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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/2222

of 30 September 2021

supplementing Regulation (EU) 2019/818 of the European Parliament and of the Council with detailed rules on the operation of the central repository for reporting and statistics

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration and amending Regulations (EU) 2018/1726, (EU) 2018/1862 and (EU) 2019/816 ⁽¹⁾, and in particular Article 39(5) thereof,

Whereas:

- (1) Regulation (EU) 2019/818, together with Regulation (EU) 2019/817 of the European Parliament and of the Council ⁽²⁾, establishes a framework to ensure interoperability between the EU information systems in the field of borders, visa, police and judicial cooperation, asylum and migration.
- (2) That framework includes a number of components and tools supporting interoperability, including a central repository for reporting and statistics ('the central repository'). The central repository stores anonymised data extracted from the underlying EU information systems, the shared biometric matching service, the common identity repository and the multi-identity detector, in order to provide cross-system statistical reporting for policy, operational and data quality purposes.
- (3) The European Agency for the Operational Management of Large-scale IT Systems in the Area of Freedom, Security and Justice ('eu-LISA') is responsible for establishing, implementing and hosting the central repository and for its operational management.
- (4) In order to enable the central repository to provide cross-system statistical data, it is necessary to lay down detailed rules on its operation, including specific standards for the processing of personal data, and security rules.
- (5) In order to make it impossible to identify individuals from the statistical data in the central repository, eu-LISA should develop a data anonymisation tool as part of its architecture. The anonymisation process should be automated.
- (6) Controlled and secured access should be granted only to authorised staff of the competent authorities, Union institutions and agencies, so that they can consult the data and statistics in the central repository. For that purpose, eu-LISA should develop a reporting tool as part of its architecture. eu-LISA staff should not have direct access to any personal data stored in the EU information systems or the interoperability components.
- (7) In order to keep trace of the cross-matching of identity files within or between the corresponding EU information systems for relevant statistical purposes, the central repository should keep a unique reference number. It should not be possible to use that number to retrieve information from the identity files.

⁽¹⁾ OJ L 135, 22.5.2019, p. 85.

⁽²⁾ Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa and amending Regulations (EC) No 767/2008, (EU) 2016/399, (EU) 2017/2226, (EU) 2018/1240, (EU) 2018/1726 and (EU) 2018/1861 of the European Parliament and of the Council and Council Decisions 2004/512/EC and 2008/633/JHA (OJ L 135, 22.5.2019, p. 27).

- (8) The technical solution hosting the central repository should be implemented at eu-LISA's technical site and at the backup site in order to ensure it remains available at all times.
- (9) Given that Regulation (EU) 2019/818 builds upon the Schengen *acquis*, in accordance with Article 4 of Protocol No 22 on the Position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark notified the implementation of Regulation (EU) 2019/818 in its national law. It is therefore bound by this Regulation.
- (10) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part ⁽³⁾. Ireland is therefore not taking part in the adoption of this Regulation and is not bound by it or subject to its application.
- (11) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* ⁽⁴⁾, which fall within the area referred to in Article 1, point A of Council Decision 1999/437/EC ⁽⁵⁾.
- (12) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁶⁾, which fall within the area referred to in Article 1, point A of Decision 1999/437/EC, read in conjunction with Article 3 of Council Decision 2008/146/EC ⁽⁷⁾.
- (13) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁸⁾ which fall within the area referred to in Article 1, point A of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU ⁽⁹⁾.
- (14) As regards Cyprus, Bulgaria and Romania and Croatia, this Regulation constitutes an act building upon, or otherwise relating to, the Schengen *acquis* within the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.

⁽³⁾ This Regulation falls outside the scope of the measures provided for in Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

⁽⁴⁾ OJ L 176, 10.7.1999, p. 36.

⁽⁵⁾ Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

⁽⁶⁾ OJ L 53, 27.2.2008, p. 52.

⁽⁷⁾ Council Decision 2008/146/EC of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

⁽⁸⁾ OJ L 160, 18.6.2011, p. 21.

⁽⁹⁾ Council Decision 2011/350/EU of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

- (15) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽¹⁰⁾ and delivered an opinion on 17 June 2021,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'statistical data' means the data, which is anonymised and used solely for the purpose of producing statistical reports pursuant to Regulation (EU) 2017/2226 ⁽¹¹⁾, Regulation (EU) 2018/1240 ⁽¹²⁾, Regulation (EU) 2018/1860 ⁽¹³⁾, Regulation (EU) 2018/1861 ⁽¹⁴⁾, Regulation (EU) 2018/1862 ⁽¹⁵⁾ and Regulation (EU) 2019/816 ⁽¹⁶⁾ of the European Parliament and of the Council;
- (2) '(statistical) reports' means an organised collection of statistical data, produced by the central repository in an automated manner according to a set of pre-established rules and stored in the central repository;
- (3) 'customisable reports' means statistical reports that are extracted on the basis of statistical data contained in the central repository in accordance with specific rules determined ad hoc by a user and stored in the central repository;
- (4) 'critical identity data' means any of the following data or a combination thereof, from which individuals can be identified:
 - (a) name, first name, surname, family name, given names, alias of any person whose data may be stored in any EU information system;
 - (b) number of travel document;
 - (c) address (street name, house number);
 - (d) telephone, IP address;
 - (e) email addresses;
 - (f) biometric data.

⁽¹⁰⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁽¹¹⁾ Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).

⁽¹²⁾ Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).

⁽¹³⁾ Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).

⁽¹⁴⁾ Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14).

⁽¹⁵⁾ Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).

⁽¹⁶⁾ Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).

*Article 2***Information to be contained in the central repository**

1. The data referred to in Article 39(2) of Regulation (EU) 2019/818 shall be made available and stored in the central repository in accordance with this Regulation.
2. The central repository shall contain statistical data, including reports on system usage for the purposes of monitoring the functioning of the interoperability components referred to in Article 62 of Regulation (EU) 2019/818.
3. The central repository shall contain technical reports to ensure monitoring by eu-LISA of the development and functioning of the interoperability components in accordance with Article 74(1) of Regulation (EU) 2019/818.
4. The central repository shall keep a unique reference number enabling to keep trace of the cross-matching of identity files within or between the corresponding EU information systems for statistical purposes. It shall not be possible to use that reference number to retrieve the underlying identity files.
5. The central repository shall enable the duly authorised staff of the competent authorities referred to in Article 39(2) of Regulation (EU) 2019/818 to obtain the following:
 - (a) reports pursuant to Article 74 of Regulation (EU) 2018/1862, containing the following statistics on records kept in the Schengen Information System:
 - (i) daily, monthly and annual statistics showing the number of records per category of alerts, both for each Member State and in aggregate, pursuant to Article 74(3) of that Regulation;
 - (ii) annual reports on the number of hits per category of alert, how many times the Schengen Information System was searched and how many times it was accessed for the purpose of entering, updating or deleting an alert, both for each Member State and in aggregate, pursuant to Article 74(3) of that Regulation;
 - (iii) at the request of the Commission, additional specific statistical reports, either on a regular or ad hoc basis, on the performance and the use of the Schengen Information System and on the exchange of supplementary information, pursuant to Article 74(6), second subparagraph of that Regulation;
 - (iv) At the request of the European Border and Coast Guard Agency, additional specific statistical reports, either on a regular or ad hoc basis, for the purpose of carrying out risk analyses and vulnerability assessments, pursuant to Article 74(6), third subparagraph of that Regulation;
 - (v) reports and statistics for the purposes of technical maintenance, reporting, data quality reporting and statistics pursuant to Article 74(2) of that Regulation;
 - (vi) data quality reports in accordance with pursuant to Article 15(4) of that Regulation.
 - (b) reports pursuant to Article 32 of Regulation (EU) 2019/816, containing the following statistics on the records kept in the European Criminal Records Information System for third-country nationals (ECRIS-TCN) and the ECRIS reference implementation:
 - (i) customisable reports and statistics relating to the recording, storage and exchange of information extracted from criminal records through the European Criminal Records Information System for third-country nationals;
 - (ii) reports and statistics for the purposes of technical maintenance, data quality reporting and statistics pursuant to Article 32(3) of that Regulation.
6. The technical reports referred to in paragraph 2 shall contain statistics on the usage of the system, availability, incidents, performance capacity, biometric accuracy, data quality and, where applicable, pending transactions.
7. The business reports produced by the central repository shall be customisable by the user in order to allow the filtering or grouping of the data by means of a reporting tool made available with the central repository.
8. A catalogue of reports shall be made available. Requests for new reports or changes to existing ones shall follow eu-LISA change management policy.

