (14) By Implementing Regulation (EU) 2017/1506 ⁽²²⁾, the Commission decided to renew the approval of the active substance maleic hydrazide under Regulation (EC) No 1107/2009, with the effect that maleic hydrazide and its choline, potassium and sodium salts are no longer banned for use in the subcategory 'pesticide in the group of plant protection products'. Therefore, those substances should be removed from the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012.
- (15) At its sixth meeting held from 28 April to 10 May 2013, the Conference of the Parties to the Rotterdam Convention decided to include commercial pentabromodiphenyl ether, including tetra- and pentabromodiphenyl ether, as well as commercial octabromodiphenyl ether, including hexa- and heptabromodiphenyl ether, in Annex III to that Convention, with the effect that those chemicals became subject to the prior informed consent procedure under that Convention. Consequently, those chemicals were added to the list of chemicals in Part 3 of Annex I to Regulation (EU) No 649/2012 by Commission Delegated Regulation (EU) 2015/2229 ⁽²³⁾. In order to facilitate the implementation of that listing and in particular the submission of export notifications for certain articles, those chemicals should also be listed in Part 1 of Annex I to Regulation (EU) No 649/2012.

⁽¹⁸⁾ Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1).

⁽¹⁹⁾ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

⁽²⁰⁾ Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266, 26.9.2006, p. 1).

⁽²¹⁾ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

⁽²²⁾ Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017 renewing the approval of the active substance maleic hydrazide in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 222, 29.8.2017, p. 21).

⁽²³⁾ Commission Delegated Regulation (EU) 2015/2229 of 29 September 2015 amending Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (OJ L 317, 3.12.2015, p. 13).

- (16) The entry on commercial octabromodiphenyl ether in Part 3 of Annex I to Regulation (EU) No 649/2012 also covers the substance octabromodiphenyl ether listed in Parts 1 and 2 of Annex I to that Regulation. Therefore, octabromodiphenyl ether should be removed from the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (17) At its ninth meeting held from 29 April to 10 May 2019, the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants ('the Stockholm Convention') decided to include the substance dicofol in Annex A to that Convention. Consequently, that substance was listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012. Since a listing in Part 1 of Annex V to Regulation (EU) No 649/2012 prohibits the export of a substance without any exemption, the listing of dicofol in Parts 1 and 2 of Annex I to that Regulation is no longer required and should be removed.
- (18) At its ninth meeting held from 29 April to 10 May 2019, the Conference of the Parties to the Stockholm Convention decided to include the substance perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex A to that Convention with a number of exemptions and with an obligation for parties to prohibit the export of fire-fighting foams that contain those chemicals. Consequently, perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds were listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012 as regards its presence in fire-fighting foams.
- (19) At its seventh meeting held from 4 to 15 May 2015, the Conference of the Parties to the Stockholm Convention decided to include the substances pentachlorophenol and its salts and esters in Annex A to that Convention. Consequently, those substances were listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012.
- (20) At its fourth meeting held from 4 to 8 May 2009, the Conference of the Parties to the Stockholm Convention decided to include the substances perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride in Annex B to that Convention. That entry was subsequently amended by Decision SC-9/4 in 2019. Those substances are listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012.
- (21) Part 1 of Annex V to Regulation (EU) No 649/2012 contains an entry on articles containing concentrations of tetra-, penta-, hexa- and heptabromodiphenyl ether at or above 0,1 % by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use. That entry is based on a restriction set out in Regulation (EC) No 850/2004 of the European Parliament and of the Council ⁽²⁴⁾. The provisions concerning those substances have been amended by Regulation (EU) 2019/1021, which reduces the allowed concentrations in articles and adds decabromodiphenyl ether to the list of polybrominated diphenyl ethers. Those changes should be reflected in Part 1 of Annex V to Regulation (EU) No 649/2012.
- (22) Regulation (EU) 2017/852 prohibits the export of mercury, certain mixtures of metallic mercury with other substances, certain mercury compounds and certain mercury-added products. Those export bans should be reflected in Part 2 of Annex V to Regulation (EU) No 649/2012.
- (23) Pursuant to Article 14(2) of Regulation (EU) No 649/2012, the Commission is required to revise the classification of each chemical listed in Annex I to that Regulation in the light of any changes made in the World Customs Organisation's Harmonised System Nomenclature or in the European Union's Combined Nomenclature. A number of classifications of chemicals in the European Union's Combined Nomenclature have been changed since those chemicals were added to Annex I to Regulation (EU) No 649/2012. Those changes should be reflected in that Annex.

⁽²⁴⁾ Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).

- (24) Regulation (EU) No 649/2012 should therefore be amended accordingly.
- (25) It is appropriate to provide for a reasonable period of time for interested parties to take the measures necessary to comply with this Regulation and for Member States to take the measures necessary for its implementation,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 649/2012 is amended as follows:

- (a) Annex I is replaced by the text in Annex I to this Regulation;
- (b) Annex V is replaced by the text in Annex II to this Regulation.

Article 2

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

It shall apply from 1 July 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

‘ANNEX I

LIST OF CHEMICALS

(referred to in Article 7)

PART 1

List of chemicals subject to export notification procedure

(referred to in Article 8)

It should be noted that where chemicals listed in this part of the Annex are subject to the PIC procedure, the export notification obligations set out in Article 8(2), (3) and (4) shall not apply provided that the conditions laid down in Article 8(6), first subparagraph, points (b) and (c), have been fulfilled. Such chemicals, which are identified by the symbol ‘#’ in the list below, are listed again in Part 3 of this Annex for ease of reference.

It should also be noted that where the chemicals listed in this part of the Annex qualify for PIC notification because of the nature of the Union's final regulatory action, those chemicals are also listed in Part 2 of this Annex. Such chemicals are identified by the symbol ‘+’ in the list below.

Chemical	CAS No	EC No	CN code (***)	Subcategory (*)	Use limitation (**)	Countries for which no notification is required
1,1-Dichloroethene	75-35-4	200-864-0	ex 2903 29 00	i(2)	sr	
1,1,1-Trichloroethane	71-55-6	200-756-3	ex 2903 19 00	i(2)	b	
1,1,2-Trichloroethane	79-00-5	201-166-9	ex 2903 19 00	i(2)	sr	
1,1,1,2-Tetrachloroethane	630-20-6	211-135-1	ex 2903 19 00	i(2)	sr	
1,1,2,2-Tetrachloroethane	79-34-5	201-197-8	ex 2903 19 00	i(2)	sr	
1,2-Dibromoethane (Ethylene dibromide) (#)	106-93-4	203-444-5	ex 2903 62 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
1,2-Dichloroethane (ethylene dichloride) (#)	107-06-2	203-458-1	ex 2903 15 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
				i(2)	b	
1,3-Dichloropropene (l) (‘)	542-75-6	208-826-5	ex 2903 29 00	p(1)	b	
1,3-Dichloropropene (cis) ((Z)-1,3-dichloropropene)	10061-01-5	233-195-8	ex 2903 29 00	p(1)-p(2)	b-b	

2-Aminobutane	13952-84-6	237-732-7	ex 2921 19 99	p(1)-p(2)	b-b	
2-Naphthylamine and its salts (*)	91-59-8 553-00-4 612-52-2 and others	202-080-4 209-030-0 210-313-6 and others	ex 2921 45 00	i(1)-i(2)	b-b	
2-Naphthyloxyacetic acid (*)	120-23-0	204-380-0	ex 2918 99 90	p(1)	b	
2,4-Dinitrotoluene (2,4-DNT) (*)	121-14-2	204-450-0	ex 2904 20 00	i(1)-i(2)	sr-b	
2,4,5-T and its salts and esters (#)	93-76-5 and others	202-273-3 and others	ex 2918 91 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
3-Decen-2-one (*)	10519-33-2	234-059-0	ex 2914 19 90	p(1)	b	
4-Aminobiphenyl (biphenyl-4-amine) and its salts (*)	92-67-1 2113-61-3 and others	202-177-1 and others	ex 2921 49 00	i(1)-i(2)	b-b	
4-Nitrobiphenyl (*)	92-93-3	202-204-7	ex 2904 20 00	i(1)-i(2)	b-b	
4,4'-Diaminodiphenylmethane (MDA) (*)	101-77-9	202-974-4	ex 2921 59 90	i(1)-i(2)	sr-b	
5-Tert-butyl-2,4,6-trinitro-m-xylene (*)	81-15-2	201-329-4	ex 2904 20 00	i(1)-i(2)	sr-b	
Acephate (*)	30560-19-1	250-241-2	ex 2930 90 98	p(1)-p(2)	b-b	
Acetochlor (*)	34256-82-1	251-899-3	ex 2924 29 70	p(1)	b	
Acifluorfen	50594-66-6	256-634-5	ex 2918 99 90	p(1)-p(2)	b-b	
Alachlor (#)	15972-60-8	240-110-8	ex 2924 25 00	p(1)	b	
Aldicarb (#)	116-06-3	204-123-2	ex 2930 80 00	p(1)-p(2)	b-b	
Ametryn	834-12-8	212-634-7	ex 2933 69 80	p(1)-p(2)	b-b	
Amitraz (*)	33089-61-1	251-375-4	ex 2925 29 00	p(1)-p(2)	b-b	
Amitrole (*)	61-82-5	200-521-5	ex 2933 99 80	p(1)	b	
Anthraquinone (*)	84-65-1	201-549-0	ex 2914 61 00	p(1)-p(2)	b-b	
Arsenic compounds				p(2)	sr	

Asbestos Fibres (*):	1332-21-4 and others		ex 2524 90 00			Please refer to PIC circular at www.pic.int/
Actinolite (#)	77536-66-4		ex 2524 90 00	i	b	
Antophyllite (#)	77536-67-5		ex 2524 90 00	i	b	
Amosite (#)	12172-73-5		ex 2524 90 00	i	b	
Crocidolite (#)	12001-28-4		ex 2524 10 00	i	b	
Tremolite (#)	77536-68-6		ex 2524 90 00	i	b	
Chrysotile (*)	12001-29-5, 132207-32-0		ex 2524 90 00	i	b	
Asulam (*)	3337-71-1 2302-17-2	222-077-1 218-953-8	ex 2935 90 90	p(1)	b	
Atrazine (*)	1912-24-9	217-617-8	ex 2933 69 10	p(1)	b	
Azinphos-ethyl (*)	2642-71-9	220-147-6	ex 2933 99 80	p(1)-p(2)	b-b	
Azinphos-methyl (#)	86-50-0	201-676-1	ex 2933 92 00	p(1)	b	
Azocyclotin (*)	41083-11-8	255-209-1	ex 2933 99 80	p(1)	b	
Benalaxyl (*)	71626-11-4	275-728-7	ex 2924 29 70	p(1)	b	
Benfuracarb (*)	82560-54-1		ex 2932 99 00	p(1)	b	
Bensultap	17606-31-4		ex 2930 90 98	p(1)-p(2)	b-b	
Benzene ⁽²⁾	71-43-2	200-753-7	ex 2902 20 00 ex 2707 10 00	i(2)	sr	
Benzene as a constituent of other substances in concentrations equal to, or greater than 0,1 % by weight ⁽²⁾			ex 2707 10 00	i(2)	sr	
Benzidine and its salts (*)	92-87-5	202-199-1	ex 2921 59 90	i(1)-i(2)	sr-b	
Benzidine derivatives (*)	36341-27-2 and others	252-984-8 and others		i(2)	b	
Benzyl butyl phthalate (*)	85-68-7	201-622-7	ex 2917 34 00	i(1)-i(2)	sr-b	
Beta-cyfluthrin (*)	1820573-27-0		ex 2926 90 70	p(1)	b	

Beta-cypermethrin (*)	65731-84-2	265-898-0	ex 2926 90 70	p(1)	b	
Bifenthrin (*)	82657-04-3		ex 2916 20 00	p(1)-p(2)	b-sr	
Binapacryl (#)	485-31-4	207-612-9	ex 2916 16 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
				i(2)	b	
Bis(pentabromophenyl) ether (*)	1163-19-5	214-604-9	ex 2909 30 38	i(1)-i(2)	sr-b	
Bitertanol (*)	55179-31-2	259-513-5	ex 2933 99 80	p(1)	b	
Bromoxynil (*)	1689-84-5	216-882-7	ex 2926 90 70	p(1)	b	
	3861-41-4	223-374-9				
	56634-95-8	260-300-4				
	1689-99-2	216-885-3				
Butralin (*)	33629-47-9	251-607-4	ex 2921 49 00	p(1)	b	
Cadmium and its compounds (*)	7440-43-9	231-152-8	ex 8112	i(1)-i(2)	sr-sr	
	and others	and others	and others			
Cadusafos (*)	95465-99-9		ex 2930 90 98	p(1)	b	
Calciferol	50-14-6	200-014-9	ex 2936 29 00	p(1)	b	
Captafol (#)	2425-06-1	219-363-3	ex 2930 80 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Carbaryl (*)	63-25-2	200-555-0	ex 2924 29 70	p(1)-p(2)	b-b	
Carbendazim	10605-21-7	234-232-0	ex 2933 99 80	p(1)	b	
Carbofuran (#)	1563-66-2	216-353-0	ex 2932 99 00	p(1)	b	
Carbon tetrachloride	56-23-5	200-262-8	ex 2903 14 00	i(2)	b	
Carbosulfan (*)	55285-14-8	259-565-9	ex 2932 99 00	p(1)	b	
Cartap	15263-53-3		ex 2930 20 00	p(1)-p(2)	b-b	
Chinomethionat	2439-01-2	219-455-3	ex 2934 99 90	p(1)-p(2)	b-b	
Chlorate (*)	7775-09-9	231-887-4	ex 2829 11 00	p(1)	b	
	10137-74-3	233-378-2	ex 2829 19 00			
	7783-92-8	232-034-9	ex 2843 29 00			
	and others	and others				

Chlordimeform (#)	6164-98-3	228-200-5	ex 2925 21 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Chlorfenapyr (*)	122453-73-0		ex 2933 99 80	p(1)	b	
Chlorfenvinphos	470-90-6	207-432-0	ex 2919 90 00	p(1)-p(2)	b-b	
Chlormephos	24934-91-6	246-538-1	ex 2930 90 98	p(1)-p(2)	b-b	
Chlorobenzilate (#)	510-15-6	208-110-2	ex 2918 18 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Chloroform	67-66-3	200-663-8	ex 2903 13 00	i(2)	b	
Chloropicrin (*)	76-06-2	200-930-9	ex 2904 91 00	p(1)	b	
Chlorothalonil (*)	1897-45-6	217-588-1	ex 2926 90 70	p(1)	b	
Chlorpropham (*)	101-21-3	202-925-7	ex 2924 29 70	p(1)	b	
Chlorpyrifos (*)	2921-88-2	220-864-4	ex 2933 39 99	p(1)	b	
Chlorpyrifos-methyl (*)	5598-13-0	227-011-5	ex 2933 39 99	p(1)	b	
Chlorthal-dimethyl (*)	1861-32-1	217-464-7	ex 2917 39 95	p(1)	b	
Chlozolate (*)	84332-86-5	282-714-4	ex 2934 99 90	p(1)-p(2)	b-b	
Cholecalciferol	67-97-0	200-673-2	ex 2936 29 00	p(1)	b	
Cinidon-ethyl (*)	142891-20-1		ex 2925 19 95	p(1)	b	
Clothianidin (*)	210880-92-5	433-460-1	ex 2934 10 00	p(1)	b	
Coumafuryl	117-52-2	204-195-5	ex 2932 20 90	p(1)-p(2)	b-b	
Creosote and creosote related substances	8001-58-9 61789-28-4 84650-04-4 90640-84-9 65996-91-0	232-287-5 263-047-8 283-484-8 292-605-3 266-026-1	ex 2707 91 00 ex 3807 00 90 ex 2707 91 00 ex 2707 40 00 ex 2707 50 00 ex 2707 91 00 ex 3807 00 90 ex 2707 99 19	 i(2)	 b	