*Article 3***Data repository and reporting tool**

1. The central repository shall use a technical solution hosting data extracted from the underlying EU information systems and interoperability components.
2. The technical solution shall contain a reporting tool configured to create, maintain and execute the reports and customisable reports referred to in Article 2.
3. The reporting tool shall allow for the generation of business reports and technical reports, and their retrieval by the user.
4. The reporting tool shall enable the provision of cross-system statistical data and analytical reporting for policy, operational and data quality purposes, where provided for by Union law.
5. All reports shall be managed within the technical solution. The appropriate security and integrity measures shall be implemented in the technical solution, in order to meet the requirements of the security plan provided for Article 42(3) of Regulation (EU) 2019/818.
6. The technical solution shall be implemented at eu-LISA's technical site and at the backup site.

*Article 4***Data extraction**

The central repository shall obtain, from the EU information systems, read-only copies of the data referred to in Article 39(2) and Article 62(1), (2) and (3) of Regulation (EU) 2019/818, in order to produce the statistics and reports referred to in Articles 39 and 62 of that Regulation. The data shall be obtained on a regular basis and at least daily, by means of one-way extraction.

*Article 5***Data anonymisation tool**

1. The data extracted from the underlying EU information systems and interoperability components shall be anonymised using a data anonymisation tool. Only anonymised data shall be stored in the central repository.
2. The data anonymisation tool shall identify critical identity data in the EU information systems and shall anonymise it by means of an automated process before statistical data is stored in the central repository. The anonymisation process shall be irreversible.

*Article 6***Access**

1. Access to the central repository by duly authorised staff shall be granted and managed in accordance with Article 74 of Regulation (EU) 2018/1862 and Article 32 of Regulation (EU) 2019/816.
2. The central repository shall be accessible by the Member States, the Commission and the Union agencies, in accordance with their access rights under Union law, via a secure network connection (TESTA).
3. Only duly authorised staff of the competent authorities in accordance with Article 39(2) and Article 62(1) to (5) of Regulation (EU) 2019/818 shall be granted access to the tool referred to in Article 3(2) of this Regulation.

4. Competent authorities shall access the central repository by means of user profiles. eu-LISA shall keep a list of the user profiles. One authority may have several profiles, depending on its access rights.
5. Access to the central repository shall be logged. The information logged shall contain at least:
 - (a) a timestamp;
 - (b) authority;
 - (c) type of the report concerned.
6. Logs enabling the identification of users accessing the central repository shall be kept at national level and by the Commission, the European Border and Coast Guard Agency and Europol. eu-LISA shall keep logs of all accessing operations. The logs shall be stored in the central repository for one year, after which they shall be automatically erased.
7. Any conflicting roles within the central repository shall be identified and access shall be granted in accordance with the following principles:
 - (a) 'need-to-know';
 - (b) least privilege access;
 - (c) segregation of duties.
8. Data quality reports issued pursuant to Article 15(4) of Regulation (EU) 2018/1862 shall include a tool for Member States to provide eu-LISA with feedback on the correction of the issues encountered.

Article 7

Data processor

For the purpose of anonymising personal data pursuant to Article 5, eu-LISA shall be the data processor within the meaning of Article 3, point (12) of Regulation (EU) 2018/1725.

Article 8

Other data protection and security aspects

1. The data stored in the central repository shall be consulted solely for the purpose of reporting and statistics.
2. eu-LISA shall implement the necessary security measures to ensure the integrity of data in the central repository. Any changes to the data shall be traceable for auditing purposes.

Article 9

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 30 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/2223**of 30 September 2021****supplementing Regulation (EU) 2019/817 of the European Parliament and of the Council with detailed rules on the operation of the central repository for reporting and statistics**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa and amending Regulations (EC) No 767/2008, (EU) 2016/399, (EU) 2017/2226, (EU) 2018/1240, (EU) 2018/1726 and (EU) 2018/1861 of the European Parliament and of the Council and Council Decisions 2004/512/EC and 2008/633/JHA⁽¹⁾, and in particular Article 39(5) thereof,

Whereas:

- (1) Regulation (EU) 2019/817 together with Regulation (EU) 2019/818 of the European Parliament and of the Council⁽²⁾, establishes a framework to ensure interoperability between the EU information systems in the field of borders, visa, police and judicial cooperation, asylum and migration.
- (2) That framework includes a number of components and tools supporting interoperability, including a central repository for reporting and statistics ('the central repository'). The central repository stores anonymised data extracted from the underlying EU information systems, the shared biometric matching service, the common identity repository and the multi-identity detector, in order to provide cross-system statistical reporting for policy, operational and data quality purposes.
- (3) The European Agency for the Operational Management of Large-scale IT Systems in the Area of Freedom, Security and Justice ('eu-LISA') is responsible for establishing, implementing and hosting the central repository and for its operational management.
- (4) In order to enable the central repository to provide cross-system statistical data, it is necessary to lay down detailed rules on its operation, including specific standards for the processing of personal data, and security rules.
- (5) In order to make it impossible to identify individuals from the statistical data in the central repository, eu-LISA should develop a data anonymisation tool as part of its architecture. The anonymisation process should be automated.
- (6) Controlled and secured access should be granted only to authorised staff of the competent authorities, Union institutions and agencies, so that they can consult the data and statistics in the central repository. For that purpose, eu-LISA should develop a reporting tool as part of its architecture. eu-LISA staff should not have direct access to any personal data stored in the EU information systems or the interoperability components.
- (7) In order to keep trace of the cross-matching of identity files within or between the corresponding EU information systems for relevant statistical purposes, the central repository should keep a unique reference number. It should not be possible to use that number to retrieve information from the identity files.
- (8) The technical solution hosting the central repository should be implemented at eu-LISA's technical site and at the backup site in order to ensure it remains available at all times.

⁽¹⁾ OJ L 135, 22.5.2019, p. 27.

⁽²⁾ Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration and amending Regulations (EU) 2018/1726, (EU) 2018/1862 and (EU) 2019/816 (OJ L 135, 22.5.2019, p. 85).

- (9) Given that Regulation (EU) 2019/817 builds upon the Schengen *acquis*, in accordance with Article 4 of Protocol No 22 on the Position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark notified the implementation of Regulation (EU) 2019/817 in its national law. It is therefore bound by this Regulation.
- (10) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part ⁽³⁾. Ireland is therefore not taking part in the adoption of this Regulation and is not bound by it or subject to its application.
- (11) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* ⁽⁴⁾, which fall within the area referred to in Article 1, point A of Council Decision 1999/437/EC ⁽⁵⁾.
- (12) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁶⁾, which fall within the area referred to in Article 1, point A of Council Decision 1999/437/EC, read in conjunction with Article 3 of Council Decision 2008/146/EC ⁽⁷⁾.
- (13) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁸⁾ which fall within the area referred to in Article 1, point A of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU ⁽⁹⁾.
- (14) As regards Cyprus, Bulgaria and Romania and Croatia, this Regulation constitutes an act building upon, or otherwise relating to, the Schengen *acquis* within the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.

⁽³⁾ This Regulation falls outside the scope of the measures provided for in Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

⁽⁴⁾ OJ L 176, 10.7.1999, p. 36.

⁽⁵⁾ Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

⁽⁶⁾ OJ L 53, 27.2.2008, p. 52.

⁽⁷⁾ Council Decision 2008/146/EC of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

⁽⁸⁾ OJ L 160, 18.6.2011, p. 21.

⁽⁹⁾ Council Decision 2011/350/EU of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

- (15) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽¹⁰⁾ and delivered an opinion on 17 June 2021,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) ‘statistical data’ means the data, which is anonymised and used solely for the purpose of producing statistical reports pursuant to Regulation (EU) 2017/2226 ⁽¹¹⁾, Regulation (EU) 2018/1240 ⁽¹²⁾, Regulation (EU) 2018/1860 ⁽¹³⁾, Regulation (EU) 2018/1861 ⁽¹⁴⁾, Regulation (EU) 2018/1862 ⁽¹⁵⁾ and Regulation (EU) 2019/816 ⁽¹⁶⁾ of the European Parliament and of the Council;
- (2) ‘(statistical) reports’ means an organised collection of statistical data, produced by the central repository in an automated manner according to a set of pre-established rules and stored in the central repository;
- (3) ‘customisable reports’ means statistical reports that are extracted on the basis of statistical data contained in the central repository in accordance with specific rules determined ad hoc by a user and stored in the central repository;
- (4) ‘critical identity data’ means any of the following data or a combination thereof, from which individuals can be identified:
 - (a) name, first name, surname, family name, given names, alias of any person whose data may be stored in any EU information system;
 - (b) number of travel document;
 - (c) address (street name, house number);
 - (d) telephone, IP address;
 - (e) email addresses;
 - (f) biometric data.

⁽¹⁰⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁽¹¹⁾ Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).

⁽¹²⁾ Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).

⁽¹³⁾ Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).

⁽¹⁴⁾ Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14).

⁽¹⁵⁾ Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).

⁽¹⁶⁾ Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).

*Article 2***Information to be contained in the central repository**

1. The data referred to in Article 39(2) of Regulation (EU) 2019/817 shall be made available and stored in the central repository in accordance with this Regulation.
2. The central repository shall contain statistical data, including reports on system usage for the purposes of monitoring the functioning of the interoperability components referred to in Article 66 of Regulation (EU) 2019/817.
3. The central repository shall contain technical reports to ensure monitoring by eu-LISA of the development and functioning of the interoperability components in accordance with Article 78(1) of Regulation (EU) 2019/817.
4. The central repository shall keep a unique reference number enabling to keep trace of the cross-matching of identity files within or between the corresponding EU information systems for statistical purposes. It shall not be possible to use that reference number to retrieve the underlying identity files.
5. The central repository shall enable the duly authorised staff of the competent authorities referred to in Article 39(2) of Regulation (EU) 2019/817 to obtain the following:
 - (a) reports pursuant to Article 63 of Regulation (EU) 2017/2226, containing the following statistics on records kept in the Entry/Exit System:
 - (i) customisable reports and statistics on entries and exits, refusals of entry and overstays of third-country nationals;
 - (ii) daily statistics on overstayers, third-country nationals who were refused entry, third-country nationals whose authorisation for stay was revoked or extended and third country nationals exempt from the requirement to give fingerprints;
 - (iii) customisable reports and statistics on data quality pursuant to Article 38(4) of Regulation (EU) 2017/2226 and regular statistics for ensuring the monitoring by eu-LISA of the development and the functioning of the Entry/Exit System referred to in Article 72(1) of that Regulation;
 - (b) reports pursuant to Article 84 of Regulation (EU) 2018/1240, containing the following statistics on the records kept in the European Travel Information and Authorisation System (ETIAS):
 - (i) daily statistics on the number and nationality of applicants whose travel authorisation was issued or refused, including the grounds for refusal, and of third-country nationals whose travel authorisation was annulled or revoked;
 - (ii) customisable reports and statistics to improve the assessment of security, illegal immigration and high epidemic risks, to enhance the efficiency of border checks, to help the ETIAS Central Unit and the ETIAS National Units process travel authorisation applications and to support evidence-based Union migration policy-making;
 - (iii) statistical data concerning the ETIAS watchlist pursuant to Article 92(4) of that Regulation;
 - (iv) regular statistics for ensuring the monitoring by eu-LISA of the development and the functioning of the ETIAS Information System pursuant to Article 92(1) of that Regulation;
 - (c) reports pursuant to Article 33(2) of Regulation (EU) 2018/1240, containing the following statistics:
 - (i) those generated by the Entry/Exit System indicating abnormal rates of overstaying and refusals of entry for a specific group of travellers;
 - (ii) those generated by the European Travel Information and Authorisation System pursuant to Article 84 of that Regulation indicating abnormal rates of refusals of travel authorisations due to a security, illegal immigration, or high epidemic risk associated with a specific group of travellers;
 - (iii) those generated by the European Travel Information and Authorisation System pursuant to Article 84 of that Regulation and the Entry/Exit System indicating correlations between information collected through the application form and overstaying by travellers or refusals of entry;

- (d) reports pursuant to Article 16 of Regulation (EU) 2018/1860, containing daily, monthly and annual statistics showing the number of records per category of alerts, both for each Member State and in aggregate;
- (e) reports pursuant to Regulation (EU) 2018/1861, containing the following statistics on the records kept in the Schengen Information System:
 - (i) daily, monthly and annual statistics showing the number of records per category of alerts, both for each Member State and in aggregate, pursuant to Article 60(3) of that Regulation;
 - (ii) annual reports on the number of hits per category of alert, how many times the Schengen Information System was searched and how many times it was accessed for the purpose of entering, updating or deleting an alert, both for each Member State and in aggregate, pursuant to Article 60(3) of Regulation (EU) 2018/1861 and Article 19 of Regulation (EU) 2018/1860;
 - (iii) at the request of the Commission, additional specific statistical reports, either on a regular or ad hoc basis, on the performance and the use of the Schengen Information System and on the exchange of supplementary information, pursuant to Article 60(5), second subparagraph of Regulation (EU) 2018/1861 and Article 19 of Regulation (EU) 2018/1860;
 - (iv) at the request of the European Border and Coast Guard Agency, additional specific statistical reports, either on a regular or ad hoc basis, for the purpose of carrying out risk analyses and vulnerability assessments, pursuant to Article 60(5), third subparagraph of Regulation (EU) 2018/1861 and Article 19 of Regulation (EU) 2018/1860;
 - (v) reports and statistics for the purposes of technical maintenance, reporting, data quality reporting and statistics pursuant to Article 60(2) of Regulation (EU) 2018/1861 and Article 19 of Regulation (EU) 2018/1860;
 - (vi) reports on data quality issues pursuant to Article 15(4) of Regulation (EU) 2018/1861 and Article 19 of Regulation (EU) 2018/1860.
- 6. The technical reports referred to in paragraph 2 shall contain statistics on the usage of the system, availability, incidents, performance capacity, biometric accuracy, data quality and, where applicable, pending transactions.
- 7. The business reports produced by the central repository shall be customisable by the user in order to allow the filtering or grouping of the data by means of a reporting tool made available with the central repository.
- 8. A catalogue of reports shall be made available. Requests for new reports or changes to existing ones shall follow eu-LISA change management policy.