	90640-80-5	292-602-7	ex 2707 99 20			
	65996-85-2	266-019-3	ex 2707 99 80			
	8021-39-4	232-419-1	ex 3807 00 90			
	122384-78-5	310-191-5	ex 3807 00 90			
Crimidine	535-89-7	208-622-6	ex 2933 59 95	p(1)	b	
Cyanamide	420-04-2	206-992-3	ex 2853 90 90	p(1)	b	
Cyanazine	21725-46-2	244-544-9	ex 2933 69 80	p(1)-p(2)	b-b	
Cybutryne (*)	28159-98-0	248-872-3	ex 2933 69 80	p(2)	b	
Cyclanilide (*)	113136-77-9	419-150-7	ex 2924 29 70	p(1)	b	
Cyfluthrin	68359-37-5	269-855-7	ex 2926 90 70	p(1)	b	
Cyhalothrine	68085-85-8	268-450-2	ex 2926 90 70	p(1)	b	
Cyhexatin (*)	13121-70-5	236-049-1	ex 2931 90 00	p(1)	b	
DBB (Di-μ-oxo-di-n-butylstannio-hydroxyborane/ dioxastannaboretan-4-ol)	75113-37-0	401-040-5	ex 2931 90 00	i(1)	b	
Desmedipham (*)	13684-56-5	237-198-5	ex 2924 29 70	p(1)	b	
Diarsenic pentaoxide (*)	1303-28-2	215-116-9	ex 2811 29 90	i(1)-i(2)	sr-b	
Diazinon (*)	333-41-5	206-373-8	ex 2933 59 10	p(1)	b	
Dibutyltin compounds	683-18-1 77-58-7 1067-33-0 and others	211-670-0 201-039-8 213-928-8 and others	ex 2931 90 00	i(2)	sr	
Dichlobenil (*)	1194-65-6	214-787-5	ex 2926 90 70	p(1)	b	
Dicloran (*)	99-30-9	202-746-4	ex 2921 42 00	p(1)	b	
Dichlorvos (*)	62-73-7	200-547-7	ex 2919 90 00	p(1)-p(2)	b-b	
Didecyldimethylammonium chloride	7173-51-5	230-525-2	ex 2923 90 00	p(1)	b	
Diisobutyl phthalate (*)	84-69-5	201-553-2	ex 2917 34 00	i(1)-i(2)	sr-b	
Dimethenamid (*)	87674-68-8		ex 2934 99 90	p(1)	b	

Dimethoate (*)	60-51-5	200-480-3	ex 2930 90 98	p(1)	b	
Diniconazole-M (*)	83657-18-5		ex 2933 99 80	p(1)	b	
Dinitro-ortho-cresol (DNOC) and its salts (such as ammonium salt, potassium salt and sodium salt) (#)	534-52-1	208-601-1	ex 2908 92 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
	2980-64-5	221-037-0				
	5787-96-2					
	2312-76-7	219-007-7				
Dinobuton	973-21-7	213-546-1	ex 2920 90 10	p(1)-p(2)	b-b	
Dinoseb and its salts and esters (#)	88-85-7	201-861-7	ex 2908 91 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
	and others	and others	ex 2915 36 00	i(2)	b	
Dinoterb (*)	1420-07-1	215-813-8	ex 2908 99 00	p(1)-p(2)	b-b	
Diocetyl tin compounds	3542-36-7	222-583-2	ex 2931 90 00	i(2)	sr	
	870-08-6	212-791-1				
	16091-18-2	240-253-6				
	and others	and others				
Diphenylamine (*)	122-39-4	204-539-4	ex 2921 44 00	p(1)	b	
Diquat, including diquat dibromide (*)	2764-72-9	220-433-0	ex 2933 99 80	p(1)	b	
	85-00-7	201-579-4				
DPX KE 459 (flupyr-sulfuron-methyl) (*)	150315-10-9 144740-54-5		ex 2935 90 90	p(1)	b	
Dustable powder formulations containing a combination of:			ex 3808 99 90	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Benomyl at or above 7 %	17804-35-2	241-775-7	ex 2933 99 80			
Carbofuran at or above 10 %	1563-66-2	216-353-0	ex 2932 99 00			
and Thiram at or above 15 % (#)	137-26-8	205-286-2	ex 2930 30 00			
Empenthrin (*)	54406-48-3	259-154-4	ex 2916 20 00	p(2)	b	
Epoxiconazole (*)	135319-73-2	406-850-2	ex 2934 99 90	p(1)	b	

Ethalfuralin (*)	55283-68-6	259-564-3	ex 2921 43 00	p(1)	b	
Ethion	563-12-2	209-242-3	ex 2930 90 98	p(1)-p(2)	b-b	
Ethoprophos (*)	13194-48-4	236-152-1	ex 2930 90 98	p(1)	b	
Ethoxysulfuron (*)	126801-58-9		ex 2933 59 95	p(1)	b	
Ethoxyquin (*)	91-53-2	202-075-7	ex 2933 49 90	p(1)	b	
Ethylene oxide (Oxirane) (#)	75-21-8	200-849-9	ex 2910 10 00	p(1)	b	Please refer to PIC circular at www.pic.int/
Fenamidone (*)	161326-34-7		ex 2933 29 90	p(1)	b	
Fenarimol (*)	60168-88-9	262-095-7	ex 2933 59 95	p(1)	b	
Fenamiphos (*)	22224-92-6	244-848-1	ex 2930 90 98	p(1)	b	
Fenbutatin oxide (*)	13356-08-6	236-407-7	ex 2931 90 00	p(1)	b	
Fenitrothion (*)	122-14-5	204-524-2	ex 2920 19 00	p(1)	b	
Fenpropathrin	39515-41-8	254-485-0	ex 2926 90 70	p(1)-p(2)	b-b	
Fenthion (*)	55-38-9	200-231-9	ex 2930 90 98	p(1)	sr	
Fentin acetate (*)	900-95-8	212-984-0	ex 2931 90 00	p(1)-p(2)	b-b	
Fentin hydroxide (*)	76-87-9	200-990-6	ex 2931 90 00	p(1)-p(2)	b-b	
Fenvalerate	51630-58-1	257-326-3	ex 2926 90 70	p(1)	b	
Ferbam (*)	14484-64-1	238-484-2	ex 2930 20 00	p(1)-p(2)	b-b	
Fipronil (*)	120068-37-3	424-610-5	ex 2933 19 90	p(1)	b	
Flufenoxuron (*)	101463-69-8	417-680-3	ex 2924 21 00	p(1)-p(2)	b-sr	
Fluoroacetamide (#)	640-19-7	211-363-1	ex 2924 12 00	p(1)	b	Please refer to PIC circular at www.pic.int/
Flurenol	467-69-6	207-397-1	ex 2918 19 98	p(1)-p(2)	b-b	
Flurprimidol (*)	56425-91-3		ex 2933 59 95	p(1)	b	
Flurtamone (*)	96525-23-4		ex 2932 19 00	p(1)	b	
Furathiocarb	65907-30-4	265-974-3	ex 2932 99 00	p(1)-p(2)	b-b	

Glufosinate, including glufosinate ammonium (*)	51276-47-2 77182-82-2	257-102-5 278-636-5	ex 2931 49 90	p(1)	b	
Guazatine (*)	108173-90-6 115044-19-4	236-855-3	ex 3808 99 90	p(1)-p(2)	b-b	
Hexachloroethane	67-72-1	200-666-4	ex 2903 19 00	i(1)	sr	
Hexazinone (*)	51235-04-2	257-074-4	ex 2933 69 80	p(1)-p(2)	b-b	
Imidacloprid	138261-41-3	428-040-8	ex 2933 39 99	p(1)	sr	
Iminoctadine	13516-27-3	236-855-3	ex 2925 29 00	p(1)-p(2)	b-b	
Indolylacetic acid (*)	87-51-4	201-748-2	ex 2933 99 80	p(1)	b	
Iprodione (*)	36734-19-7	253-178-9	ex 2933 21 00	p(1)	b	
Isoproturon (*)	34123-59-6	251-835-4	ex 2924 21 00	p(1)	b	
Isoxathion	18854-01-8	242-624-8	ex 2934 99 90	p(1)	b	
Lead and its compounds	7439-92-1 598-63-0 1319-46-6 7446-14-2 7784-40-9 7758-97-6 1344-37-2 25808-74-6 13424-46-9 301-04-2 7446-27-7 15245-44-0 and others	231-100-4 209-943-4 215-290-6 231-198-9 232-064-2 231-846-0 215-693-7 247-278-1 236-542-1 206-104-4 231-205-5 239-290-0 and others	ex 7801 10 00, ex 7804 20 00 ex 2836 99 17 ex 3206 49 70 ex 2833 29 60 ex 2842 90 80 ex 2841 50 00 ex 3206 20 00 ex 2826 90 80 ex 2850 00 60 ex 2915 29 00 ex 2835 29 90, ex 3206 49 70 ex 2908 99 00	i(2)	sr	
Linuron (*)	330-55-2	206-356-5	ex 2928 00 90	p(1)	b	
Malathion	121-75-5	204-497-7	ex 2930 90 98	p(2)	b	

Maleic hydrazide salts other than choline, potassium and sodium salts	5716-15-4 42489-17-8 36518-59-9 65445-74-1 51137-11-2 and others	227-213-3 255-849-1 253-082-7 265-780-9 and others	ex 2933 99 80	p(1)	b	
Mancozeb (*)	8018-01-7		ex 3808 92 30	p(1)	b	
Maneb (*)	12427-38-2	235-654-8	ex 3824 99 93	p(1)-p(2)	b-b	
Mecoprop (*)	7085-19-0 93-65-2	230-386-8 202-264-4	ex 2918 99 90	p(1)	b	
Mercury (*)	7439-97-6	231-106-7	ex 2805 40	i(1)-i(2)	sr-b	
Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds except mercury compounds listed in Annex V (#)	62-38-4, 26545-49-3 and others	200-532-5, 247-783-7 and others	ex 2852 10 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Methamidophos (#)	10265-92-6	233-606-0	ex 2930 80 00	p(1)	b	
Methidathion	950-37-8	213-449-4	ex 2934 99 90	p(1)-p(2)	b-b	
Methiocarb (*)	2032-65-7	217-991-2	ex 2930 90 98	p(1)	b	
Methomyl (*)	16752-77-5	240-815-0	ex 2930 90 98	p(1)-p(2)	b-b	
Methyl bromide (*)	74-83-9	200-813-2	ex 2903 61 00	p(1)-p(2)	b-b	
Methyl-parathion (*) (#)	298-00-0	206-050-1	ex 2920 11 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Metoxuron	19937-59-8	243-433-2	ex 2924 21 00	p(1)-p(2)	b-b	

Monocrotophos (#)	6923-22-4	230-042-7	ex 2924 12 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Monolinuron	1746-81-2	217-129-5	ex 2928 00 90	p(1)	b	
Monomethyl-dibromo-diphenyl methane Tradename: DBBT (*)	99688-47-8	402-210-1	ex 2903 99 80	i(1)	b	
Monomethyl-dichloro-diphenyl methane; Tradename: Ugilec 121 or Ugilec 21 (*)		400-140-6	ex 2903 99 80	i(1)-i(2)	b-b	
Monomethyl-tetrachlorodiphenyl methane; Tradename: Ugilec 141 (*)	76253-60-6	278-404-3	ex 2903 99 80	i(1)-i(2)	b-b	
Monuron	150-68-5	205-766-1	ex 2924 21 00	p(1)	b	
Naled (*)	300-76-5	206-098-3	ex 2919 90 00	p(1)-p(2)	b-b	
Nicotine (*)	54-11-5	200-193-3	ex 2939 79 10	p(1)	b	
Nitrofen (*)	1836-75-5	217-406-0	ex 2909 30 90	p(1)-p(2)	b-b	
Nonylphenols C ₆ H ₄ (OH)C ₉ H ₁₉ (*)	25154-52-3 (phenol, nonyl-)	246-672-0	ex 2907 13 00	i(1)-i(2)	sr-sr	
	84852-15-3 (phenol, 4-nonyl-, branched)	284-325-5	ex 2907 13 00			
	11066-49-2 (isononylphe- nol)	234-284-4	ex 2907 13 00			
	90481-04-2, (phenol, nonyl-, branched)	291-844-0	ex 2907 13 00			
	104-40-5 (p-nonylphenol) and others	203-199-4 and others	ex 2907 13 00			

Nonylphenol ethoxylates (C ₂ H ₄ O) _n C ₁₅ H ₂₄ O (*)	9016-45-9 26027-38-3 68412-54-4 37205-87-1 127087-87-0 and others		ex 3402 42 00 ex 3907 29 11 ex 3824 99 92	i(1)-i(2) p(1)-p(2)	sr-sr b-b	
Commercial octabromodiphenyl ether, including — hexabromo diphenyl ether — heptabromo diphenyl ether (#)	36483-60-0 68928-80-3	253-058-6 273-031-2	ex 3824 88 00 ex 2909 30 38	i(1)-i(2)	b-b	
Omethoate	1113-02-6	214-197-8	ex 2930 90 98	p(1)-p(2)	b-b	
Orthosulfamuron (*)	213464-77-8		ex 2933 59 95	p(1)	b	
Oxadiargyl (*)	39807-15-3	254-637-6	ex 2934 99 90	p(1)	b	
Oxasulfuron (*)	144651-06-9		ex 2935 90 90	p(1)	b	
Oxydemeton-methyl (*)	301-12-2	206-110-7	ex 2930 90 98	p(1)	b	
Paraquat (*)	4685-14-7 1910-42-5 2074-50-2	225-141-7 217-615-7 218-196-3	ex 2933 39 99	p(1)	b	
Parathion (#)	56-38-2	200-271-7	ex 2920 11 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Pebulate	1114-71-2	214-215-4	ex 2930 20 00	p(1)-p(2)	b-b	
Commercial pentabromodiphenyl ether, including — tetrabromo diphenyl ether — pentabromo diphenyl ether (#)	40088-47-9 32534-81-9	254-787-2 251-084-2	ex 2909 30 31 ex 2909 30 38 ex 3824 88 00	i(1)-i(2)	b-b	
Pentachloroethane	76-01-7	200-925-1	ex 2903 19 00	i(2)	sr	
Pentachlorophenol and its salts and esters (#)	87-86-5 and others	201-778-6 and others	ex 2908 11 00 and others	p(1)-p(2)	b-sr	Please refer to PIC circular at www.pic.int/

Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds (*)	335-67-1 and others	206-397-9 and others	ex 2915 90 70 and others	i(1)-i(2)	sr-b	
Perfluorooctane sulfonates (PFOS) C8F17SO2X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers) (*)/ (#)	1763-23-1 2795-39-3 70225-14-8 56773-42-3 4151-50-2 57589-85-2 68081-83-4 and others	217-179-8 220-527-1 274-460-8 260-375-3 223-980-3 260-837-4 268-357-7 and others	ex 2904 31 00 ex 2904 34 00 ex 2922 16 00 ex 2923 30 00 ex 2935 20 00 ex 2924 29 70 ex 3824 99 92	i(1)	sr	
Permethrin	52645-53-1	258-067-9	ex 2916 20 00	p(1)	b	
Phorate (#)	298-02-2	206-052-2	ex 2930 90 98	p(1)	b	
Phosalone (*)	2310-17-0	218-996-2	ex 2934 99 90	p(1)	b	
Phosphamidon (soluble liquid formulations of the substance that exceed 1 000 g active ingredient/l) (#)	13171-21-6 (mixture, (E) & (Z) isomers) 23783-98-4 ((Z)-isomer) 297-99-4 ((E)- isomer)	236-116-5	ex 2924 12 00 ex 3808 59 00	p(1)-p(2)	b-b	Please refer to PIC circular at www.pic.int/
Picoxystrobin (*)	117428-22-5		ex 2933 39 99	p(1)	b	
Polybrominated biphenyls (PBB) except hexabromo-biphenyl (#)	13654-09-6, 27858-07-7 and others	237-137-2, 248-696-7 and others	ex 2903 99 80	i(1)	sr	Please refer to PIC circular at www.pic.int/
Polychlorinated terphenyls (PCT) (#)	61788-33-8	262-968-2	ex 2903 99 80	i(1)	b	Please refer to PIC circular at www.pic.int/

Procymidone (*)	32809-16-8	251-233-1	ex 2925 19 95	p(1)	b	
Propachlor (*)	1918-16-7	217-638-2	ex 2924 29 70	p(1)	b	
Propanil (*)	709-98-8	211-914-6	ex 2924 29 70	p(1)	b	
Propham	122-42-9	204-542-0	ex 2924 29 70	p(1)	b	
Propargite (*)	2312-35-8	219-006-1	ex 2920 90 70	p(1)	b	
Propiconazole	60207-90-1	262-104-4	ex 2934 99 90	p(1)	b	
Propineb (*)	12071-83-9 9016-72-2	235-134-0	ex 2930 20 00	p(1)	b	
Propisochlor (*)	86763-47-5		ex 2924 29 70	p(1)	b	
Pymetrozine (*)	123312-89-0		ex 2933 69 80	p(1)	b	
Pyrazophos (*)	13457-18-6	236-656-1	ex 2933 59 95	p(1)-p(2)	b-b	
Quinoxifen (*)	124495-18-7		ex 2933 49 90	p(1)	b	
Quintozene (*)	82-68-8	201-435-0	ex 2904 99 00	p(1)-p(2)	b-b	
Rotenone (*)	83-79-4	201-501-9	ex 2932 99 00	p(1)	b	
Scilliroside	507-60-8	208-077-4	ex 2938 90 90	p(1)	b	
Simazine (*)	122-34-9	204-535-2	ex 2933 69 10	p(1)-p(2)	b-b	
Strychnine	57-24-9	200-319-7	ex 2939 79 90	p(1)	b	
Tecnazene (*)	117-18-0	204-178-2	ex 2904 99 00	p(1)-p(2)	b-b	
Tepraloxydim (*)	149979-41-9		ex 2932 99 00 ex 3808 93 27	p(1)	b	
Terbufos	13071-79-9	235-963-8	ex 2930 90 98	p(1)-p(2)	b-b	
Tetraethyl lead (#)	78-00-2	201-075-4	ex 2931 10 00	i(1)	sr	Please refer to PIC circular at www.pic.int/
Tetramethyl lead (#)	75-74-1	200-897-0	ex 2931 10 00	i(1)	sr	Please refer to PIC circular at www.pic.int/
Thallium sulphate	7446-18-6	231-201-3	ex 2833 29 80	p(1)	b	

Thiacloprid (*)	111988-49-9		ex 2934 10 00	p(1)-p(2)	b-b	
Thiamethoxam (*)	153719-23-4	428-650-4	ex 2934 10 00	p(1)	b	
Thiobencarb (*)	28249-77-6	248-924-5	ex 2930 20 00	p(1)	b	
Thiocyclam	31895-22-4	250-859-2	ex 2934 99 90	p(1)-p(2)	b-b	
Thiodicarb (*)	59669-26-0	261-848-7	ex 2930 90 98	p(1)	b	
Thiophanate-methyl (*)	23564-05-8	245-740-7	ex 2930 90 98	p(1)	b	
Thiram (*)	137-26-8	205-286-2	ex 2930 30 00	p(1)-p(2)	b-sr	
Tolylfluanid (*)	731-27-1	211-986-9	ex 2930 90 98	p(1)	b	
Triasulfuron (*)	82097-50-5		ex 2935 90 90	p(1)	b	
Triazophos	24017-47-8	245-986-5	ex 2933 99 80	p(1)-p(2)	b-b	
All tributyltin compounds, including: (#)			ex 2931 20 00	p(2)	b	
Tributyltin oxide	56-35-9	200-268-0		i(1)-i(2)	sr-sr	
Tributyltin fluoride	1983-10-4	217-847-9				
Tributyltin methacrylate	2155-70-6	218-452-4				
Tributyltin benzoate	4342-36-3	224-399-8				
Tributyltin chloride	1461-22-9	215-958-7				
Tributyltin linoleate	24124-25-2	246-024-7				
Tributyltin naphthenate	85409-17-2	287-083-9				
	and others	and others				
Trichlorfon (#)	52-68-6	200-149-3	ex 2931 54 00	p(1)-p(2)	b-b	
Trichlorobenzene	120-82-1	204-428-0	ex 2903 99 80	i(2)	sr	
Triclosan (*)	3380-34-5	222-182-2	ex 2909 50 00	p(2)	b	
Tricyclazole (*)	41814-78-2	255-559-5	ex 2934 99 90	p(1)	b	
Tridemorph	24602-86-6	246-347-3	ex 2934 99 90	p(1)-p(2)	b-b	
Triflumuron	64628-44-0	264-980-3	ex 2924 21 00	p(2)	b	
Trifluralin (*)	1582-09-8	216-428-8	ex 2921 43 00	p(1)	b	

Triorganostannic compounds other than tributyltin compounds (*)			ex 2931 90 00 and others	p(2) i(2)	sr sr	
Tris (2-chloroethyl) phosphate (*)	115-96-8	204-118-5	ex 2919 90 00	i(1)-i(2)	sr-b	
Tris (2,3-dibromopropyl) phosphate (#)	126-72-7	204-799-9	ex 2919 10 00	i(1)	sr	Please refer to PIC circular at www.pic.int/
Tris(aziridinyl)phosphin oxide (1,1',1'-phosphoryl triaziridine)	545-55-1	208-892-5	ex 2933 99 80	i(1)	sr	
Vamidothion	2275-23-2	218-894-8	ex 2930 90 98	p(1)-p(2)	b-b	
Vinclozolin (*)	50471-44-8	256-599-6	ex 2934 99 90	p(1)	b	
Warfarin	81-81-2	201-377-6	ex 2932 20 90	p(1)	b	
Zineb	12122-67-7	235-180-1	ex 3824 99 93 ex 3808 92 30	p(1)	b	

(*) Subcategory: p(1) — pesticide in the group of plant protection products, p(2) — other pesticide including biocides. i(1) — industrial chemical for professional use and i(2) — industrial chemical for public use.

(**) Use limitation: sr — severe restriction, b — ban (for the subcategory or subcategories concerned) according to Union legislation.

(***) An 'ex' before a code implies that chemicals other than those referred to in the column 'Chemical' may also fall under that subheading.

(¹) This entry does not affect the existing entry for 1,3-Dichloropropene (cis) (CAS No 10061-01-5).

(²) Except motor fuels subject to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (OJ L 350, 28.12.1998, p. 58).

CAS No = Chemical Abstracts Service Registry Number.

(#) Chemical subject or partially subject to the PIC procedure.

(*) Chemical qualifying for PIC notification.

List of chemicals qualifying for PIC notification*(referred to in Article 11)*

This list comprises chemicals qualifying for PIC notification. It does not include chemicals that are already subject to the PIC procedure, which are listed in Part 3 of this Annex.

Chemical	CAS No	EC No	CN code (***)	Category (*)	Use limitation (**)
1,3-Dichloropropene	542-75-6	208-826-5	ex 2903 29 00	p	b
2-Naphthylamine (naphthalen-2-amine) and its salts	91-59-8, 553-00-4, 612-52-2 and others	202-080-4, 209-030-0, 210-313-6 and others	ex 2921 45 00	i	b
2-Naphthoxyacetic acid	120-23-0	204-380-0	ex 2918 99 90	p	b
2,4-Dinitrotoluene (2,4-DNT)	121-14-2	204-450-0	ex 2904 20 00	i	sr
3-Decen-2-one	10519-33-2	234-059-0	ex 2914 19 90	p	b
4-Aminobiphenyl (biphenyl-4-amine) and its salts	92-67-1 2113-61-3 and others	202-177-1 and others	ex 2921 49 00	i	b
4-Nitrobiphenyl	92-92-3	202-204-7	ex 2904 20 00	i	b
4,4'- Diaminodiphenylmethane (MDA)	101-77-9	202-974-4	ex 2921 59 90	i	sr
5-Tert-butyl-2,4,6-trinitro-m-xylene	81-15-2	201-329-4	ex 2904 20 00	i	sr
Acephate	30560-19-1	250-241-2	ex 2930 90 98	p	b
Acetochlor	34256-82-1	251-899-3	ex 2924 29 70	p	b
Amitraz	33089-61-1	251-375-4	ex 2925 29 00	p	b
Amitrole	61-82-5	200-521-5	ex 2933 99 80	p	b
Anthraquinone	84-65-1	201-549-0	ex 2914 61 00	p	b

Asbestos fibres: Chrysotile	12001-29-5 132207-32-0		ex 2524 90 00	i	b
Asulam	3337-71-1 2302-17-2	222-077-1 218-953-8	ex 2935 90 90	p	b
Atrazine	1912-24-9	217-617-8	ex 2933 69 10	p	b
Azinphos-ethyl	2642-71-9	220-147-6	ex 2933 99 80	p	b
Azocyclotin	41083-11-8	255-209-1	ex 2933 99 80	p	b
Benalaxyl	71626-11-4	275-728-7	ex 2924 29 70	p	b
Benfuracarb	82560-54-1		ex 2932 99 00	p	b
Benzidine and its salts Benzidine derivatives	92-87-5 36341-27-2 and others	202-199-1 252-984-8 and others	ex 2921 59 90	i	sr
Benzyl butyl phthalate	85-68-7	201-622-7	ex 2917 34 00	i	sr
Beta-cyfluthrin	1820573-27-0		ex 2926 90 70	p	b
Beta-cypermethrin	65731-84-2	265-898-0	ex 2926 90 70	p	b
Bifenthrin	82657-04-3		ex 2916 20 00	p	sr
Bis(pentabromophenyl) ether	1163-19-5	214-604-9	ex 2909 30 38	i	sr
Bitertanol	55179-31-2	259-513-5	ex 2933 99 80	p	b
Bromoxynil	1689-84-5 3861-41-4 56634-95-8 1689-99-2	216-882-7 223-374-9 260-300-4 216-885-3	ex 2926 90 70	p	b
Butralin	33629-47-9	251-607-4	ex 2921 49 00	p	b
Cadmium and its compounds	7440-43-9 and others	231-152-8 and others	ex 8112 and others	i	sr
Cadusafos	95465-99-9		ex 2930 90 98	p	b
Carbaryl	63-25-2	200-555-0	ex 2924 29 70	p	b

Carbosulfan	55285-14-8	259-565-9	ex 2932 99 00	p	b
Chlorate	7775-09-9 10137-74-3 7783-92-8 and others	231-887-4 233-378-2 232-034-9 and others	ex 2829 11 00 ex 2829 19 00 ex 2843 29 00	p	b
Chlorfenapyr	122453-73-0		ex 2933 99 80	p	sr
Chloropicrin	76-06-2	200-930-9	ex 2904 91 00	p	b
Chlorothalonil	1897-45-6	217-588-1	ex 2926 90 70	p	b
Chlorpropham	101-21-3	202-925-7	ex 2924 29 70	p	b
Chlorpyrifos	2921-88-2	220-864-4	ex 2933 39 99	p	b
Chlorpyrifos-methyl	5598-13-0	227-011-5	ex 2933 39 99	p	b
Chlorthal-dimethyl	1861-32-1	217-464-7	ex 2917 39 95	p	b
Chlozolate	84332-86-5	282-714-4	ex 2934 99 90	p	b
Cinidon-ethyl	142891-20-1		ex 2925 19 95	p	b
Clothianidin	210880-92-5	433-460-1	ex 2934 10 00	p	sr
Cybutryne	28159-98-0	248-872-3	ex 2933 69 80	p	b
Cyclanilide	113136-77-9	419-150-7	ex 2924 29 70	p	b
Cyhexatin	13121-70-5	236-049-1	ex 2931 90 00	p	b
Desmedipham	13684-56-5	237-198-5	ex 2924 29 70	p	b
Diarsenic pentaoxide	1303-28-2	215-116-9	ex 2811 29 90	i	sr
Diazinon	333-41-5	206-373-8	ex 2933 59 10	p	sr
Dichlobenil	1194-65-6	214-787-5	ex 2926 90 70	p	b
Dicloran	99-30-9	202-746-4	ex 2921 42 00	p	b
Dichlorvos	62-73-7	200-547-7	ex 2919 90 00	p	b
Diisobutyl phthalate	84-69-5	201-553-2	ex 2917 34 00	i	sr
Dimethenamid	87674-68-8		ex 2934 99 90	p	b

Dimethoate	60-51-5	200-480-3	ex 2930 90 98	p	b
Diniconazole-M	83657-18-5		ex 2933 99 80	p	b
Dinoterb	1420-07-1	215-813-8	ex 2908 99 00	p	b
Diphenylamine	122-39-4	204-539-4	ex 2921 44 00	p	b
Diquat, including diquat dibromide	2764-72-9 85-00-7	220-433-0 201-579-4	ex 2933 99 80	p	b
DPX KE 459 (flupyrsulfuron-methyl)	150315-10-9 144740-54-5		ex 2935 90 90	p	b
Empenthrin	54406-48-3	259-154-4	ex 2916 20 00	p	b
Epoxiconazole	135319-73-2	406-850-2	ex 2934 99 90	p	b
Ethalfuralin	55283-68-6	259-564-3	ex 2921 43 00	p	b
Ethoprophos	13194-48-4	236-152-1	ex 2930 90 98	p	b
Ethoxysulfuron	126801-58-9		ex 2933 59 95	p	b
Ethoxyquin	91-53-2	202-075-7	ex 2933 49 90	p	b
Fenamidone	161326-34-7		ex 2933 29 90	p	b
Fenarimol	60168-88-9	262-095-7	ex 2933 59 95	p	b
Fenamiphos	22224-92-6	244-848-1	ex 2930 90 98	p	b
Fenbutatin oxide	13356-08-6	236-407-7	ex 2931 90 00	p	b
Fenitrothion	122-14-5	204-524-2	ex 2920 19 00	p	sr
Fenthion	55-38-9	200-231-9	ex 2930 90 98	p	sr
Fentin acetate	900-95-8	212-984-0	ex 2931 90 00	p	b
Fentin hydroxide	76-87-9	200-990-6	ex 2931 90 00	p	b
Ferbam	14484-64-1	238-484-2	ex 2930 20 00	p	b
Fipronil	120068-37-3	424-610-5	ex 2933 19 90	p	sr
Flufenoxuron	101463-69-8	417-680-3	ex 2924 21 00	p	sr
Flurprimidol	56425-91-3		ex 2933 59 95	p	b
Flurtamone	96525-23-4		ex 2932 19 00	p	b

Glufosinate, including glufosinate ammonium	51276-47-2 77182-82-2	257-102-5 278-636-5	ex 2931 49 90	p	b
Guazatine	108173-90-6 115044-19-4	236-855-3	ex 3808 99 90	p	b
Hexazinone	51235-04-2	257-074-4	ex 2933 69 80	p	b
Indolylacetic acid	87-51-4	201-748-2	ex 2933 99 80	p	b
Iprodione	36734-19-7	253-178-9	ex 2933 21 00	p	b
Isoproturon	34123-59-6	251-835-4	ex 2924 21 00	p	sr
Linuron	330-55-2	206-356-5	ex 2928 00 90	p	b
Mancozeb	8018-01-7		ex 3808 92 30	p	b
Maneb	12427-38-2	235-654-8	ex 3824 99 93	p	b
Mecoprop	7085-19-0 93-65-2	230-386-8 202-264-4	ex 2918 99 90	p	b
Mercury	7439-97-6	231-106-7	ex 2805 40	i	sr
Methiocarb	2032-65-7	217-991-2	ex 2930 90 98	p	b
Methomyl	16752-77-5	240-815-0	ex 2930 90 98	p	b
Methyl bromide	74-83-9	200-813-2	ex 2903 61 00	p	b
Methyl parathion (*)	298-00-0	206-050-1	ex 2920 11 00	p	b
Monomethyl-dibromo-diphenyl methane Tradename: DBBT	99688-47-8	401-210-1	ex 2903 99 80	i	b
Monomethyl-dichloro-diphenyl methane; Tradename: Ugilec 121 or Ugilec 21	—	400-140-6	ex 2903 99 80	i	b
Monomethyl-tetrachlorodiphenyl methane; Tradename: Ugilec 141	76253-60-6	278-404-3	ex 2903 99 80	i	b
Naled	300-76-5	206-098-3	ex 2919 90 00	p	b
Nicotine	54-11-5	200-193-3	ex 2939 79 10	p	b
Nitrofen	1836-75-5	217-406-0	ex 2909 30 90	p	b

Nonylphenols $C_6H_4(OH)C_9H_{19}$	25154-52-3 (phenol, nonyl-)	246-672-0	ex 2907 13 00	i	sr
	84852-15-3 (phenol, 4-nonyl-, branched)	284-325-5			
	11066-49-2 (isononylphenol)	234-284-4			
	90481-04-2, (phenol, nonyl-, branched)	291-844-0			
	104-40-5 (P-nonylphenol) and others	203-199-4 and others			
Nonylphenol ethoxylates $(C_2H_4O)_nC_{15}H_{24}O$	9016-45-9		ex 3402 42 00	i	sr
	26027-38-3		ex 3907 29 11		
	68412-54-4		ex 3824 99 92	p	b
	37205-87-1				
	127087-87-0 and others				
Orthosulfamuron	213464-77-8		ex 2933 59 95	p	b
Oxadiargyl	39807-15-3	254-637-6	ex 2934 99 90	p	b
Oxasulfuron	144651-06-9		ex 2935 90 90	p	b
Oxydemeton-methyl	301-12-2	206-110-7	ex 2930 90 98	p	b
Paraquat	4685-14-7	225-141-7	ex 2933 39 99	p	b
	1910-42-5	217-615-7			
	2074-50-2	218-196-3			

Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds	335-67-1 and others	206-397-9 and others	2915 90 70 and others	i	sr
Perfluorooctane sulfonate derivatives (including polymers), not covered by Perfluorooctane sulfonic acid, Perfluorooctane sulfonates, Perfluorooctane sulfonamides, Perfluorooctane sulfonyls	57589-85-2 68081-83-4 and others	260-837-4 268-357-7 and others	ex 2924 29 70 ex 3824 99 92	i	sr
Phosalone	2310-17-0	218-996-2	ex 2934 99 90	p	b
Picoxystrobin	117428-22-5		ex 2933 39 99	p	b
Procymidone	32809-16-8	251-233-1	ex 2925 19 95	p	b
Propachlor	1918-16-7	217-638-2	ex 2924 29 70	p	b
Propanil	709-98-8	211-914-6	ex 2924 29 70	p	b
Propargite	2312-35-8	219-006-1	ex 2920 90 70	p	b
Propineb	12071-83-9 9016-72-2	235-134-0	ex 2930 20 00	p	b
Propisochlor	86763-47-5		ex 2924 29 70	p	b
Pymetrozine	123312-89-0		ex 2933 69 80	p	b
Pyrazophos	13457-18-6	236-656-1	ex 2933 59 95	p	b
Quinoxifen	124495-18-7		ex 2933 49 90	p	b
Quintozene	82-68-8	201-435-0	ex 2904 99 00	p	b
Rotenone	83-79-4	201-501-9	ex 2932 99 00	p	sr
Simazine	122-34-9	204-535-2	ex 2933 69 10	p	b
Tecnazene	117-18-0	204-178-2	ex 2904 99 00	p	b
Tepraloxydim	149979-41-9		ex 2932 99 00 ex 3808 93 27	p	b
Thiacloprid	111988-49-9		ex 2934 10 00	p	b
Thiamethoxam	153719-23-4	428-650-4	ex 2934 10 00	p	sr

Thiobencarb	28249-77-6	248-924-5	ex 2930 20 00	p	b
Thiodicarb	59669-26-0	261-848-7	ex 2930 90 98	p	b
Thiophanate-methyl	23564-05-8	245-740-7	ex 2930 90 98	p	b
Thiram	137-26-8	205-286-2	ex 2930 30 00	p	sr
Tolylfluanid	731-27-1	211-986-9	ex 2930 90 98	p	sr
Triasulfuron	82097-50-5		ex 2935 90 90	p	b
Triclosan	3380-34-5	222-182-2	ex 2909 50 00	p	b
Tricyclazole	41814-78-2	255-559-5	ex 2934 99 90	p	b
Trifluralin	1582-09-8	216-428-8	ex 2921 43 00	p	b
Triorganostannic compounds other than tributyltin compounds			ex 2931 90 00 and others	p	sr
Tris (2-chloroethyl) phosphate	115-96-8	204-118-5	ex 2919 90 00	i	sr
Vinclozolin	50471-44-8	256-599-6	ex 2934 99 90	p	b

(*) Category: p — pesticides; i — industrial chemical.