Article 3

Data repository and reporting tool

- 1. The central repository shall use a technical solution hosting data extracted from the underlying EU information systems and interoperability components.
- 2. The technical solution shall contain a reporting tool configured to create, maintain and execute the reports and customisable reports referred to in Article 2.
- 3. The reporting tool shall allow for the generation of business reports and technical reports, and their retrieval by the user.
- 4. The reporting tool shall enable the provision of cross-system statistical data and analytical reporting for policy, operational and data quality purposes, where provided for by Union law.
- 5. All reports shall be managed within the technical solution. The appropriate security and integrity measures shall be implemented in the technical solution, in order to meet the requirements of the security plan provided for Article 42(3) of Regulation (EU) 2019/817.

6. The technical solution shall be implemented at eu-LISA's technical site and at the backup site.

Article 4

Data extraction

The central repository shall obtain from the EU information systems read-only copies of the data referred to in Article 39(2) and Article 66(1), (2) and (3) of Regulation (EU) 2019/817 in order to produce the statistics and reports referred to in Articles 39 and 66 of that Regulation. The data shall be obtained on a regular basis and at least daily, by means of one-way extraction.

Article 5

Data anonymisation tool

1. The data extracted from the underlying EU information systems and interoperability components shall be anonymised using a data anonymisation tool. Only anonymised data shall be stored in the central repository.
2. The data anonymisation tool shall identify critical identity data in the EU information systems and shall anonymise it by means of an automated process before statistical data is stored in the central repository. The anonymisation process shall be irreversible.

Article 6

Access

1. Access to the central repository by duly authorised staff shall be granted and managed in accordance with Article 63 of Regulation (EU) 2017/2226, Article 84 of Regulation (EU) 2018/1240, Article 60 of Regulation (EU) 2018/1861, and Article 16 of Regulation (EU) 2018/1860.
2. The central repository shall be accessible by the Member States, the Commission and the Union agencies, in accordance with their access rights under Union law, via a secure network connection (TESTA).
3. Only duly authorised staff of the competent authorities in accordance with Article 39(2) and Article 66(1) to (5) of Regulation (EU) 2019/817 shall be granted access to the tool referred to in Article 3(2) of this Regulation.
4. Competent authorities shall access the central repository by means of user profiles. eu-LISA shall keep a list of the user profiles. One authority may have several profiles, depending on its access rights.
5. Access to the central repository shall be logged. The information logged shall contain at least:
 - (a) a timestamp;
 - (b) authority;
 - (c) type of the report concerned.
6. Logs enabling the identification of users accessing the central repository shall be kept at national level and by the Commission, the European Border and Coast Guard Agency and Europol. eu-LISA shall keep logs of all accessing operations. The logs shall be stored in the central repository for one year, after which they shall be automatically erased.
7. Any conflicting roles within the central repository shall be identified and access shall be granted in accordance with the following principles:
 - (a) 'need-to-know';
 - (b) least privilege access;
 - (c) segregation of duties.

8. Data quality reports issued pursuant to Article 15(4) of Regulation (EU) 2018/1861 shall include a tool for Member States to provide eu-LISA with feedback on the correction of the issues encountered.

Article 7

Data processor

For the purpose of anonymising personal data pursuant to Article 5, eu-LISA shall be the data processor within the meaning of Article 3, point (12) of Regulation (EU) 2018/1725.

Article 8

Other data protection and security aspects

1. The data stored in the central repository shall be consulted solely for the purpose of reporting and statistics.
2. eu-LISA shall implement the necessary security measures to ensure the integrity of data in the central repository. Any changes to the data shall be traceable for auditing purposes.

Article 9

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 30 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2224**of 16 November 2021****laying down the details of the automated data quality control mechanisms and procedures, the common data quality indicators and the minimum quality standards for storage of data, pursuant to Article 37(4) of Regulation (EU) 2019/818 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration and amending Regulations (EU) 2018/1726, (EU) 2018/1862 and (EU) 2019/816 ⁽¹⁾, and in particular Article 37(4) thereof,

Whereas:

- (1) Regulation (EU) 2019/818, together with Regulation (EU) 2019/817 of the European Parliament and of the Council ⁽²⁾ establishes a framework to ensure interoperability between the EU information systems in the field of borders, visa, police and judicial cooperation, asylum and migration.
- (2) In order to improve data quality and harmonise the quality requirements, it is necessary to lay down the details of the automated data quality control mechanisms and procedures, the common data quality indicators and the minimum quality standards for the data entered and stored in the underlying EU information systems, the shared biometric matching service and the common identity repository.
- (3) Those measures should be implemented and assessed by the European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice (eu-LISA) taking into consideration the specific provisions laid down for each EU information system and the interoperability component. To perform these tasks, eu-LISA should be advised by experts from the Commission, the Member States and the Union agencies using the EU information systems and interoperability components.
- (4) Data quality control mechanisms and procedures should determine the compliance of the input data with the blocking and soft rules applicable to the underlying EU information systems, the shared biometric matching service and the common identity repository. eu-LISA should be responsible for ensuring that the data quality rules remain appropriate for achieving the objectives of the EU information systems and the interoperability components.
- (5) For each quality control indicator, eu-LISA should determine and assess the appropriateness of the minimum quality standard indispensable to store the data in the EU information systems and the interoperability components. Data quality standards should enable the automatic identification of apparently incorrect or inconsistent data submissions, so that the originating Member State is able to verify the data and carry out any necessary remedial action.

⁽¹⁾ OJ L 135, 22.5.2019, p. 85.

⁽²⁾ Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa and amending Regulations (EC) No 767/2008, (EU) 2016/399, (EU) 2017/2226, (EU) 2018/1240, (EU) 2018/1726 and (EU) 2018/1861 of the European Parliament and of the Council and Council Decisions 2004/512/EC and 2008/633/JHA (OJ L 135, 22.5.2019, p. 27).

- (6) The data cleaning and issue detection mechanisms should be established in order to regularly check the validity and compliance of the data stored in the underlying EU information systems and the interoperability components with the data quality standards.
- (7) eu-LISA should ensure a central monitoring capacity for data quality and for producing reports on data quality on a regular basis to the Member States. These reports should be produced by the central repository for reporting and statistics in accordance with Article 39(1) of Regulation (EU) 2019/818 and the rules laid down in the Commission Delegated Regulation 2021/2222 ⁽³⁾.
- (8) Given that Regulation (EU) 2019/818 builds upon the Schengen *acquis*, in accordance with Article 4 of Protocol No 22 on the Position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark notified the implementation of Regulation (EU) 2019/818 in its national law. It is therefore bound by this Regulation.
- (9) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part ⁽⁴⁾. Ireland is therefore not taking part in the adoption of this Regulation and is not bound by it or subject to its application.
- (10) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* ⁽⁵⁾, which fall within the area referred to in Article 1, point A of Council Decision 1999/437/EC ⁽⁶⁾.
- (11) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁷⁾, which fall within the area referred to in Article 1, point A of Decision 1999/437/EC, read in conjunction with Article 3 of Council Decision 2008/146/EC ⁽⁸⁾.
- (12) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁹⁾ which fall within the area referred to in Article 1, point A of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU ⁽¹⁰⁾.

⁽³⁾ Commission Delegated Regulation 2021/2222 of 30 September 2021 supplementing Regulation (EU) 2019/818 of the European Parliament and of the Council with detailed rules on the operation of the central repository for reporting and statistics. (See page 1 of this Official Journal).

⁽⁴⁾ This Regulation falls outside the scope of the measures provided for in Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

⁽⁵⁾ OJ L 176, 10.7.1999, p. 36.

⁽⁶⁾ Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

⁽⁷⁾ OJ L 53, 27.2.2008, p. 52.

⁽⁸⁾ Council Decision 2008/146/EC of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

⁽⁹⁾ OJ L 160, 18.6.2011, p. 21.