(**) Use limitation: sr — severe restriction, b — ban (for the category or categories concerned) according to Union legislation.

(***) An 'ex' before a code implies that chemicals other than those referred to in the column 'Chemical' may also fall under that subheading.

CAS No = Chemical Abstracts Service Registry Number.

(*) Chemical subject or partially subject to the PIC procedure.

List of chemicals subject to the PIC procedure*(referred to in Articles 13 and 14)**(The categories shown are those referred to in the Convention)*

Chemical	Relevant CAS number(s)	HS code Pure substance (**)	HS code Mixtures containing substance (**)	Category
2,4,5-T and its salts and esters	93-76-5 (#)	ex 2918.91	ex 3808.59	Pesticide
Alachlor	15972-60-8	ex 2924.25	ex 3808.93	Pesticide
Aldicarb	116-06-3	ex 2930.80	ex 3808.91	Pesticide
Aldrin (*)	309-00-2	ex 2903.82	ex 3808.59	Pesticide
Azinphos-methyl	86-50-0	ex 2933.92	ex 3808.59	Pesticide
Binapacryl	485-31-4	ex 2916.16	ex 3808.59	Pesticide
Captafol	2425-06-1	ex 2930.80	ex 3808.59	Pesticide
Carbofuran	1563-66-2	ex 2932.99	ex 3808.91 ex 3808.59	Pesticide
Chlordane (*)	57-74-9	ex 2903.82	ex 3808.59	Pesticide
Chlordimeform	6164-98-3	ex 2925.21	ex 3808.59	Pesticide
Chlorobenzilate	510-15-6	ex 2918.18	ex 3808.59	Pesticide
DDT (*)	50-29-3	ex 2903.92	ex 3808.59	Pesticide
Dieldrin (*)	60-57-1	ex 2910.40	ex 3808.59	Pesticide
Dinitro-ortho-cresol (DNOC) and its salts (such as ammonium salt, potassium salt and sodium salt)	534-52-1 2980-64-5 5787-96-2 2312-76-7	ex 2908.92	ex 3808.91 ex 3808.92 ex 3808.93	Pesticide
Dinoseb and its salts and esters	88-85-7 (#)	ex 2908.91	ex 3808.59	Pesticide
1,2-Dibromoethane (EDB)	106-93-4	ex 2903.62	ex 3808.59	Pesticide

Endosulfan (*)	115-29-7	ex 2920.30	ex 3808.91	Pesticide
Ethylene dichloride (1,2-dichloroethane)	107-06-2	ex 2903.15	ex 3808.59	Pesticide
Ethylene oxide	75-21-8	ex 2910.10	ex 3808.59 ex 3824.81	Pesticide
Fluoroacetamide	640-19-7	ex 2924.12	ex 3808.59	Pesticide
HCH (mixed isomers) (*)	608-73-1	ex 2903.81	ex 3808.59	Pesticide
Heptachlor (*)	76-44-8	ex 2903.82	ex 3808.59	Pesticide
Hexabromocyclododecane (*)	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8 and others	ex 2903.89		Industrial
Hexachlorobenzene (*)	118-74-1	ex 2903.92	ex 3808.59	Pesticide
Lindane (*)	58-89-9	ex 2903.81	ex 3808.59	Pesticide
Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds	10112-91-1 21908-53-2 and others See also: www.pic.int/	ex 2852.10	ex 3808.59	Pesticide
Methamidophos	10265-92-6	ex 2930.80	ex 3808.59	Pesticide
Monocrotophos	6923-22-4	ex 2924.12	ex 3808.59	Pesticide
Commercial octabromodiphenyl ether, including		ex 3824.88 ex 2909.30	ex 3824.88	Industrial
— hexabromodiphenyl ether (*)	36483-60-0			
— heptabromodiphenyl ether (*)	68928-80-3			
Parathion	56-38-2	ex 2920.11	ex 3808.59	Pesticide
Commercial pentabromodiphenyl ether, including		ex 2909.30	ex 3824.88	Industrial
— tetrabromodiphenyl ether (*)	40088-47-9			
— pentabromodiphenyl ether (*)	32534-81-9			

Pentachlorophenol and its salts and esters (*)	87-86-5 (#)	ex 2908.11	ex 3808.59 ex 3808.91 ex 3808.92 ex 3808.93 ex 3808.94 ex 3808.99	Pesticide
Perfluorooctane sulfonic acid, Perfluorooctane sulfonates, Perfluorooctane sulfonamides, Perfluorooctane sulfonyls (*)	1763-23-1 2795-39-3 29457-72-5 29081-56-9 70225-14-8 56773-42-3 251099-16-8 4151-50-2 31506-32-8 1691-99-2 24448-09-7 307-35-7 and others	ex 2904.31 ex 2904.34 ex 2904.33 ex 2904.32 ex 2922.16 ex 2923.30 ex 2923.40 ex 2935.20 ex 2935.10 ex 2935.30 ex 2935.40 ex 2904.36	ex 3824.87	Industrial
Phorate	298-02-2	ex 2930.90	ex 3808.91	Pesticide
Toxaphene (*)	8001-35-2	ex 3808.59	ex 3808.59	Pesticide
Dustable powder formulations containing a combination of: Benomyl at or above 7 %, Carbofuran at or above 10 % and Thiram at or above 15 %	17804-35-2 1563-66-2 137-26-8	ex 2933.99 ex 2932.99 ex 2930.30	ex 3808.92	Severely hazardous pesticide formulation
Methyl-parathion (emulsifiable concentrates (EC) at or above 19,5 % active ingredient and dusts at or above 1,5 % active ingredient)	298-00-0	ex 2920.11	ex 3808.59	Severely hazardous pesticide formulation

Phosphamidon (soluble liquid formulations of the substance that exceed 1 000 g active ingredient/l)	13171-21-6 (mixture, (E) & (Z) isomers) 23783-98-4 ((Z)-isomer) 297-99-4 ((E)-isomer)	ex 2924.12	ex 3808.59	Severely hazardous pesticide formulation
Asbestos fibres:		ex 2524.10 ex 2524.90	ex 6811.40 ex 6812.80	Industrial
Actinolite	77536-66-4	ex 2524.90	ex 6812.99	
Anthophyllite	77536-67-5	ex 2524.90	ex 6812.99	
Amosite	12172-73-5	ex 2524.90	ex 6812.99	
Crocidolite	12001-28-4	ex 2524.10	ex 6812.91	
Tremolite	77536-68-6	ex 2524.90	ex 6813.20	
Polybrominated biphenyls (PBB)				Industrial
— (hexa-) (*)	36355-01-8	ex 2903.94	ex 3824.82	
— (octa-)	27858-07-7	ex 2903.99		
— (deca-)	13654-09-6	ex 2903.99		
Polychlorinated biphenyls (PCB) (*)	1336-36-3	ex 2903.99	ex 3824.82	Industrial
Polychlorinated terphenyls (PCT)	61788-33-8	ex 2903.99	ex 3824.82	Industrial
Short-chain chlorinated paraffins (*)	85535-84-8	ex 3824.99		Industrial
Tetraethyl lead	78-00-2	ex 2931.10	ex 3811.11	Industrial
Tetramethyl lead	75-74-1	ex 2931.10	ex 3811.11	Industrial
All tributyltin compounds, including:		ex 2931.20	ex 3808.59	Pesticide Industrial
Tributyltin oxide	56-35-9	ex 2931.20	ex 3808.59	
Tributyltin fluoride	1983-10-4	ex 2931.20	ex 3808.92	
Tributyltin methacrylate	2155-70-6	ex 2931.20		
Tributyltin benzoate	4342-36-3	ex 2931.20		

Tributyltin chloride	1461-22-9	ex 2931.20		
Tributyltin linoleate	24124-25-2	ex 2931.20		
Tributyltin naphthenate	85409-17-2	ex 2931.20		
Trichlorfon	52-68-6	ex 2931.54	ex 3808.91	Pesticide
Tris (2,3-dibromopropyl) phosphate	126-72-7	ex 2919.10	ex 3824.83	Industrial'

(*) These substances are subject to an export ban in accordance with Article 15(2) of and Annex V to this Regulation.

(**) An 'ex' before a code implies that chemicals other than those referred to in the column 'Chemical' may also fall under that subheading.

(#) Only the CAS numbers of parent compounds are listed.

ANNEX II

ANNEX V

Chemicals and articles subject to export ban*(referred to in Article 15)*

PART 1

Persistent organic pollutants as listed in Annexes A and B to the Stockholm Convention on Persistent Organic Pollutants ⁽¹⁾ according to the provisions thereof.

Description of chemicals/article(s) subject to export ban	Additional details, where relevant (e.g. name of chemical, EC No, CAS No, etc.)	
	Aldrin	EC No 206-215-8 CAS No 309-00-2 CN code ex 2903 82 00
	Chlordane	EC No 200-349-0 CAS No 57-74-9 CN code ex 2903 82 00
	Chlordecone	EC No 205-601-3 CAS No 143-50-0 CN code ex 2914 71 00
	Dicofol	EC No 204-082-0 CAS No 115-32-2 CN code ex 2906 29 00
	Dieldrin	EC No 200-484-5 CAS No 60-57-1 CN code ex 2910 40 00
	DDT (1,1,1-trichloro-2,2-bis (p-chlorophenyl) ethane)	EC No 200-024-3 CAS No 50-29-3 CN code ex 2903 92 00
	Endosulfan	EC No 204-079-4 CAS No 115-29-7 CN code 2920 30 00
	Endrin	EC No 200-775-7 CAS No 72-20-8 CN code ex 2910 50 00

⁽¹⁾ OJ L 209, 31.7.2006, p. 3.

	Heptabromodiphenyl ether $C_{12}H_3Br_7O$	EC No 273-031-2 CAS No 68928-80-3 and others CN code ex 2909 30 38
	Heptachlor	EC No 200-962-3 CAS No 76-44-8 CN code ex 2903 82 00
	Hexabromobiphenyl	EC No 252-994-2 CAS No 36355-01-8 CN code ex 2903 94 00
	Hexabromocyclododecane	EC No 247-148-4, 221-695-9 CAS No 25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8 and others CN code ex 2903 89 80
	Hexabromodiphenyl ether $C_{12}H_4Br_6O$	EC No 253-058-6 CAS No 36483-60-0 and others CN code ex 2909 30 38
	Hexachlorobenzene	EC No 204-273-9 CAS No 118-74-1 CN code ex 2903 92 00
	Hexachlorobutadiene	EC No 201-765-5 CAS No 87-68-3 CN code ex 2903 29 00
	Hexachlorocyclohexanes, including lindane	EC No 200-401-2, 206-270-8, 206-271-3, 210-168-9 CAS No 58-89-9, 319-84-6, 319-85-7, 608-73-1 CN code ex 2903 81 00
	Mirex	EC No 219-196-6 CAS No 2385-85-5 CN code ex 2903 83 00

	Pentabromodiphenyl ether C ₁₂ H ₅ Br ₅ O	EC No 251-084-2 and others CAS No 32534-81-9 and others CN code ex 2909 30 31
	Pentachlorobenzene	EC No 210-172-0 CAS No 608-93-5 CN code ex 2903 93 00
	Pentachlorophenol and its salts and esters	EC No 201-778-6 and others CAS No 87-86-5 and others CN codes ex 2908 11 00, ex 2908 19 00 and others
The export ban only applies to fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds.	Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds	EC No 206-397-9 and others CAS No 335-67-1 and others CN codes ex 2915 90 70 and others
The export ban does not apply when PFOS, its salts and perfluorooctane sulfonyl fluoride is used as a mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems.	Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride	EC No 217-179-8, 220-527-1, 274-460-8, 260-375-3 and others CAS No 1763-23-1, 2795-39-3, 70225-14-8, 56773-42-3 and others CN codes 2904 31 00, 2904 34 00, 2922 16 00, 2923 30 00 and others
	Polychlorinated biphenyls (PCBs)	EC No 215-648-1 and others CAS No 1336-36-3 and others CN code ex 2903 99 80
	Polychlorinated naphthalenes	EC No 274-864-4 CAS No 70776-03-3 and others CN code ex 3824 99 92
	Short-chain chlorinated paraffins	EC No 287-476-5 CAS No 85535-84-8 CN code ex 3824 99 92
	Tetrabromodiphenyl ether C ₁₂ H ₆ Br ₄ O	EC No 254-787-2 and others CAS No 40088-47-9 and others CN code ex 2909 30 38

The export ban only applies to articles where the sum of the concentration of tetra-, penta-, hexa-, hepta- and decabromodiphenyl ether is 500 mg/kg or more. By way of derogation from the first paragraph, articles where the concentration is 500 mg/kg or more, due to a higher concentration of decabromodiphenyl ether, are exempted from the export ban, provided that the presence of decabromodiphenyl ether is in compliance with Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).	Tetrabromodiphenyl ether	EC No 254-787-2 and others CAS No 40088-47-9 and others CN code ex 2909 30 38
	Pentabromodiphenyl ether	EC No 251-084-2 and others CAS No 32534-81-9 and others CN code ex 2909 30 31
	Hexabromodiphenyl ether	EC No 253-058-6 and others CAS No 36483-60-0 and others CN code ex 2909 30 38
	Heptabromodiphenyl ether	EC No 273-031-2 and others CAS No 68928-80-3 and others CN code ex 2909 30 38
	Decabromodiphenyl ether	EC No 214-604-9 and others CAS No 1163-19-5 and others CN code ex 2909 30 38
	Toxaphene	EC No 232-283-3 CAS No 8001-35-2 CN code ex 3808 59 00

PART 2

Chemicals other than persistent organic pollutants as listed in Annexes A and B to the Stockholm Convention on Persistent Organic Pollutants according to the provisions thereof.

No	Description of chemicals/article(s) subject to export ban (*)	Additional details, where relevant (e.g. name of chemical, EC No, CAS No, etc.)
1	Cosmetic soaps containing mercury.	CN codes ex 3401 11 00, ex 3401 19 00, ex 3401 20 10, ex 3401 20 90, ex 3401 30 00
2	Metallic mercury and mixtures of metallic mercury with other substances, including alloys of mercury, with a mercury concentration of at least 95 % by weight.	CAS No 7439-97-6 EC No 231-106-7 CN code ex 2805 40
3	The following mercury compounds except where they are exported for laboratory-scale research or laboratory analysis: — Cinnabar ore; — Mercury (I) chloride (Cl ₂ Hg ₂); — Mercury (II) oxide (HgO);	CAS No 10112-91-1, 21908-53-2, 1344-48-5, 7783-35-9, 10045-94-0 EC No 233-307-5, 244-654-7, 215-696-3, 231-992-5, 233-152-3

	— Mercury sulphide (HgS); — Mercury (II) sulphate (HgSO₄); — Mercury (II) nitrate (Hg(NO₃)₂).	CN codes ex 2852 10 00, ex 2617 90 00
4	All mixtures of metallic mercury with other substances, including alloys of mercury, not covered by entry 2 and all mercury compounds not covered by entry 3, if the export of that mixture or compound is for the purpose of reclaiming metallic mercury.	Including: Mercury(I) sulphate (Hg₂SO₄, CAS No 7783-36-0), mercury(II) thiocyanate (Hg(SCN)₂, CAS No 592-85-8), mercury(I) iodide (Hg₂I₂, CAS No 15385-57-6) CN codes ex 2852 10 00
5	Compact fluorescent lamps (CFLs) for general lighting purposes: (a) CFL.i ≤ 30 watts with a mercury content exceeding 2,5 mg per lamp burner; (b) CFL.ni ≤ 30 watts with a mercury content exceeding 3,5 mg per lamp burner.	
6	The following linear fluorescent lamps for general lighting purposes: (a) Triband phosphor < 60 watts with a mercury content exceeding 5 mg per lamp; (b) Halophosphate phosphor ≤ 40 watts with a mercury content exceeding 10 mg per lamp.	
7	High pressure mercury vapour lamps for general lighting purposes.	
8	The following mercury-added cold cathode fluorescent lamps and external electrode fluorescent lamps for electronic displays: (a) short length (≤ 500 mm) with mercury content exceeding 3,5 mg per lamp; (b) medium length (> 500 mm and ≤ 1 500 mm) with mercury content exceeding 5 mg per lamp; (c) long length (> 1 500 mm) with mercury content exceeding 13 mg per lamp.	
9	Batteries or accumulators that contain more than 0,0005 % of mercury by weight.	
10	Switches and relays, except very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge, switch or relay.	
11	Cosmetics with mercury and mercury compounds, except those special cases included in entries 16 and 17 of Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).	

12	Pesticides, biocides and topical antiseptics that contain mercury or a mercury compound that was intentionally added.	
13	The following non-electronic measuring devices that contain mercury or a mercury compound that was intentionally added: (a) barometers; (b) hygrometers; (c) manometers; (d) thermometers and other non-electrical thermometric applications; (e) sphygmomanometers; (f) strain gauges to be used with plethysmographs; (g) mercury pycnometers; (h) mercury metering devices for determination of the softening point. This entry does not cover the following measuring devices: — non-electronic measuring devices installed in large-scale equipment or used for high precision measurement where no suitable mercury-free alternative is available; — measuring devices more than 50 years old on 3 October 2007; — measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.'	

(*) The export ban shall not apply to any of the following mercury-added products:

- (a) products that are essential for civil protection and military uses;
- (b) products for research, for calibration of instrumentation, or for use as a reference standard;
- (c) switches and relays, cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFLs and EEFLs) for electronic displays and measuring devices, when they are used to replace a component of larger equipment and provided that no feasible mercury-free alternative for that component is available, in accordance with Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34) and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

DECISIONS

COUNCIL DECISION (EU) 2022/644

of 12 April 2022

on the position to be adopted on behalf of the European Union within the International Maritime Organization's Maritime Safety Committee during its 105th session and within the International Maritime Organization's Facilitation Committee during its 46th session as regards the adoption of amendments to the resolutions on performance standards in relation to equipment used in the Global Maritime Distress and Safety System and of amendments to the Annex to the Convention on Facilitation of International Maritime Traffic (FAL)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Action by the Union in the sector of maritime transport should aim to improve maritime safety and protect the marine environment and human health.
- (2) The Maritime Safety Committee of the International Maritime Organization ('IMO'), during its 105th session ('MSC 105') from 20 to 29 April 2022, is expected to adopt amendments to the resolutions on performance standards in relation to equipment used in order to reflect the modernisation of the Global Maritime Distress and Safety System (GMDSS). Those resolutions comprise A.699(17), A.700(17), MSC.148(77), A.530(13), A.802(19), A.803(19), A.804(19), A.806(19), A.807(19), MSC.149(77), MSC.80(70) and A.811(19).
- (3) The Facilitation Committee of the IMO, during its 46th session ('FAL 46') from 9 to 13 May 2022, is expected to adopt amendments to the Annex to the Convention on Facilitation of International Maritime Traffic ('FAL Convention').
- (4) It is appropriate to establish the position to be adopted on the Union's behalf during MSC 105, since the Maritime Safety Committee's resolutions on performance standards are capable of decisively influencing the content of Union law, namely Directive 2014/90/EU of the European Parliament and of the Council ⁽¹⁾.
- (5) The adoption of amendments to the MSC resolutions on performance standards would improve the previously adopted performance standards in relation to equipment used in order to reflect the modernisation of the GMDSS. The Union should therefore support the adoption of the amendments to the MSC resolutions.

⁽¹⁾ Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

- (6) It is appropriate to establish the position to be adopted on the Union's behalf during the 46th session of the Facilitation Committee, since the envisaged amendments to the Annex to the FAL Convention are capable of decisively influencing the content of Union law, namely Directive 2010/65/EU of the European Parliament and of the Council ⁽²⁾ and, as from 15 August 2025, Regulation (EU) 2019/1239 of the European Parliament and of the Council ⁽³⁾.
- (7) The amendments to the Annex to the FAL Convention would bring that Annex closer to the requirements of Regulation (EU) 2019/1239 and the agreed business rules for implementing that Regulation, namely by making electronic transmission through a single window mandatory, preventing data elements from being repeated, preventing paper forms from being used for the transmission of information, and waiving the requirement for manual signatures.
- (8) The Union is neither a member of the IMO, nor a contracting party to the relevant conventions and codes. The Council should therefore authorise the Member States to express the position of the Union.
- (9) The scope of this Decision should be limited to the content of the proposed amendments, to the extent that those amendments are capable of affecting Union common rules and fall under the exclusive competence of the Union. This Decision should not affect the division of competences between the Union and the Member States,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on behalf of the Union within the International Maritime Organization's Maritime Safety Committee during its 105th session shall be to support the adoption of the amendments to the following resolutions on performance standards in relation to equipment used in the Global Maritime Distress and Safety System: A.699(17), A.700(17), MSC.148(77), A.530(13), A.802(19), A.803(19), A.804(19), A.806(19), A.807(19), MSC.149(77), MSC.80(70) and A.811(19).

Article 2

The position to be adopted on behalf of the Union within the International Maritime Organization's Facilitation Committee during its 46th session shall be to support the adoption of the amendments to the Annex to the Convention on Facilitation of International Maritime Traffic.

Article 3

1. The positions to be adopted on behalf of the Union specified in this Decision cover the amendments concerned to the extent that those amendments fall under the exclusive competence of the Union and are capable of affecting Union common rules. Those positions shall be expressed by the Member States, which are all members of the IMO, acting jointly in the interests of the Union.
2. Minor changes to the positions referred to in Articles 1 and 2 may be agreed upon without further decision of the Council.

⁽²⁾ Directive 2010/65/EU of the European Parliament and of the Council of 20 October 2010 on reporting formalities for ships arriving in and/or departing from ports of the Member States and repealing Directive 2002/6/EC (OJ L 283, 29.10.2010, p. 1).

⁽³⁾ Regulation (EU) 2019/1239 of the European Parliament and of the Council of 20 June 2019 establishing a European Maritime Single Window environment and repealing Directive 2010/65/EU (OJ L 198, 25.7.2019, p. 64).

Article 4

Member States are hereby authorised to give their consent to be bound, in the interests of the Union, by the amendments referred to in Articles 1 and 2, to the extent that those amendments fall under the exclusive competence of the Union.

Article 5

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 12 April 2022.

For the Council
The President
C. BEAUNE

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

BILATERAL OVERSIGHT BOARD FOR THE AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN COMMUNITY ON COOPERATION IN THE REGULATION OF CIVIL AVIATION SAFETY

RECORD OF DECISION

DECISION N°0010 [2022/645]

Noting that Amendment 1 to the Agreement between the United States of America and the European Community on Cooperation in the Regulation of Civil Aviation Safety (the 'Agreement') expands the scope of Article 2.B of the Agreement to include, *inter alia*, personnel licensing and training;

Further noting that Article 5 of the Agreement, as amended, provides for the development of new Annexes to the Agreement for matters within the scope of the Agreement, which are then, pursuant to Article 19.C, brought into force upon a decision of the Bilateral Oversight Board ('BOB') established pursuant to Article 3,

The BOB hereby decides as follows:

1. To adopt Annex 3 (Pilot Licensing) to the Agreement as attached to this Decision in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish languages. In case of divergence of interpretation between the different language texts, the English text shall prevail.
2. To take note of the Joint Declaration to be signed by the Representatives of the Parties concerning the authentication of the Croatian language version of Annex 3.
3. Annex 3 (Pilot Licensing) to the Agreement shall enter into force on the date of the last signature below.

For the Bilateral Oversight Board:

FEDERAL AVIATION ADMINISTRATION
DEPARTMENT OF TRANSPORTATION
UNITED STATES OF AMERICA

EUROPEAN COMMISSION
EUROPEAN UNION

BY: Mr Ali BAHRAMI

BY: Mr Filip CORNELIS

TITLE: Associate Administrator for Aviation
Safety

TITLE: Director, Aviation
Directorate-General for Mobility and
Transport, European Commission

DATE: 19 November 2020

DATE: 19 November 2020

PLACE: Washington, DC

PLACE: Brussels, Belgium

ANNEX 3

PILOT LICENSING

1. PURPOSE AND SCOPE

- 1.1. The Parties have assessed each other's standards, rules, practices, and procedures related to private pilot licensing, including night and instrument ratings for the single-engine piston (SEP) land airplane and multi-engine piston (MEP) land airplane categories, but excluding the type ratings, and concluded that they are sufficiently compatible to permit acceptance of each other's approvals and findings. This Annex covers the reciprocal acceptance of findings of compliance and documentation, and the provision of technical assistance regarding private pilot licensing and compliance monitoring. Nothing in this Annex shall be construed to limit the authority of a Party to act in accordance with Article 15 of the Agreement.
- 1.2. The scope of this Annex covers private pilot EU Part-FCL licenses and FAA private pilot certificates, and private pilot privileges included in other EU Part-FCL licenses and FAA pilot certificates, as well as night and instrument ratings, as specified in Appendix 1 to this Annex, in SEP land airplane and MEP land airplane categories in single-pilot operations, excluding any type ratings. EU Part-FCL commercial pilot licenses for airplanes (CPL (A)) and airline transport pilot licenses for airplanes (ATPL (A)) contain private pilot privileges. The multi-crew pilot license (MPL) only contains private pilot privileges if specifically endorsed in the license. Similarly, FAA commercial pilot and air transport pilot certificates contain private pilot privileges. These licenses and pilot certificates are eligible for conversion under the terms of this Annex if the privileges are applicable.
- 1.3. The scope of this Annex may be extended to other EU Part-FCL licenses and FAA pilot certificates, ratings and aircraft categories through an amendment to this Annex pursuant to a decision of the Bilateral Oversight Board (BOB) taken in accordance with Article 19.B of the Agreement.
- 1.4. The extension of the scope of this Annex shall take place following the necessary confidence-building process conducted by the Technical Agents.
- 1.5. This Annex does not apply to any pilot license or pilot certificate issued by another Contracting State to the Convention on International Civil Aviation of 1944 (Chicago Convention) that has been rendered valid by the FAA or by an Aviation Authority, as detailed in the Technical Implementation Procedures - Licensing (TIP-L).
- 1.6. This Annex does not limit the right of a holder of an FAA pilot certificate or an EU Part-FCL license issued by an Aviation Authority, to have the pilot certificate or license rendered valid by the other Party in accordance with applicable laws and regulations.

2. DEFINITIONS

- 2.1. In addition to those definitions found in the Agreement, for the purposes of this Annex, the following definitions apply:
 - (a) 'Class rating' means:
 - (i) with respect to an EU Part-FCL license, a valid rating attached to a pilot license. The privileges of the holder of a SEP and MEP class rating are to act as pilot on the class of aircraft specified in the rating as outlined in the 'List of Aeroplanes – Class and Type Ratings and Endorsement List' published on the European Aviation Safety Agency (EASA) website.
 - (ii) with respect to an FAA pilot certificate, a classification of aircraft within a category having similar operating characteristics as outlined in Title 14, Code of Federal Regulations (14 CFR) § 61.5 (e.g., single-engine land and multi-engine land).
 - (b) 'Conversion' means the issuance of an EU Part-FCL license on the basis of an FAA pilot certificate or the issuance of an FAA pilot certificate on the basis of an EU Part-FCL license, in accordance with the provisions of this Annex.

- (c) 'Currency' means the acceptance of the privileges of a class or type rating on an FAA pilot certificate, based on the recent experience of the certificate holder. (14 CFR Part 61 and Regulation (EU) No 1178/2011 Annex III Part C).
- (d) 'EU Part-FCL license' means a valid flight crew license that complies with the requirements of Part-FCL.
- (e) 'FAA pilot certificate' means a valid Federal Aviation Administration pilot certificate that complies with the appropriate requirements prescribed in 14 CFR Part 61.
- (f) 'Flight review' means an assessment of flying skills taken with a certified flight instructor holding appropriate FAA examining authority.
- (g) 'Instrument rating' means:
 - (i) with respect to an EU Part-FCL instrument rating, a valid rating on an EU Part-FCL licence allowing for operation under Instrument Flight Rules (IFR) or in weather conditions less than the minimums prescribed for Visual Flight Rules (VFR) that is restricted to single-engine or multi-engine operation, or in the case of a multi-crew pilot license (MPL) additionally restricted to multi-crew operation.
 - (ii) with respect to an FAA instrument rating, means a valid rating on an FAA pilot certificate subject to currency and class of aircraft requirements, allowing for operation under IFR or in weather conditions less than the minimums prescribed for VFR.
- (h) 'Night rating' means a rating attached to an EU Part-FCL license with which the privileges of the private pilot license for airplanes are to be exercised in VFR conditions at night. The night rating is issued without an expiration date.
- (i) 'Skill test' means a demonstration of skill for a license or rating issue, including such oral examination as may be required in accordance with Annex I to Commission Regulation (EU) No 1178/2011, (Part-FCL).
- (j) 'Special Conditions' means those requirements that have been found, based on a comparison of the respective regulatory licensing systems, not to be common to both systems and that are significant enough to be addressed in this Annex. The list of Special Conditions is contained in Appendix 1 to this Annex.
- (k) 'Type rating' means:
 - (i) with respect to an EU Part-FCL license, a rating attached to a pilot license. The privileges of the holder of a type rating are to act as pilot on the type of aircraft specified in the rating as outlined in the EASA type rating and license endorsement list flight crew - all aircraft excluding helicopters.
 - (ii) with respect to an FAA pilot certificate, the rating on an FAA pilot certificate for any large aircraft (except lighter than air), turbojet powered airplane, or other aircraft specified by the FAA Administrator through type certification procedures for which a pilot must meet specific aeronautical knowledge and experience and testing requirements in order to act as pilot in command of the aircraft.
- (l) 'Valid' means:
 - (i) With respect to an FAA pilot certificate or EU Part-FCL license, that such certificate or license is not surrendered, suspended, revoked, or expired.
 - (ii) With respect to an EU Part-FCL rating, the rating's validity period has not expired. The validity date of a rating is stated on the pilot license.

3. JOINT AIRCREW COORDINATION BOARD

3.1. Composition

- 3.1.1. A Joint Aircrew Coordination Board (JACB), accountable to the BOB, is hereby established under the joint leadership of the EASA and the FAA Executive Directors responsible for Flight Standards. The JACB shall include, from each Technical Agent, representatives responsible for pilot licensing and quality management systems/management systems, as appropriate.

3.1.2. The joint leadership may invite additional participants to the JACB to facilitate the fulfilment of the objectives of this Annex.

3.2. Mandate

3.2.1. The JACB shall meet at least once a year to ensure the effective functioning and implementation of this Annex. Its functions shall include:

- (a) developing, approving, and revising the TIP-L, including cooperation, assistance, exchange of information, and continued confidence activities to be used for processes covered by this Annex;
- (b) sharing information on relevant safety issues and developing action plans to address them;
- (c) ensuring the consistent application of this Annex;
- (d) exchanging information on planned and ongoing rulemaking activities that could affect the basis and scope of this Annex.
- (e) sharing information on significant changes to the Parties' pilot licensing systems that could affect the basis and scope of the Annex.
- (f) resolving technical issues falling within the responsibilities of the Technical Agents and Aviation Authorities that cannot be solved at their level; and
- (g) proposing to the BOB amendments to this Annex.