⁽¹⁰⁾ Council Decision 2011/350/EU of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

- (13) As regards Cyprus, Bulgaria and Romania and Croatia, this Regulation constitutes an act building upon, or otherwise relating to, the Schengen *acquis* within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.
- (14) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽¹⁾ and delivered an opinion on 30 April 2021.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Interoperability Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Scope and subject matter

1. This Regulation lays down the details of the automated data quality control mechanisms and procedures on the data stored in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818.
2. This Regulation also lays down details concerning the common data quality indicators and the minimum quality standards for storage of data, in particular regarding biometric data, in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818.
3. The measures referred to in paragraphs 2 and 3 are without prejudice to any specific provisions concerning data quality related to the EU information systems laid down in Union law.
4. This Regulation applies to the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (a) 'input data' means data, subject to data quality checks for the purpose of being stored in a EU information system or interoperability component referred to in Article 37(1) of Regulation (EU) 2019/818;
- (b) 'data cleaning mechanism' means a mechanism carrying out checks in order to ensure the scheduled erasure of data stored in a EU information system or interoperability component in accordance with Union law;
- (c) 'issue detection mechanism' means a mechanism carrying out checks in order to identify data that does not meet the data quality rules or standards;

⁽¹⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

- (d) 'blocking rules' means rules or a set of rules that measure the degree to which input data is compliant with defined data requirements conditioning their storage or use or both. They also include data quality rules governing each EU information system that must be complied with before data can be entered in the system. Input data not complying with a blocking rule will be rejected from being entered and stored in the EU information system and interoperability component;
- (e) 'soft rules' means rules or a set of rules that measure the degree to which the input data is compliant with the defined data requirements conditioning its relevance or optimal use or both. Soft rules shall not prevent the entry and storage of non-compliant input data. They also include data quality rules governing each EU information system that should be complied with before data can be entered in the system. Input data not complying with a soft rule shall be entered into the EU information system or interoperability component with a data quality issue flag, notification or warning message.

Article 3

Automated data quality control mechanisms and procedures

1. Automated quality checks shall be conducted on the data entered and stored in the shared biometric matching service and the common identity repository in accordance with the rules laid down in Article 4.
2. Automated quality checks shall be conducted on the data entered and stored in the EU information systems referred to in Article 37(1) of Regulation (EU) 2019/818 in accordance with the rules governing data quality control mechanisms in those systems.
3. Data quality control mechanisms shall be triggered in accordance with the rules governing data quality in those EU information systems and interoperability components.
4. In order to determine compliance of input data with the blocking or soft rules applying to them, the data quality control mechanisms referred to in paragraph 3 shall comply with Section 1 of the Annex to this Regulation.
5. If the input data is to be entered into the EU information system or interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818, the data quality control mechanisms shall assess the extent to which the data complies with each data quality indicator by applying the data quality standard of each indicator. As a result of that assessment, the data quality control mechanisms shall assign to the input data a data quality classification pursuant to the process laid down in Sections 2 and 3 of the Annex to this Regulation.
6. The common data quality indicators shall be the following: completeness, accuracy, timeliness, uniqueness and consistency.
7. eu-LISA shall implement the data quality standards for each indicator pursuant to the procedures laid down in Article 5.
8. Data cleaning and issue detection mechanisms shall regularly check the validity and the data quality compliance of the data stored in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818, in accordance with Section 4 of the Annex to this Regulation.

Article 4

Automated data quality control mechanisms for data entered and stored

1. To enhance data quality, automated data quality control mechanisms shall be set up to support the entering and storage of data complying with data quality requirements in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818. The data shall be entered and stored in accordance with the rules governing data quality in those EU information systems or interoperability components.

2. For the purpose of the entry of data by the duly authorised staff in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818, the automated quality control mechanisms shall verify the common quality indicators referred to in Section 2 of the Annex to this Regulation.
3. Data quality control mechanisms shall allow the application of blocking rules and soft rules in accordance with Article 3(4) governing data quality in the EU Information Systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818.

Article 5

Procedures governing the data quality control indicators, standards and mechanisms

1. eu-LISA shall be responsible for ensuring that the data quality rules are appropriate for achieving the objectives of the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818.
2. eu-LISA shall also be responsible for implementing the minimum quality standards for storage of biometric data in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818.
3. For the purposes of paragraphs 1 and 2 of this Article, eu-LISA shall take into consideration the specific needs of each EU information system and interoperability component referred to in Article 37(1) of Regulation (EU) 2019/818 and shall be assisted and advised by experts from the Commission, the Member States and the Union agencies using those EU information systems and interoperability components.
4. The following data quality control procedures shall apply:
 - (a) eu-LISA shall implement the data quality standards for each data quality indicator in accordance with Section 2 of the Annex to this Regulation;
 - (b) values shall be assigned to the standards separately for each of the data quality indicators referred to in Article 3(6). For each indicator, the standards may assign different values depending on the category of data;
 - (c) when so required and after the issuance of the regular data quality reports in accordance with Article 6, eu-LISA shall assess the appropriateness of the values and the standards and amend them to the extent to which they are no longer appropriate;
 - (d) when so required and after the issuance of the regular data quality reports in accordance with Article 6, eu-LISA shall assess the appropriateness of the data quality control mechanisms allowing for the application of blocking and soft rules and amend them where relevant;
 - (e) with a view of amending the data quality standards and their values, and to taking any decision on the data quality control mechanisms pursuant to points (c) and (d) of this paragraph, eu-LISA shall consult the Advisory Groups for each of the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/818.
5. eu-LISA shall base itself on the assessment of the functioning of the data quality control mechanisms with a view to amending the values of the data quality standards and to taking any decision on the data quality control mechanisms.

Article 6

Reports on automated data quality control mechanisms and procedures and common data quality indicators pursuant to Article 37(3) of Regulation (EU) 2019/818

1. Reports referred to in Article 37(3) of Regulation (EU) 2019/818 shall be produced by the central repository for reporting and statistics pursuant to Article 39(1) of Regulation (EU) 2019/818 and the rules laid down in the Delegated Regulation 2021/2222.

2. Reports shall not include personal data and contain at least the following information metrics on the quality of data, extracted via a tool or set of tools developed for these purposes:

- (a) for alphanumeric and biometric data assessed against blocking rules and soft rules, compliance with data quality indicators:
 - (1) completeness (%);
 - (2) accuracy (%);
 - (3) uniqueness (%);
 - (4) timeliness (%);
 - (5) consistency of data (%);
- (b) completeness of application files (%);
- (c) compliance of data with the 'good quality' classification (%);
- (d) compliance of data with the 'low quality' classification (%);
- (e) results of the data cleaning mechanism;
- (f) results of the issue detection mechanism;
- (g) data fields that cause frequent quality issues;
- (h) top 10 issues list for each of the categories referred to in points (a) to (g);
- (i) the Member States concerned by the top 10 quality issues.

3. eu-LISA shall develop a central monitoring capacity for data quality and for producing the reports referred to in this Article on a weekly basis.

Article 7

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 16 November 2021

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SECTION 1

Automated data quality control mechanism for data to be entered

Data entered into the EU information systems and interoperability components will be subject to automated data quality control mechanisms based on blocking and soft rules as defined in Article 2. These are the rules established in the EU information systems and interoperability components which determine whether the entry and storage of input data shall be allowed or rejected. The blocking and soft rules are established based on the following parameters: length, format, type, conformity to quality standards, semantics, repetition and syntax.

SECTION 2

General considerations on the common data quality indicators and minimum quality standards for data to be entered

The input data subject to the quality verification process shall be assessed against the data quality rules defined in each EU information system and interoperability component, as set out in Section 1. If the rules applying to the input data do not prevent entry and storage, the data quality control mechanisms shall measure the quality of the input data by using the data quality indicators applying to them.