3.2.2. The JACB shall report unresolved issues to the BOB and ensure the implementation of decisions reached by the BOB regarding this Annex.

4. IMPLEMENTATION

4.1. The Parties agree that a person holding an EU Part-FCL license for airplanes, including a class rating, with or without night rating, or an instrument rating for airplanes, and who has demonstrated compliance with the applicable FAA Special Conditions set forth in Appendix 1, shall be considered to meet the requirements for obtaining an FAA pilot certificate, class rating(s), or an instrument rating in the airplane category.

4.2. The Parties agree that a person holding a FAA pilot certificate for airplanes, or an instrument rating for airplanes, and who has demonstrated compliance with the applicable EU Special Conditions set forth in Appendix 1, shall be considered to meet the requirements for obtaining an EU Part-FCL license, a class rating(s), with or without a night rating, or an instrument rating in the airplane category.

4.3. EU Part-FCL licenses or FAA pilot certificates that have been surrendered, suspended, or revoked shall not be reinstated through the terms of this Annex.

4.4. The scope of the ratings and limitations of an FAA pilot certificate or an EU Part-FCL license issued in accordance with this Annex is further specified in the TIP-L.

4.5. Once an EU Part-FCL license or an FAA pilot certificate has been issued in accordance with this Annex, the holder must, to exercise the privileges of this license or pilot certificate, meet the revalidation or renewal requirements, as applicable, of the EU Part-FCL or FAA requirements.

4.6. The FAA, upon issuing an FAA pilot certificate based on an EU Part-FCL license in accordance with this Annex, shall not require the surrender of that EU Part-FCL license. An Aviation Authority, upon issuing an EU Part-FCL license based on an FAA pilot certificate in accordance with this Annex, shall not require the surrender of that FAA pilot certificate.

4.7. The Technical Agents, and where applicable the Aviation Authorities, shall:

- 4.7.1. upon request from the FAA or Aviation Authority that issues an EU Part-FCL license or an FAA pilot certificate in accordance with this Annex, provide each other with the verification or confirmation of authenticity of the original EU Part-FCL license, FAA pilot certificate, or rating; and
- 4.7.2. provide in a form, manner, and schedule established by the JACB, statistical data regarding the EU Part-FCL licenses, FAA pilot certificates, and ratings that have been issued in accordance with this Annex.
- 4.8. Each Party's Technical Agent, or where applicable an Aviation Authority, shall provide as necessary upon request and after mutual agreement, technical assistance in pilot licensing activities to the other Party's Technical Agent, or where applicable to an Aviation Authority, to advance the purpose of this Annex. The Technical Agents or an Aviation Authority may decline to provide such technical assistance due to lack of resource availability.
- 4.9. Revisions by either Party to its civil aviation organisation, laws, regulations, procedures, policy, or standards, including those of the Technical Agents and Aviation Authorities, may affect the basis upon which this Annex is executed. Therefore, the Parties, through the Technical Agents and Aviation Authorities, as appropriate, shall advise one another of plans for such changes at the earliest possible opportunity, and discuss the extent to which such planned changes affect the basis of this Annex. If consultations pursuant to Article 15.C of the Agreement result in an agreement to amend this Annex, the Parties shall seek to ensure that such an amendment enters into force at the same time as, or as soon as possible thereafter, the entry into force or implementation of the change that prompted such amendment.

5. COMMUNICATION AND COOPERATION

- 5.1. The Technical Agents, through the JACB, shall maintain and exchange a list of contact points for the various technical aspects of this Annex.
- 5.2. All communications between the Technical Agents, including technical documentation provided for review or approval as detailed in this Annex, shall be in the English language.
- 5.3. The format for all dates used in communications shall be DD MMM YYYY, e.g., '05 MAY 2014'.
- 5.4. When urgent or unusual situations develop, the Technical Agents', and where applicable, the Aviation Authorities' points of contact, as identified in the TIP-L, shall communicate and ensure that the appropriate immediate actions are taken.

6. QUALIFICATION REQUIREMENTS FOR THE ACCEPTANCE OF FINDINGS OF COMPLIANCE

6.1. Basic Requirements

- 6.1.1. Each Technical Agent and any Aviation Authority, as applicable, shall demonstrate to the other Technical Agent the effectiveness of their respective systems for the regulatory oversight of pilots. They shall demonstrate, in particular, effective and adequate:
 - (a) legal and regulatory structure;
 - (b) organisational structure;
 - (c) resources, including sufficient qualified staff;
 - (d) training program for their technical staff;
 - (e) internal policies, processes, and procedures including a quality system;
 - (f) documentation and records;
 - (g) oversight program; and
 - (h) authority over regulated EU Part-FCL license or FAA pilot certificate holders.

6.2. Initial Confidence

Each Technical Agent has demonstrated to the other Technical Agent the effectiveness of its respective system for the regulatory oversight of activities covered under this Annex through initial confidence building activities. The Technical Agents have also demonstrated to each other the effectiveness of their quality audits and standardisation activities, including audits of Aviation Authorities, as referred to in paragraph 6.3.1.

6.3. Continued Confidence

6.3.1. The Technical Agents and Aviation Authorities shall continue to demonstrate to each other effective oversight as detailed in paragraph 6.1.1 of this Annex according to the relevant provisions of the TIP-L developed by the JACB.

(a) In particular, Technical Agents shall:

- (i) have the right to participate, as an observer, in each other's quality audits and standardisation inspections;
- (ii) make available to the other Technical Agent the reports from quality audits and standardisation inspections applicable to this Annex, as specified in the TIP-L; and
- (iii) assist each other in the resolution of audit and inspection findings impacting the implementation of this Annex, where relevant.

(b) In particular, the FAA and the Aviation Authorities shall:

- (i) allow quality audits and standardisation inspections as detailed in paragraph 6.3.1(a)(i) above;
- (ii) share relevant safety information and known limitations that may affect an Aviation Authority's or Technical Agent's capability to fully meet applicable international safety standards or any safety requirements established under the Agreement;
- (iii) subject to applicable laws and regulations on personal data protection, make available the relevant pilot licensing records and inspection reports including completed enforcement actions; and
- (iv) provide language interpretation assistance at the Aviation Authority's office during the review of records and documentation that are recorded in its national language, where necessary.

(c) The Technical Agents shall notify each other at the earliest opportunity in the event that a Technical Agent or an Aviation Authority is not able to meet a requirement in paragraph 6.3. If either Technical Agent believes that technical competency is no longer adequate, the Technical Agents shall consult each other and propose an action plan, including any necessary corrective activities, in order to address deficiencies.

(d) In the event that a Technical Agent or an Aviation Authority does not correct deficiencies within the timeframe specified in the action plan, either Technical Agent may refer the matter to the JACB.

(e) When a Party intends to suspend acceptance of findings or approvals made by a Technical Agent or an Aviation Authority, the Party shall promptly notify the other Party in accordance with Article 18.A of the Agreement.

7. FEES

Fees applied shall comply with Article 14 of the Agreement and with applicable statutory and regulatory requirements.

*Appendix 1***SPECIAL CONDITIONS****1. General Conditions**

- 1.1. The applicant shall submit an application for conversion of an EU Part-FCL license or an FAA pilot certificate according to this Annex in a standardised form and manner as specified in the TIP-L.
- 1.2. An applicant who holds an EU Part-FCL license or an FAA pilot certificate that carries a restriction or limitation may be denied application if a similar restriction or limitation is not available in the other system.

2. EU Special Conditions

To be approved in accordance with Part-FCL, pursuant to the terms of this Annex, the applicant shall comply with all of the following EU Special Conditions.

2.1. EU Special Conditions Applicable to the Issuance of an EU Part-FCL License for Airplanes (PPL(A)) and Associated Class and Night Ratings, as Applicable, on the Basis of an FAA Pilot Certificate

- 2.1.1. The applicant shall demonstrate or provide evidence that he/she has acquired language proficiency in accordance with FCL.055 of Part-FCL unless he/she holds an 'English Proficient' endorsement on the FAA pilot certificate. The 'English Proficient' endorsement shall be deemed to be equal to English language proficiency Level 4, as detailed in the TIP-L.
- 2.1.2. The applicant shall meet the EU medical requirements as stipulated in Commission Regulation (EU) No 1178/2011 applicable to the PPL(A).
- 2.1.3. The applicant shall complete a skill test, as detailed in the TIP-L, with an examiner qualified according to Part-FCL.
- 2.1.4. The applicant shall demonstrate to the examiner before the skill test that he/she has acquired an adequate level of the required theoretical knowledge, as detailed in the TIP-L, within the 24-calendar-month period preceding the month of application.
- 2.1.5. The applicant applying for a Part-FCL night rating shall provide evidence that he/she has fulfilled the night flying requirements set out in FCL.810 of Part-FCL. Night flying training experience may be credited, as detailed in the TIP-L.
- 2.1.6. The applicant applying for a single-pilot MEP class rating shall provide evidence that the requirements for the issuance of a MEP land class rating as stated in Part FCL Subpart H are fulfilled. In this case the skill test specified under paragraph 2.1.3 above shall be completed in a MEP land airplane. An applicant who has prior training and flight experience on MEP airplanes may be credited towards the requirements of Part-FCL Subpart H, as detailed in the TIP-L.
- 2.1.7. An Aviation Authority, upon converting an FAA pilot certificate in accordance with this Annex, shall enter the following statement in item VIII (or XIII) of the EU Part-FCL license: 'PPL(A) issued on the basis of the EU-US Agreement'.
- 2.2. EU Special Conditions Applicable to the Issuance of an EU PART-FCL Instrument Rating for Airplanes (IR(A)) on the Basis of an FAA Instrument Rating.
 - 2.2.1. The applicant shall demonstrate or provide evidence that he/she has acquired language proficiency in accordance with FCL.055 of Part-FCL unless he/she has an 'English Proficient' endorsement on the FAA pilot certificate. The 'English Proficient' endorsement shall be deemed to be equal to English language proficiency Level 4, as detailed in the TIP-L.

- 2.2.2. The applicant shall meet the EU medical requirements as stipulated in Commission Regulation (EU) No 1178/2011 applicable to the IR(A).
- 2.2.3. The applicant shall complete an IR(A) skill test, as detailed in the TIP-L, with an examiner qualified according to Part-FCL.
- 2.2.4. With regard to the demonstration of theoretical knowledge and as detailed in the TIP-L, if the applicant has a minimum experience of at least 50 hours of flight time under Instrument Flight Rules (IFR) as pilot in command on airplanes, he/she shall demonstrate to the examiner before the IR(A) skill test that he/she has acquired an adequate level of the required theoretical knowledge. In other cases, the applicant shall pass a written examination within the 24-calendar-month period preceding the month of application.
- 2.2.5. An applicant applying for an instrument rating for single-pilot MEP land airplanes shall provide evidence that the requirements for the issuance of an instrument rating for MEP land airplanes as stated in Part-FCL Subpart G are fulfilled. In this case the IR(A) skill test specified under paragraph 2.2.3 above shall be completed in a MEP land airplane. An applicant who has prior instrument training and flight experience on multi-engine airplanes may be credited towards the requirements of Part-FCL Subpart G, as detailed in the TIP-L.
- 2.2.6. As detailed in the TIP-L, an applicant applying for an instrument rating shall have completed acclimatisation flying in an EU Member State, within a training organisation approved in accordance with Commission Regulation (EU) No 1178/2011, before the IR(A) skill test is administered. The applicant is exempt from this requirement if he/she has prior experience of at least 50 hours of flight time under IFR as pilot in command on airplanes or prior experience of at least 10 hours of flight time under IFR as pilot in command on airplanes in any of the EU Member States or any European State that participates in EASA in accordance with Article 129 of Regulation (EU) No 2018/1139 of the European Parliament and of the Council (OJ L 212, 22.8.2018, p. 1-22).
- 2.2.7. An applicant who has obtained an EU Part-FCL instrument rating on the basis of this Annex shall be required to undergo the entire set of theoretical knowledge examinations according to FCL.025 and FCL.615 IR of Part-FCL prior to exercising his/her instrument rating privileges with an EU Part-FCL CPL, MPL or ATPL.
- 2.2.8. An applicant who has obtained an EU Part-FCL instrument rating on the basis of this Annex shall be required to undergo the entire set of theoretical knowledge examinations according to FCL.025 of Part-FCL before being given the full credit for the IR(A) in the different category of aircraft according FCL.035 of Part-FCL.
- 2.2.9. An Aviation Authority, upon converting an FAA pilot certificate in accordance with this Annex, shall enter the following statement in item VIII (or XIII) of the EU Part-FCL license: 'PPL(A) / IR(A) issued on the basis of the EU-US Agreement'.
3. FAA Special Conditions
- To be approved in accordance with 14 CFR Part 61, pursuant to the terms of this Annex, the applicant shall comply with all of the following FAA Special Conditions:
- 3.1. FAA Special Conditions Applicable to the Issuance of an FAA Pilot Certificate, Airplane Category Single-Engine Land Class Rating and Airplane Category Multi-Engine Land Class Rating on the Basis of an EU Part-FCL License.
- 3.1.1. The applicant shall be able to read, speak, write and understand the English language. A Part-FCL English language proficiency endorsement of Level 4 or higher shall be accepted as English proficient.
- 3.1.2. The applicant shall meet the FAA medical certificate requirements to exercise the privileges of an FAA pilot certificate, as prescribed in 14 CFR Part 61.

- 3.1.3. The applicant shall have passed the required knowledge test, as detailed in the TIP-L, within the 24-calendar-months period preceding the month of application.
 - 3.1.4. The applicant shall complete a flight review with an FAA certified flight instructor who holds appropriate FAA examining authority, as detailed in the TIP-L.
 - 3.1.5. An applicant applying for a multi-engine land rating shall provide evidence that he/she has fulfilled the requirements for the issuance of a multi-engine land rating as stated in 14 CFR Part 61. Training and experience on MEP land airplanes may be credited, as detailed in the TIP-L.
 - 3.2. FAA Special Conditions Applicable to the Issuance of an FAA Instrument-Airplane Rating on the Basis of an EU Part-FCL Instrument Rating.
 - 3.2.1. The applicant shall be able to read, speak, write and understand the English language. A Part-FCL English language proficiency endorsement of Level 4 or higher shall be accepted as English proficient.
 - 3.2.2. The applicant shall meet the FAA medical certificate requirements to exercise the privileges of an FAA pilot certificate, as prescribed in 14 CFR Part 61.
 - 3.2.3. As detailed in the TIP-L, an applicant applying for an instrument rating shall have completed acclimatisation flying in the United States, including its territories, with an FAA certified flight instructor, before the instrument proficiency check with an examiner is administered. The applicant is exempt from this requirement if he/she has prior experience of at least 50 hours of flight time under IFR as pilot in command on airplanes or prior experience of at least 10 hours of flight time under IFR as pilot in command on airplanes in the United States, including its territories;
 - 3.2.4. The applicant shall complete an instrument proficiency check with an examiner, as detailed in the TIP-L.
 - 3.2.5. The applicant shall have passed the required knowledge test, as detailed in the TIP-L, within the 24-calendar-month period preceding the month of application.
-

JOINT DECLARATION

Representatives of the United States of America and of the European Union confirmed that the Croatian language version of Annex 3 to the Agreement on Cooperation in the Regulation of Civil Aviation Safety between the United States of America and the European Community, signed in Brussels on 30 June 2008 (the 'Agreement'), can be authenticated by an exchange of diplomatic notes between the United States and the European Union.

They further confirmed that, as provided for by the Agreement, in the case of divergences of interpretation between the different language texts of the Agreement or of Annex 3 thereto, the English text prevails.

This Joint Declaration is an integral part of the Agreement.

For the United States of America

For the European Union

**BILATERAL OVERSIGHT BOARD FOR THE AGREEMENT BETWEEN THE UNITED STATES OF
AMERICA AND THE EUROPEAN COMMUNITY ON COOPERATION IN THE REGULATION OF
CIVIL AVIATION SAFETY**

RECORD OF DECISION

DECISION N°0011 [2022/646]

Noting that Amendment 1 to the Agreement between the United States of America and the European Community on Cooperation in the Regulation of Civil Aviation Safety (the 'Agreement') expands the scope of Article 2.B of the Agreement to include, *inter alia*, personnel licensing and training;

Further noting that Article 5 of the Agreement, as amended, provides for the development of new Annexes to the Agreement for matters within the scope of the Agreement, which are then, pursuant to Article 19.C, brought into force upon a decision of the Bilateral Oversight Board ('BOB') established pursuant to Article 3,

The BOB hereby decides as follows:

1. To adopt Annex 4 (Flight Simulation Training Devices) to the Agreement, as attached to this Decision in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish languages. In case of divergence of interpretation between the different language texts, the English text shall prevail.
2. To take note of the Joint Declaration to be signed by the Representatives of the Parties concerning the authentication of the Croatian language version of Annex 4.
3. Annex 4 (Flight Simulation Training Devices) to the Agreement shall enter into force on the date of the last signature below.

For the Bilateral Oversight Board:

FEDERAL AVIATION ADMINISTRATION
DEPARTMENT OF TRANSPORTATION
UNITED STATES OF AMERICA

EUROPEAN COMMISSION
EUROPEAN UNION

BY: Mr Ali BAHRAMI
TITLE: Associate Administrator for Aviation
Safety

BY: Mr Filip CORNELIS
TITLE: Director, Aviation
Directorate-General for Mobility and
Transport, European Commission

DATE: 19 November 2020

DATE: 19 November 2020

PLACE: Washington, DC

PLACE: Brussels, Belgium

ANNEX 4

FLIGHT SIMULATION TRAINING DEVICES**1. PURPOSE AND SCOPE**

- 1.1. The Parties have assessed each other's standards, rules, practices, and procedures relating to the recurrent evaluation and continuing qualification of Full Flight Simulators (FFS) for airplanes and concluded that they are sufficiently compatible to permit acceptance of each other's approvals and findings. This Annex covers the reciprocal acceptance of findings of compliance and documentation, and the provision of technical assistance regarding recurrent evaluation and qualification of FFS. Nothing in this Annex shall be construed to limit the authority of a Party to act in accordance with Article 15 of the Agreement.
- 1.2. The scope of this Annex covers recurrent evaluation and continuing qualification of level C, CG, D and DG FFS for airplanes that hold a qualification issued by the Federal Aviation Administration (FAA) and by the European Aviation Safety Agency (EASA) or an Aviation Authority, as applicable. This scope may be extended through an amendment to this Annex pursuant to a decision of the Bilateral Oversight Board (BOB) taken in accordance with Article 19.B of the Agreement.
- 1.3. The extension of the scope of this Annex shall take place following the necessary confidence building process conducted by the Technical Agents.
- 1.4. The scope of this Annex does not cover Flight Simulation Training Devices (FSTD) that are located outside the scope of applicability specified in Article 12 of the Agreement.

2. DEFINITIONS

- 2.1. For the purposes of this Annex, the following definitions apply, in addition to those definitions found in the Agreement:
 - (a) 'FFS Qualification Level' means the level of compliance based on the technical capability of the FFS as determined by an evaluation of the FFS against the established technical evaluation criteria as defined in the applicable requirements. FFS are categorised as level A, B, C, D. Additionally, some EU qualified devices hold qualification level AG, BG, CG, DG under Grandfather Rights.
 - (b) 'Finding' means a verification whether the FSTD is in compliance or non-compliance with the applicable requirements and which shall be recorded as results/discrepancies in the evaluation report compiled by the FAA, EASA, or an Aviation Authority, as applicable.
 - (c) 'Flight Simulation Training Device' (FSTD) means:
 - (i) For the European Union, a training device which is, in the case of airplanes, a full flight simulator (FFS), a flight training device (FTD), a flight and navigation procedures trainer (FNPT), or a basic instrument training device (BITD).
 - (ii) For the United States, a training device which is, in the case of airplanes, a full flight simulator (FFS) or a flight training device (FTD).
 - (d) 'Full Flight Simulator' (FFS) means a full-size replica of a specific type or make, model and series of aircraft flight deck/cockpit, including the assemblage of all equipment and computer programmes necessary to represent the aircraft in ground and flight operations, a visual system providing an out-of-the-flight deck/cockpit view, and a force cueing motion system.
 - (e) 'FSTD Evaluation' means the measure of the FSTD against the established technical criteria for the respective level leading to a FSTD qualification.

- (f) 'FSTD Operator' identifies the organisation directly responsible to EASA or an Aviation Authority, as applicable, for requesting and maintaining the qualification of a particular FSTD and which has to comply with Part-ORA requirements of Regulation (EU) No 1178/2011.
- (g) 'FSTD Sponsor' identifies the organisation directly responsible to FAA for requesting and maintaining the qualification of a particular FSTD and which has to comply with Title 14 of the United States Code of Federal Regulations, part 60 (hereinafter referred to as part 60) requirements.
- (h) 'Grandfather Rights' means:
 - (i) For the United States, the right of an FSTD operator/sponsor to retain the qualified level granted under a previous advisory circular.
 - (ii) For the European Union, the right of an FSTD operator/sponsor to retain the qualified level granted under a previous regulation. It also means the right for an FSTD user to retain the training, testing and checking credits that were gained under that previous regulation.
- (i) 'Master Qualification Test Guide' (MQTG) is the authority-approved Qualification Test Guide (QTG) that incorporates the results of tests witnessed by the FAA, EASA, or Aviation Authority, as applicable. The MQTG serves as a reference for future evaluations.
- (j) 'Qualification Test Guide' (QTG) means a document used to demonstrate that performance and handling qualities are within prescribed limits with those of the aircraft and that all applicable requirements have been met.
- (k) 'Special Conditions' means those requirements that have been found, based on a comparison of the respective regulatory systems related to evaluation and qualification of FFS, not to be common to both systems and which are significant enough to be addressed in this Annex.

3. JOINT COORDINATION BODY

3.1. Composition

3.1.1. The joint coordination body called the FSTD Oversight Board (FOB), accountable to the Bilateral Oversight Board, is hereby established under the joint leadership of the EASA Flight Standards Director and the FAA Executive Director of Flight Standards. The FOB shall include FSTD experts from each Technical Agent.

3.1.2. The joint leadership may invite additional participants to the FOB to facilitate the fulfilment of the objectives of this Annex.

3.2. Mandate

3.2.1. The FOB shall meet at least once a year to ensure the effective functioning and implementation of this Annex. The FOB functions include:

- (a) developing, approving, and revising the Technical Implementation Procedures - Simulator (TIP-S) for FFS evaluation and qualification, including cooperation, assistance, exchange of information, and continued confidence activities to be used for the processes covered by this Annex;
- (b) sharing information on relevant safety issues and developing action plans to address them;
- (c) ensuring the consistent application of this Annex;
- (d) exchanging information on planned and ongoing rulemaking activities that could affect the basis and the scope of the Annex;
- (e) sharing information on significant changes to the Parties' FSTD qualification systems that could affect the basis and the scope of the Annex;
- (f) resolving technical issues falling within the responsibilities of the Technical Agents and Aviation Authorities that cannot be solved at lower level; and
- (g) proposing to the BOB amendments to this Annex.

- 3.2.2. The FOB shall report unresolved issues to the BOB and ensure the implementation of decisions adopted by the BOB regarding this Annex.

4. IMPLEMENTATION

- 4.1. The Technical Agents shall, for monitoring purposes, establish and maintain a Master List of FFSs whose qualification falls within the scope of this Annex. The procedures to establish and maintain this Master List shall be detailed in the TIP-S.

4.2. FAA Continuing Qualification

- 4.2.1. The Parties agree that an FFS that:

- (a) holds a current qualification in accordance with the applicable EU qualification basis, and
- (b) complies with the conditions set forth in this Annex, including the FAA Special Conditions set forth in Appendix 1, notwithstanding part 60 Simulator Quality Management System requirements applicable to the FFS certificate holder,

shall be considered to meet the technical requirements for an FAA continuing qualification upon receipt, review and acceptance of the evaluation and special conditions reports issued by EASA or by an Aviation Authority, as applicable.

- 4.2.2. The competent Aviation Authorities shall carry out the actions defined in Appendix 2 of this Annex when acting on behalf of the FAA for the recurrent evaluation of each FFS covered under this Annex.

4.3. EASA Continuing Qualification

- 4.3.1. The Parties agree that an FFS that:

- (a) holds a current qualification by the FAA in accordance with the applicable U.S. qualification basis, and
- (b) complies with the conditions set forth in this Annex, including the EU Special Conditions set forth in Appendix 1, notwithstanding Part-ORA requirements applicable to the FSTD certificate holder,

shall be considered to meet the technical requirements for an EASA continuing qualification upon receipt, review and acceptance of the evaluation and special conditions reports issued by the FAA.

4.4. Mutual Acceptance of Evaluation Reports

- 4.4.1. Subject to the terms of this Annex, the Parties agree that the Technical Agents and the Aviation Authorities, as appropriate, shall provide to the Technical Agent of the other Party, FFS recurrent evaluation and special conditions reports. These reports shall include findings of compliance with the respective EU and U.S. requirements as the basis for issuance or continued validity of their respective FFS qualifications, as applicable.

4.5. Follow-up on Evaluation Report Findings

- 4.5.1. The FSTD operator/sponsor shall resolve findings with the Technical Agent or the Aviation Authority that conducted the evaluation unless otherwise instructed by the relevant Technical Agent for the cases defined in the TIP-S. In such cases, when an on-site visit is necessary to assess the closure of the finding, this on-site visit shall be conducted, as resources permit, by the Technical Agent or, where applicable, an Aviation Authority that conducted the evaluation.

- 4.6. When circumstances arise outside the scope of recurrent evaluations, each Party's Technical Agent, or where applicable an Aviation Authority, shall provide, as necessary, upon request and after mutual agreement, technical assistance in FFS evaluations to the other Party's Technical Agent, or where applicable to an Aviation Authority. The Technical Agents or an Aviation Authority may decline to provide such technical assistance due to lack of resource availability. Such areas of assistance may include, but are not limited to:
- (a) conducting and reporting on investigations upon request;
 - (b) obtaining and providing data where requested; and
 - (c) conducting a special evaluation of an FFS in the event of a relocation or a modification to the device.
- 4.7. In accordance with Article 15.B of the Agreement, the Technical Agents may conduct independent evaluations of devices in the event of specific safety concerns.
- 4.8. Revisions by either Party to its organisational structure, laws, regulations, procedures, policy, or standards, including those of the Technical Agents and Aviation Authorities, may affect the basis on which this Annex is executed. The Parties, through the Technical Agents and Aviation Authorities, as appropriate, shall advise one another of plans for such changes at the earliest possible opportunity, and discuss the extent to which such planned changes affect the basis of this Annex. If consultations pursuant to Article 15.C of the Agreement result in an agreement to amend this Annex, the Parties shall seek to ensure that such an amendment enters into force at the same time as, or as soon as possible thereafter, the entry into force or implementation of the change that prompted such amendment.
5. COMMUNICATION AND COOPERATION
- 5.1. The Technical Agents shall exchange and maintain a list of contact points for the various technical aspects of this Annex.
- 5.2. All communications, including technical documentation, between the Technical Agents, and where applicable the Aviation Authorities, shall be in the English language.
- 5.3. The format for all dates used in communications shall be DD MMM YYYY, e.g., '05 MAY 2014'.
- 5.4. The Technical Agents and the Aviation Authorities shall inform each other of exemptions and derogations granted to FFSs falling within the scope of this Annex.
- 5.5. Evaluation Instructions
- The Technical Agents and the Aviation Authorities shall submit for review any special instructions or requests to be completed during an evaluation at least 30 calendar days prior to the evaluation.
6. QUALIFICATION REQUIREMENTS FOR THE ACCEPTANCE OF FINDINGS OF COMPLIANCE
- 6.1. Basic Requirements
- 6.1.1. Each Technical Agent and Aviation Authority, as applicable, shall demonstrate to the other Technical Agent the effectiveness of its respective system for the regulatory oversight of FSTD. In order to carry out evaluations of FFSs on each other's behalf, the Technical Agents and the Aviation Authorities, as applicable, shall demonstrate effective and adequate:
- (a) legal and regulatory structure;
 - (b) organisational structure;
 - (c) resources, including sufficient qualified staff;
 - (d) training programme for their technical staff;

- (e) internal policies, processes and procedures including a quality system;
- (f) documentation and records;
- (g) oversight programme; and
- (h) authority on regulated entities and devices.

6.2. Initial Confidence

- 6.2.1. Each Technical Agent has demonstrated to the other Technical Agent the effectiveness of its respective system for the regulatory oversight of activities covered under this Annex through initial confidence building activities. The Technical Agents have also demonstrated to each other the effectiveness of their quality audits and standardisation activities, including audits of Aviation Authorities, as referred to in paragraph 6.3.1.

The EU Technical Agent shall, before an Aviation Authority starts carrying out evaluations of FFS on behalf of the U.S. Technical Agent, conduct an assessment of that Aviation Authority in accordance with the provisions of the TIP-S.

6.3. Continued Confidence

- 6.3.1. The Technical Agents and the Aviation Authorities shall continue to demonstrate effective oversight, as detailed in paragraph 6.1.1 in accordance with the relevant provisions of the TIP-S developed and approved by the FOB.

(a) In particular, Technical Agents and, as applicable, Aviation Authorities shall:

- (i) have the right to participate as observer: for EASA, to FAA quality audits and standardisation meetings; for the FAA, to EASA standardisation activities;
- (ii) ensure that FSTD operators/sponsors provide access to both Technical Agents for audits, evaluations and inspections, as applicable;
- (iii) make available the reports from audits, standardisation and mutual inspections applicable to this Annex;
- (iv) share relevant safety information and known limitations that may affect an Aviation Authority or Technical Agent's capability to fully meet applicable international safety standards or any safety requirements established under the Agreement;
- (v) make the appropriate personnel available to participate in audits and inspections applicable to this Annex;
- (vi) make available FSTD operators'/sponsors' records, including evaluation reports and Special Conditions reports;
- (vii) provide interpretive assistance at the Aviation Authorities' office during the review of FFS records and documentation that are recorded in its national language, where necessary; and
- (viii) assist each other in the closure of any findings from mutual inspections.

(b) The EU Technical Agent shall conduct supplemental standardisation audits to ensure the Aviation Authority's compliance with the terms of the Annex and, in particular, the FAA Special Conditions that are applicable to EU-based FFS, as specified in the TIP-S.

(c) The Technical Agents shall notify each other at the earliest opportunity in the event that a Technical Agent or an Aviation Authority is not able to meet a requirement in paragraph 6.3.1. If either Technical Agent believes that technical competency is no longer adequate, the Technical Agents shall consult and propose an action plan, including any necessary corrective activities, in order to address deficiencies.

(d) In the event that a Technical Agent or an Aviation Authority does not correct deficiencies within the timeframe specified in the action plan, either Technical Agent may refer the matter to the FOB.

(e) When a Party intends to suspend acceptance of findings or qualifications made by a Technical Agent or Aviation Authority within the scope of this Annex, the Party shall promptly notify the other Party in accordance with Article 18.A of the Agreement.

7. INVESTIGATION AND ENFORCEMENT ACTION

- 7.1. The Parties retain the right to take enforcement actions against the operators/sponsors of FSTDs that have FAA or EASA approvals
- 7.2. In accordance with the provisions of Article 8 of the Agreement, each Party, through its Technical Agent and, where applicable, the Aviation Authorities, shall notify the other promptly of any investigation and subsequent closure actions for non-compliance within the scope of this Annex, when the non-compliance could result in a penalty, revocation, suspension or downgrade of the FFS qualification.
- 7.3. In the event of a revocation or suspension of an FFS qualification, the Technical Agent and, where applicable, an Aviation Authority shall notify the other Technical Agent of the revocation or suspension.
- 7.4. The above notifications shall be sent to the other Party's appropriate contact point.

8. TRANSFER PROVISIONS

- 8.1. Recurrent evaluations for FFS whose qualifications were issued by the FAA under the provisions defined in the U.S. - UK Simulator Implementation Procedures (SIP) shall continue to be conducted until the transition of evaluation activities as defined in paragraph 8.2 has been completed. (The U.S. - UK SIP, which was agreed on December 20, 1995, was revised on October 6, 2005. It was concluded pursuant to the Agreement between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland for Promotion of Aviation Safety, signed at London on December 12, 1995.)
- 8.2. The Parties agree that the transfer of the FFS evaluations under this Annex shall be accomplished in accordance with the following transfer provisions:
 - (a) An Aviation Authority and the Technical Agents shall complete training of sufficient personnel regarding procedures relating to the Agreement, this Annex, and the EU and U.S. Special Conditions, as applicable, prior to the transfer.
 - (b) Once a sufficient number of staff has completed the training, the Technical Agents shall transfer evaluation activities of qualified FFS to the Technical Agents or the Aviation Authorities, as applicable.
 - (c) The transfers shall take place within 18 months of the date of the entry into force of this Annex.
 - (d) The Technical Agents and the Aviation Authorities shall agree on a procedural plan and time schedule for:
 - (i) synchronising recurrent evaluations, and
 - (ii) conducting all evaluations in accordance with this Annex.