The data quality control mechanisms shall measure the quality of input data according to each relevant indicator. The data quality control mechanisms shall take into account a weighing coefficient to calculate the relative weight of each indicator on the overall quality of the input data.

To that effect, the data quality control mechanisms shall be adapted to apply to a single collection of data within a record, or to a database.

After applying the weighing coefficient to the input data, the data quality control mechanisms shall produce an input data profile containing the results of the application of the indicator standards, for example numerical values evaluating the quality of the input data under each indicator.

Table 1 lists the minimum set of data quality indicators, for example indicators that shall always apply to input data, in accordance with the rules applied by each EU information system and interoperability component. Such indicators are the following: completeness, accuracy, consistency, timeliness, uniqueness.

Table 1

List of minimum data quality indicators

<i>Indicator</i>	<i>Description</i>	<i>Main scope of applicability</i>	<i>Unit of measurement</i>
Completeness	Means the degree to which the input data has values for all the expected attributes and related requirements in a specific context of use. Measures whether all the mandatory data is provided and the database (or sectoral) listings meet the set demands.	Mandatory data fields (alphanumeric and biometric)	Data completeness rate: ratio of the number of data cells provided to the number of data cells required
Accuracy	Means the degree to which the input data represents closeness of estimates to the unknown true values. It can be either or both among data regarding one entity and across similar data for comparable entities	Alphanumeric and biometric data	Sampling error rates, unit non-response rate, item non-response rate, data capture error rates, etc.

Consistency	Means the degree to which the input data has attributes that are free from contradiction and are coherent with other data in a specific context of use. Measures the degree to which a set of data satisfies defined business rules applying to those data across them, means the absence of a conflict of data content. It can be either or both among data regarding one entity and across similar data for comparable entities.	Alphanumeric data	Percentage
Timeliness	Means the degree to which the input data is provided within a predefined date or time that condition the validity of the data or its context of use. Measures how up-to-date the data is, and whether the data required can be provided by the required time.	Alphanumeric and biometric data	Time lag -final: number of days from the last day of the reference to the day the input data is provided
Uniqueness	Means the degree to which the input data is not duplicated in the same EU information system or interoperability component.	Mandatory data fields (alphanumeric and biometric)	Percentage of data units which are not duplicated

The accuracy indicator for biometric data also includes resolution. Resolution measures the degree to which the input data contains the required amount of points or pixels by unit of length. Unit to display on screen pixel: *pi unit* for printing; *dot pi* for output systems. Pixel one or several bits (range of colours ex: 16 colours 4b, 256 8b, 16b 65k, 24b 16.5mio)

SECTION 3

Data Quality Classification

After the development of the input data profile, referred to in Section 2, the input data shall be assigned with a data quality classification. The following data quality classifications shall apply:

- (a) 'good quality' means the input data profile demonstrates the required compliance with the applicable data quality indicator;
- (b) 'low quality' means the input data profile does not demonstrate the required compliance with the applicable data quality indicators, in the case of a soft rule;
- (c) 'rejected' means the input data profile does not demonstrate the required compliance with the applicable data quality indicators in case of a blocking rule.

Where the input data is assigned with a 'good quality' classification, the data shall be stored into the system or component without any data quality alert.

Where the input data is assigned with a 'low quality' classification, the data shall be stored into the system or component and with a data quality alert. An alert shall indicate that the input data shall be rectified and the reason why the input data does not demonstrate the required compliance with the applicable data quality indicators. Where possible, the alert shall identify the data field(s) or the data content(s) or both affected by data quality issues and suggest the changes necessary for the input data to meet the 'good quality' classification.

SECTION 4

Data Quality Monitoring

Two types of mechanisms shall be used for the purposes of Article 3(8):

- (a) Data cleaning mechanisms. Such mechanisms shall carry out checks to identify data for which the remaining retention period is less than the time defined in the legislation governing the relevant EU information system or interoperability component. Data cleaning mechanisms shall inform the Member State of the scheduled erasure of the data and allow them to adopt, if necessary, the appropriate measures.
- (b) Issue detection mechanisms. Such mechanisms shall carry out checks to identify the data that no longer meet one or more data quality rules or standards related to data quality indicators. Such checks may return an alert or notification to the responsible authority of the Member State indicating the reason why the data no longer meets one or more data quality rules or standards. Where possible, the alert shall suggest the changes necessary for the input data to meet the new rules or standards. In no case the application of such checks shall lead to automated deletion of data stored in the EU information systems or interoperability components. When new data is being entered into an EU information system or interoperability component while the issue detection mechanisms are running, the issue detection mechanisms shall not apply to those data.

eu-LISA may decide that ad hoc issue detection mechanisms shall be carried out in the EU information system and in the interoperability components upon the revision of the data quality rules or standards.

eu-LISA may consult the Advisory Group for one of the EU information systems or the interoperability components on whether to carry out an ad hoc issue detection mechanisms in its corresponding EU information system or interoperability component to the extent necessary for the purposes of that EU information system or interoperability component.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2225**of 16 November 2021****laying down the details of the automated data quality control mechanisms and procedures, the common data quality indicators and the minimum quality standards for storage of data, pursuant to Article 37(4) of Regulation (EU) 2019/817 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa and amending Regulations (EC) No 767/2008, (EU) 2016/399, (EU) 2017/2226, (EU) 2018/1240, (EU) 2018/1726 and (EU) 2018/1861 of the European Parliament and of the Council and Council Decisions 2004/512/EC and 2008/633/JHA ⁽¹⁾, and in particular Article 37(4) thereof,

Whereas:

- (1) Regulation (EU) 2019/817, together with Regulation (EU) 2019/818 of the European Parliament and of the Council ⁽²⁾ establishes a framework to ensure interoperability between the EU information systems in the field of borders, visa, police and judicial cooperation, asylum and migration.
- (2) In order to improve data quality and harmonise the quality requirements, it is necessary to lay down the details of the automated data quality control mechanisms and procedures, the common data quality indicators and the minimum quality standards for the data entered and stored in the underlying EU information systems, the shared biometric matching service and the common identity repository.
- (3) Those measures should be implemented and assessed by the European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice (eu-LISA) taking into consideration the specific provisions laid down for each EU information system and the interoperability component. To perform these tasks, eu-LISA should be advised by experts from the Commission, the Member States and the Union agencies using the EU information systems and interoperability components.
- (4) Data quality control mechanisms and procedures should determine the compliance of the input data with the blocking and soft rules applicable to the underlying EU information systems, the shared biometric matching service and the common identity repository. eu-LISA should be responsible for ensuring that the data quality rules remain appropriate for achieving the objectives of the EU information systems and the interoperability components.
- (5) For each quality control indicator, eu-LISA should determine and assess the appropriateness of the minimum quality standard indispensable to store the data in the EU information systems and the interoperability components. Data quality standards should enable the automatic identification of apparently incorrect or inconsistent data submissions, so that the originating Member State is able to verify the data and carry out any necessary remedial action.

⁽¹⁾ OJ L 135, 22.5.2019, p. 27.

⁽²⁾ Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration and amending Regulations (EU) 2018/1726, (EU) 2018/1862 and (EU) 2019/816 (OJ L 135, 22.5.2019, p. 85).

- (6) The data cleaning and issue detection mechanisms should be established in order to regularly check the validity and compliance of the data stored in the underlying EU information systems and the interoperability components with the data quality standards.
- (7) eu-LISA should ensure a central monitoring capacity for data quality and for producing reports on data quality on a regular basis to the Member States. These reports should be produced by the central repository for reporting and statistics in accordance with Article 39(1) of Regulation (EU) 2019/817 and the rules laid down in Commission Delegated Regulation 2021/2223 ⁽³⁾.
- (8) Given that Regulation (EU) 2019/817 builds upon the Schengen *acquis*, in accordance with Article 4 of Protocol No 22 on the Position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark notified the implementation of Regulation (EU) 2019/817 in its national law. It is therefore bound by this Regulation.
- (9) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part ⁽⁴⁾. Ireland is therefore not taking part in the adoption of this Regulation and is not bound by it or subject to its application.
- (10) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* ⁽⁵⁾, which fall within the area referred to in Article 1, point A of Council Decision 1999/437/EC ⁽⁶⁾.
- (11) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁷⁾, which fall within the area referred to in Article 1, point A of Decision 1999/437/EC, read in conjunction with Article 3 of Council Decision 2008/146/EC ⁽⁸⁾.
- (12) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁹⁾ which fall within the area referred to in Article 1, point A of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU ⁽¹⁰⁾.

⁽³⁾ Commission Delegated Regulation 2021/2223 of 30 September 2021 supplementing Regulation (EU) 2019/817 of the European Parliament and of the Council with detailed rules on the operation of the central repository for reporting and statistics (see page 7 of this Official Journal).

⁽⁴⁾ This Regulation falls outside the scope of the measures provided for in Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

⁽⁵⁾ OJ L 176, 10.7.1999, p. 36.

⁽⁶⁾ Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

⁽⁷⁾ OJ L 53, 27.2.2008, p. 52.

⁽⁸⁾ Council Decision 2008/146/EC of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

⁽⁹⁾ OJ L 160, 18.6.2011, p. 21.

⁽¹⁰⁾ Council Decision 2011/350/EU of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

- (13) As regards Cyprus, Bulgaria and Romania and Croatia, this Regulation constitutes an act building upon, or otherwise relating to, the Schengen *acquis* within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.
- (14) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽¹¹⁾ and delivered an opinion on 30 April 2021.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Interoperability Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Scope and subject matter

1. This Regulation lays down the details of the automated data quality control mechanisms and procedures on the data stored in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817.
2. This Regulation also lays down details concerning the common data quality indicators and the minimum quality standards for storage of data, in particular regarding biometric data, in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817.
3. The measures referred to in paragraphs 2 and 3 are without prejudice to any specific provisions concerning data quality related to the EU information systems laid down in Union law.
4. This Regulation applies to the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (a) 'input data' means data, subject to data quality checks for the purpose of being stored in a EU information system or interoperability component referred to in Article 37(1) of Regulation (EU) 2019/817;
- (b) 'data cleaning mechanism' means a mechanism carrying out checks in order to ensure the scheduled erasure of data stored in a EU information system or interoperability component in accordance with Union law;
- (c) 'issue detection mechanism' means a mechanism carrying out checks in order to identify data that does not meet the data quality rules or standards;
- (d) 'blocking rules' means rules or a set of rules that measure the degree to which input data is compliant with defined data requirements conditioning their storage or use or both. They also include data quality rules governing each EU information system that must be complied with before data can be entered in the system. Input data not complying with a blocking rule will be rejected from being entered and stored in the EU information system and interoperability component;

⁽¹¹⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

- (e) 'soft rules' means rules or a set of rules that measure the degree to which the input data is compliant with the defined data requirements conditioning its relevance or optimal use or both. Soft rules shall not prevent the entry and storage of non-compliant input data. They also include data quality rules governing each EU information system that should be complied with before data can be entered in the system. Input data not complying with a soft rule shall be entered into the EU information system or interoperability component with a data quality issue flag, notification or warning message.

Article 3

Automated data quality control mechanisms and procedures

1. Automated quality checks shall be conducted on the data entered and stored in the shared biometric matching service and the common identity repository in accordance with the rules laid down in Article 4.
2. Automated quality checks shall be conducted on the data entered and stored in the EU information systems referred to in Article 37(1) of Regulation (EU) 2019/817 in accordance with the rules governing data quality control mechanisms in those systems.
3. Data quality control mechanisms shall be triggered in accordance with the rules governing data quality in those EU information systems and interoperability components.
4. In order to determine compliance of input data with the blocking or soft rules applying to them, the data quality control mechanisms referred to in paragraph 3 shall comply with Section 1 of the Annex to this Regulation.
5. If the input data is to be entered into the EU information system or interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817, the data quality control mechanisms shall assess the extent to which the data complies with each data quality indicator by applying the data quality standard of each indicator. As a result of that assessment, the data quality control mechanisms shall assign to the input data a data quality classification pursuant to the process laid down in Sections 2 and 3 of the Annex to this Regulation.
6. The common data quality indicators shall be the following: completeness, accuracy, timeliness, uniqueness and consistency.
7. eu-LISA shall implement the data quality standards for each indicator pursuant to the procedures laid down in Article 5.
8. Data cleaning and issue detection mechanisms shall regularly check the validity and the data quality compliance of the data stored in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817, in accordance with Section 4 of the Annex to this Regulation.

Article 4

Automated data quality control mechanisms for data entered and stored

1. To enhance data quality, automated data quality control mechanisms shall be set up to support the entering and storage of data complying with data quality requirements in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817. The data shall be entered and stored in accordance with the rules governing data quality in those EU information systems or interoperability components.
2. For the purpose of the entry of data by the duly authorised staff in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817, the automated quality control mechanisms shall verify the common quality indicators referred to in Section 2 of the Annex to this Regulation.

3. Data quality control mechanisms shall allow the application of blocking rules and soft rules in accordance with Article 3(4) governing data quality in the EU Information Systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817.

Article 5

Procedures governing the data quality control indicators, standards and mechanisms

1. eu-LISA shall be responsible for ensuring that the data quality rules are appropriate for achieving the objectives of the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817.

2. eu-LISA shall also be responsible for implementing the minimum quality standards for storage of biometric data in the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817.

3. For the purposes of paragraphs 1 and 2 of this Article, eu-LISA shall take into consideration the specific needs of each EU information system and interoperability component referred to in Article 37(1) of Regulation (EU) 2019/817 and shall be assisted and advised by experts from the Commission, the Member States and the Union agencies using those EU information systems and interoperability components.

4. The following data quality control procedures shall apply:

- (a) eu-LISA shall implement the data quality standards for each data quality indicator in accordance with Section 2 of the Annex to this Regulation;
- (b) values shall be assigned to the standards separately for each of the data quality indicators referred to in Article 3(6). For each indicator, the standards may assign different values depending on the category of data;
- (c) when so required and after the issuance of the regular data quality reports in accordance with Article 6, eu-LISA shall assess the appropriateness of the values and the standards and amend them to the extent to which they are no longer appropriate;
- (d) when so required and after the issuance of the regular data quality reports in accordance with Article 6, eu-LISA shall assess the appropriateness of the data quality control mechanisms allowing for the application of blocking and soft rules and amend them where relevant;
- (e) with a view of amending the data quality standards and their values, and to taking any decision on the data quality control mechanisms pursuant to points (c) and (d) of this paragraph, eu-LISA shall consult the Advisory Groups for each of the EU information systems and interoperability components referred to in Article 37(1) of Regulation (EU) 2019/817.

5. eu-LISA shall base itself on the assessment of the functioning of the data quality control mechanisms with a view to amending the values of the data quality standards and to taking any decision on the data quality control mechanisms.

Article 6

Reports on automated data quality control mechanisms and procedures and common data quality indicators pursuant to Article 37(3) of Regulation (EU) 2019/817

1. Reports referred to in Article 37(3) of Regulation (EU) 2019/817 shall be produced by the central repository for reporting and statistics pursuant to Article 39(1) of Regulation (EU) 2019/817 and the rules laid down in the Delegated Regulation 2021/2223.