9. FEES

- 9.1. Fees shall be applied in accordance with Article 14 of the Agreement and in accordance with applicable regulatory requirements.
-

*Appendix 1***SPECIAL CONDITIONS****1. EU SPECIAL CONDITIONS APPLICABLE TO U.S.-BASED FULL FLIGHT SIMULATORS (FFS) IN THE AIRPLANE AIRCRAFT CATEGORY****1.1. The special conditions referred to in paragraph 4.3.1, as detailed in the TIP-S, are the following:**

- (a) The FSTD sponsor shall provide to the FAA the following:
 - (i) recurrent evaluation dossier;
 - (ii) annual fly-out records;
 - (iii) simulator safety features check records (ORA.FSTD.115 (b) Installations of Regulation (EU) 1178/2011); and
 - (iv) changes to the published EASA FSTD datasheet.
- (b) The instructor operating station manual shall include operating instructions with EU standards.
- (c) Instructor operating station settings and indications shall conform to the International System of Units (SI).
- (d) At least one declared qualification European airport/airfield model featuring proper modelling and navigation/communication facilities shall be evaluated.
- (e) Category I, II, or III (as applicable) instrument approaches and low visibility take-off operations shall be demonstrated at a European airport and with corresponding settings selectable from the instructor operating station.
- (f) The FFS shall reflect the European configuration of the simulated airplane.
- (g) A continuous, uninterrupted flight phase shall be conducted during the evaluation.
- (h) All engine fits listed in the EASA FFS qualification certificate shall be evaluated during each evaluation.
- (i) When several EASA FFS qualification certificates are issued for several avionics configuration of a single FFS, each configuration – with each engine fit if applicable – shall be evaluated during each evaluation.
- (j) FFS-specific objective, functional and subjective tests as per applicable European requirements that are not covered by the applicable FAA FFS standard level of qualification shall be performed.

2. FAA SPECIAL CONDITIONS APPLICABLE TO EU BASED APPROVED FULL FLIGHT SIMULATORS (FFS) IN THE AIRPLANE AIRCRAFT CATEGORY**2.1. The special conditions referred to in paragraph 4.2.1, as detailed in the TIP-S, are the following:**

- (a) The FSTD operator shall:
 - (i) provide to the Aviation Authority or EASA, as applicable, evidence that FAA FSTD directives have been incorporated into the MQTG, and
 - (ii) identify any changes to the published FAA FFS configuration list.
- (b) The instructor operating station manual shall include operating instructions with U.S. standards.
- (c) Instructor operating station settings and indications shall conform to the U.S. units of measurement.
- (d) At least one declared qualification U.S. airport/airfield model featuring proper modelling and navigation/communication facilities shall be evaluated.
- (e) Category I, II, or III (as applicable) instrument approaches shall be demonstrated at a U.S. airport and with corresponding settings selectable from the instructor operating station.

- (f) The FFS shall reflect the U.S. configuration of the simulated airplane.
 - (g) All configurations listed in the FAA FFS qualification certificate shall be evaluated during each evaluation.
 - (h) A circling approach to a U.S. airport at the maximum demonstrated landing weight shall be conducted.
 - (i) FFS-specific objective, functional, and subjective tests as per applicable U.S. requirements that are not covered by the applicable European FFS standard level of qualification shall be performed.
-

*Appendix 2***AVIATION AUTHORITY ACTIONS**

The competent Aviation Authority acting on behalf of the FAA shall carry out the following actions for the recurrent evaluations of each FFS covered under this Annex, as detailed in the TIP-S:

1. Schedule the recurrent evaluation and provide the scheduled date for the evaluation to the FAA.
 2. Perform evaluation preparation. The evaluating Aviation Authority inspector(s) shall:
 - (a) identify the special conditions;
 - (b) obtain the appropriate forms and checklists; and
 - (c) identify any modifications that have occurred between recurrent evaluations.
 3. Perform the evaluation, taking the special conditions and the relevant TIP-S provisions into account.
 4. Perform post evaluation activities to include:
 - (a) Transmitting the following information/documents to the FAA within five working days following completion of the evaluation:
 - (i) evaluation report;
 - (ii) FFS configuration list; and
 - (iii) special Conditions report.
 - (b) Performing the on-site visit referred to in paragraph 4.5.1. of this Annex.
-

JOINT DECLARATION

Representatives of the United States of America and of the European Union confirmed that the Croatian language version of Annex 4 to the Agreement on Cooperation in the Regulation of Civil Aviation Safety between the United States of America and the European Community, signed in Brussels on 30 June 2008 (the 'Agreement'), can be authenticated by an exchange of diplomatic notes between the United States and the European Union.

They further confirmed that, as provided for by the Agreement, in the case of divergences of interpretation between the different language texts of the Agreement or of Annex 4 thereto, the English text prevails.

This Joint Declaration is an integral part of the Agreement.

For the United States of America

For the European Union

DECISION OF THE EU/ICAO JOINT COMMITTEE**of 10 March 2022****on the adoption of a Working Arrangement between the European Union and the International Civil Aviation Organization regarding the cooperation in the area of accident and incident reporting in civil aviation (2022/647)**

THE EU/ICAO JOINT COMMITTEE,

Having regard to the Memorandum of Cooperation between the European Union and ICAO providing a framework for enhanced cooperation, signed at Montréal and Brussels on 28 April and 4 May 2011 (MoC), and in particular its Articles 3.3 and 7.3(c);

Having regard to the Annex on Aviation Safety to the MoC, and in particular its Article 3.1;

Having regard to the ICAO Global Aviation Safety Plan (GASP) (ICAO Doc 10004) and the global safety initiatives (GSI);

Having regard to the Global Aviation Safety Roadmap (GASR, 2006) regarding the implementation of international sharing of data/global data reporting system;

Having regard to Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 ⁽¹⁾;

Having regard to Regulation (EU) No 996/2010 of the European Parliament and of the Council (EU) of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC ⁽²⁾;

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽³⁾,

Considering that the definitions of ICAO Accident/Incident Data Reporting (ADREP) taxonomy are primarily based on ICAO Standards and Recommended Practices (SARPs), manuals and guidance material;

Considering that there is a need amongst the ADREP and the European Coordination Centre for Accidents and Incident Reporting System (ECCAIRS) users in ICAO Member States to further utilise information derived from data collection, analysis and sharing to identify safety threats and contributing factors on a global scale;

Considering that the safety of air navigation and harmonisation progress of international civil aviation rely on recognised standards such as the ADREP system and recognising the importance of mutual assistance and cooperation in the field of safety management and data base systems;

⁽¹⁾ OJ L 122, 24.4.2014, p. 18.

⁽²⁾ OJ L 295, 12.11.2010, p. 35.

⁽³⁾ OJ L 212, 22.8.2018, p. 1.

Considering the obligation within the European Union of the European Union Aviation Safety Agency (EASA) to assist the European Commission in the management of the European Central Repository that stores all occurrence reports collected in the European Union, and in particular its task to develop and maintain a new version of the ECCAIRS software suite called ECCAIRS 2;

Considering that EASA has taken over all the functions that the European Commission Directorate-General of the Joint Research Centre (JRC) currently performs in relation to the ECCAIRS software suite as of 1 January 2021;

Considering that it is therefore necessary to replace the Working Arrangement done at Montréal on 21 September 2011 regarding the cooperation in the area of accident and incident reporting in civil aviation;

HAS ADOPTED THIS DECISION:

Article 1

The Working Arrangement annexed to this Decision is hereby adopted, and replaces the Working Arrangement done at Montréal on 21 September 2011 regarding the cooperation in the area of accident and incident reporting in civil aviation.

Article 2

This Decision shall enter into force on the day of its adoption.

For the EU/ICAO Joint Committee:
The Chairpersons [only signatures]

ATTACHMENT TO THE DECISION OF THE EU/ICAO JOINT COMMITTEE OF 10 MARCH 2022

**WORKING ARRANGEMENT BETWEEN THE INTERNATIONAL CIVIL AVIATION
ORGANIZATION AND THE EUROPEAN UNION**

**REGARDING THE COOPERATION IN THE AREA OF ACCIDENT AND INCIDENT REPORTING IN
CIVIL AVIATION**

This Working Arrangement contains mutually agreed mechanisms and procedures necessary to effectively implement cooperation activities between the International Civil Aviation Organization (ICAO) and the European Union (EU).

ICAO and the EU are hereinafter referred to individually as the 'Party' or collectively as the 'Parties'.

1. OBJECTIVE OF THE WORKING ARRANGEMENT

1.1. This Working Arrangement, which comes under purview of the Memorandum of Cooperation (MoC) and its Annex on Aviation Safety, in particular Articles 3.3 and 7.3(c) of the MoC, has the objective to implement cooperation between the Parties aimed at supporting and promoting, where possible, each other's activities in the area of accident and incident reporting in civil aviation.

1.2. In order to achieve the objectives of this Working Arrangement, the Parties agree on the following general approach:

- a) For the effective implementation of this Working Arrangement, the EU designates the European Union Aviation Safety Agency (EASA) ⁽¹⁾ as its 'technical agent'.
- b) EASA will promote the usage of ICAO's Accident/Incident Data Reporting (ADREP) taxonomy as the standard for reporting and exchanging accident and incident information within the European Union Member States, European Economic Area (EEA) States and Switzerland.
- c) The ICAO will promote the usage of the EU's ECCAIRS 2 software suite of applications for the collection of accident and incident information to the ICAO Member States.
- d) In relation to the use of the ECCAIRS 2 software suite, the ICAO and EASA will coordinate the sharing and harmonizing of their training and supporting efforts and material for the benefit of all ECCAIRS end-users.
- e) ICAO and EASA will collaborate on the establishment of a global, and accessible central accident and incident database using ECCAIRS 2 software. The database will be operated in accordance with the relevant information system security policies in force.

2. SPECIFIC ACCOMMODATION BETWEEN THE PARTIES

2.1. In order to promote the usage of the ADREP taxonomy, see point 1.2 b) above, the Parties agree on the following:

- a) ICAO is the owner and the responsible Party for the development and active maintenance of the ADREP taxonomy.
- b) ICAO and the ECCAIRS Taxonomy Working Group coordinate and work in close cooperation to ensure a consistent evolution and implementation of the ADREP taxonomy including in the ECCAIRS Reporting System.
- c) ICAO will publish on its website the ADREP taxonomy as a formal ICAO document and will update this document when necessary.
- d) ICAO's ADREP taxonomy is the basis for the aviation accident and incident reporting approach as defined in Regulation (EU) No 376/2014. Changes in the ICAO ADREP taxonomy will, in principle, be integrated in the ECCAIRS aviation software releases.

⁽¹⁾ <https://www.easa.europa.eu/>

- e) EASA will continue to encourage EU Member States, European Economic Area (EEA) States and Switzerland to use the ECCAIRS Reporting System for reporting their accidents and incidents electronically to ICAO as per the provisions set forth in Annex 13 – *Aircraft Accident and Incident Investigation*.
- f) EASA and the competent authorities of the EU Member States, the EEA States and Switzerland can use the ADREP taxonomy in the ECCAIRS 2 Reporting System and related tools free of charge.
- g) EASA can provide a link to the ADREP taxonomy on the ICAO website to the ECCAIRS community via the ECCAIRS 2 community web portal.
- h) ICAO will invite EASA to participate in Secretariat meetings or groups set up for the purpose of developing taxonomies and/or addressing issues with respect to the use of ADREP (e.g. interoperability, modelling, testing new technologies and further development of reporting tools, methods and support).
- i) ICAO can use the ECCAIRS 2 logo in conjunction with ADREP.

2.2. In order to promote the usage of the ECCAIRS 2, see point 1.2 c) above, the Parties agree on the following:

- a) EASA is responsible for the development and active maintenance of the ECCAIRS 2 system comprised of database and software;
- b) ICAO acknowledges ECCAIRS 2 as, in principle, aimed to be compatible with ADREP.
- c) ICAO is using the ECCAIRS 2 software and related tools for implementing ICAO's ADREP system. ICAO may use the ECCAIRS 2 system, free of charge for their own needs, including the data collection of Annex 13 – *Aircraft Accident and Incident Investigation* (Accidents & Incidents) and other potential safety data collection processes, such as the IBIS-birdstrike collection or future relevant occurrence reporting.
- d) ICAO recommends to the ICAO Member States to use the ECCAIRS 2 system, for reporting their accidents and incidents electronically to ICAO as per the provisions of ICAO Annex 13 – *Aircraft Accident and Incident Investigation*. If an ICAO Member State does so, the ECCAIRS 2 solution, its maintenance and support will be free of charge.
- e) ICAO will be invited to participate in the ECCAIRS Steering Committee with the same rights extended to committee members by the Terms of Reference of the Steering Committee.
- f) The ICAO Secretariat recommends to the ICAO Member States the usage of the ECCAIRS 2 system, comprised of database and software, and run by EASA, as the method to capture and maintain their national repository of aviation accidents and incidents. If an ICAO State wishes to use the ECCAIRS 2 system, then EASA will engage in setting up an agreement with those States.

2.3. In order to harmonise and share efforts in training and support, see point 1.2 d) above, the Parties agree to the following:

- a) In principle, EASA is responsible for the coordination of ECCAIRS 2-related training and providing support to EU Member States, EEA States and Switzerland, international organisations, and all States with whom EASA collaborates under the International Cooperation programme of EASA.
- b) In principle, ICAO is responsible for the coordination of ECCAIRS 2-related training and providing support to parties not mentioned in point (a).
- c) Where possible, taking into account its resources and the priority of EASA referred to in point (a), EASA will assist ICAO in its tasks, presuming that travelling costs and daily allowances (following ICAO internal procedures) will be covered by ICAO.
- d) In relation to the use of the ECCAIRS 2 software suite, ICAO and EASA will endeavour to share their training and support material for the benefit of the ECCAIRS community.
- e) When relevant, ICAO and EASA will endeavour to cooperate with third parties in terms of ADREP/ECCAIRS training and support.

- f) The ECCAIRS 2 Central Hub, which is used to coordinate training and support activities of the ECCAIRS 2 solution, is accessible to competent authorities of ICAO Member States after an appropriate online registration has taken place.

2.4. In order to collaborate on the establishment of the ECCAIRS 2 database, the Parties agree to the following:

- a) In principle, EASA is responsible for the installation and maintenance of the ECCAIRS 2 system, comprised of database and software.
- b) In principle, ICAO is responsible for managing the access rights to the ECCAIRS 2 system for all Member States except EU Member States, EEA States and Switzerland
- c) EASA agrees to provide the infrastructure related to the al ECCAIRS 2 system, comprised of database and software, free of charge to ICAO and the ICAO Member States for them to use the system as their accident and incident reporting database as per ICAO Annex 13 – *Aircraft Accident and Incident Investigation*.
- d) It is agreed that access to and the sharing of data stored in the ECCAIRS 2 database will be subject to the confidentiality provisions set out in Article 6 of the MoC, as well as the protection of accident and incident investigation records set forth in Annex 13 – *Aircraft Accident and Incident Investigation*.
- e) ICAO and EASA shall obtain the express written consent of the concerned State to access any other data that may be stored in the ECCAIRS 2 system and that does not fall within the scope of point (d)
- f) ICAO and EASA will collaborate on improving the quality of the data by researching solutions supporting central classification service and automated quality control processes to all users.

3. MANAGEMENT

- 3.1. ICAO and EASA shall each designate points of contact to serve as coordinators with responsibility for joint activities. The coordinators may nominate other staff members to represent them or to attend meetings.
- 3.2. Correspondence on all practical matters related to this Working Arrangement shall be between the coordinators.
- 3.3. The Parties will, as necessary, hold meetings to consider the progress of cooperation activities in accordance with this Working Arrangement.

4. FUNDING

- 4.1. Except where otherwise specifically agreed by the Parties through separate arrangements, each Party bears the cost of any expenditure it incurs relating to the performance of its tasks under this Working Arrangement.
- 4.2. All activities conducted pursuant to this Working Arrangement shall be subject to the availability of appropriate funds, personnel and other resources as well as to the applicable laws and regulations, policies and programmes of each Party.

5. INTELLECTUAL PROPERTY

- 5.1. The ADREP taxonomy is and remains intellectual property of ICAO.
- 5.2. The ECCAIRS 2 system and related software tools are and remain intellectual property of the EU.
- 5.3. The Parties are not responsible for the quality or the quantity of the data collected.

5.4. Each Party acknowledges the ownership and all rights in and to its copyrights, trademarks, name, logos and any other intellectual property. Either Party's use of the other Party's intellectual property is subject to the other Party's prior written approval. If such approval is given, the usage shall be on a non-exclusive basis and the Party using the intellectual property of the other Party shall strictly comply in good faith with the written instructions of the other Party and with its guidelines and specifications.

6. AMENDMENTS AND TERMINATION

6.1. This Working Arrangement may be modified or amended by a decision of the EU/ICAO Joint Committee.

6.2. This Working Arrangement may be terminated at any time by either Party giving six (6) months' notice in writing to the other Party.

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