2. Reports shall not include personal data and contain at least the following information metrics on the quality of data, extracted via a tool or set of tools developed for these purposes:
- (a) for alphanumeric and biometric data assessed against blocking rules and soft rules, compliance with data quality indicators:
 - (1) completeness (%);
 - (2) accuracy (%);
 - (3) uniqueness (%);
 - (4) timeliness (%);
 - (5) consistency of data (%);
 - (b) completeness of application files (%);
 - (c) compliance of data with the 'good quality' classification (%);
 - (d) compliance of data with the 'low quality' classification (%);
 - (e) results of the data cleaning mechanism;
 - (f) results of the issue detection mechanism;
 - (g) data fields that cause frequent quality issues;
 - (h) top 10 issues list for each of the categories referred to in points (a) to (g);
 - (i) the Member States concerned by the top 10 quality issues.
3. eu-LISA shall develop a central monitoring capacity for data quality and for producing the reports referred to in this Article on a weekly basis.

Article 7

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 16 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SECTION 1

Automated data quality control mechanism for data to be entered

Data entered into the EU information systems and interoperability components will be subject to automated data quality control mechanisms based on blocking and soft rules as defined in Article 2. These are the rules established in the EU information systems and interoperability components which determine whether the entry and storage of input data shall be allowed or rejected. The blocking and soft rules are established based on the following parameters: length, format, type, conformity to quality standards, semantics, repetition and syntax.

SECTION 2

General considerations on the common data quality indicators and minimum quality standards for data to be entered

The input data subject to the quality verification process shall be assessed against the data quality rules defined in each EU information system and interoperability component, as set out in Section 1. If the rules applying to the input data do not prevent entry and storage, the data quality control mechanisms shall measure the quality of the input data by using the data quality indicators applying to them.

The data quality control mechanisms shall measure the quality of input data according to each relevant indicator. The data quality control mechanisms shall take into account a weighing coefficient to calculate the relative weight of each indicator on the overall quality of the input data.

To that effect, the data quality control mechanisms shall be adapted to apply to a single collection of data within a record, or to a database.

After applying the weighing coefficient to the input data, the data quality control mechanisms shall produce an input data profile containing the results of the application of the indicator standards, for example numerical values evaluating the quality of the input data under each indicator.

Table 1 lists the minimum set of data quality indicators, for example indicators that shall always apply to input data, in accordance with the rules applied by each EU information system and interoperability component. Such indicators are the following: completeness, accuracy, consistency, timeliness, uniqueness.

Table 1

List of minimum data quality indicators

<i>Indicator</i>	<i>Description</i>	<i>Main scope of applicability</i>	<i>Unit of measurement</i>
Completeness	Means the degree to which the input data has values for all the expected attributes and related requirements in a specific context of use. Measures whether all the mandatory data is provided and the database (or sectoral) listings meet the set demands.	Mandatory data fields (alphanumeric and biometric)	Data completeness rate: ratio of the number of data cells provided to the number of data cells required
Accuracy	Means the degree to which the input data represents closeness of estimates to the unknown true values. It can be either or both among data regarding one entity and across similar data for comparable entities	Alphanumeric and biometric data	Sampling error rates, unit non-response rate, item non-response rate, data capture error rates, etc.

Consistency	Means the degree to which the input data has attributes that are free from contradiction and are coherent with other data in a specific context of use. Measures the degree to which a set of data satisfies defined business rules applying to those data across them, means the absence of a conflict of data content. It can be either or both among data regarding one entity and across similar data for comparable entities.	Alphanumeric data	Percentage
Timeliness	Means the degree to which the input data is provided within a predefined date or time that condition the validity of the data or its context of use. Measures how up-to-date the data is, and whether the data required can be provided by the required time.	Alphanumeric and biometric data	Time lag -final: number of days from the last day of the reference to the day the input data is provided
Uniqueness	Means the degree to which the input data is not duplicated in the same EU information system or interoperability component.	Mandatory data fields (alphanumeric and biometric)	Percentage of data units which are not duplicated

The accuracy indicator for biometric data also includes resolution. Resolution measures the degree to which the input data contains the required amount of points or pixels by unit of length. Unit to display on screen pixel: *pi unit* for printing; *dot pi* for output systems. Pixel one or several bits (range of colours ex: 16 colours 4b, 256 8b, 16b 65k, 24b 16.5mio).

SECTION 3

Data Quality Classification

After the development of the input data profile, referred to in Section 2, the input data shall be assigned with a data quality classification. The following data quality classifications shall apply:

- (a) 'good quality' means the input data profile demonstrates the required compliance with the applicable data quality indicator;
- (b) 'low quality' means the input data profile does not demonstrate the required compliance with the applicable data quality indicators, in the case of a soft rule;
- (c) 'rejected' means the input data profile does not demonstrate the required compliance with the applicable data quality indicators in case of a blocking rule.

Where the input data is assigned with a 'good quality' classification, the data shall be stored into the system or component without any data quality alert.

Where the input data is assigned with a 'low quality' classification, the data shall be stored into the system or component and with a data quality alert. An alert shall indicate that the input data shall be rectified and the reason why the input data does not demonstrate the required compliance with the applicable data quality indicators. Where possible, the alert shall identify the data field(s) or the data content(s) or both affected by data quality issues and suggest the changes necessary for the input data to meet the 'good quality' classification.

SECTION 4

Data Quality Monitoring

Two types of mechanisms shall be used for the purposes of Article 3(8):

- (a) Data cleaning mechanisms. Such mechanisms shall carry out checks to identify data for which the remaining retention period is less than the time defined in the legislation governing the relevant EU information system or interoperability component. Data cleaning mechanisms shall inform the Member State of the scheduled erasure of the data and allow them to adopt, if necessary, the appropriate measures.
- (b) Issue detection mechanisms. Such mechanisms shall carry out checks to identify the data that no longer meet one or more data quality rules or standards related to data quality indicators. Such checks may return an alert or notification to the responsible authority of the Member State indicating the reason why the data no longer meets one or more data quality rules or standards. Where possible, the alert shall suggest the changes necessary for the input data to meet the new rules or standards. In no case the application of such checks shall lead to automated deletion of data stored in the EU information systems or interoperability components. When new data is being entered into an EU information system or interoperability component while the issue detection mechanisms are running, the issue detection mechanisms shall not apply to those data.

eu-LISA may decide that ad hoc issue detection mechanisms shall be carried out in the EU information system and in the interoperability components upon the revision of the data quality rules or standards.

eu-LISA may consult the Advisory Group for one of the EU information systems or the interoperability components on whether to carry out an ad hoc issue detection mechanisms in its corresponding EU information system or interoperability component to the extent necessary for the purposes of that EU information system or interoperability component.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226**of 14 December 2021****laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices**

THE EUROPEAN COMMISSION,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ⁽¹⁾, and in particular Article 5(6) thereof,

Whereas:

- (1) For some medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial. It can reduce the environmental burden and reduce costs for the medical device industry while maintaining or improving the level of safety.
- (2) Commission Regulation (EU) No 207/2012 ⁽²⁾ has established conditions under which instructions for use of medical devices subject to Council Directive 90/385/EEC ⁽³⁾ and Council Directive 93/42/EEC ⁽⁴⁾ could be provided in electronic form instead of in paper form. Both Council Directives have been repealed and replaced by Regulation (EU) 2017/745. The rules as regards electronic instructions for use should therefore be adapted to the new requirements of Regulation (EU) 2017/745 and technological developments in the field.
- (3) The possibility of providing instructions for use in electronic form instead of in paper form should be limited to certain medical devices and accessories intended to be used under specific conditions. For reasons of safety and efficiency, users should always have the possibility to obtain those instructions for use in paper form upon request.
- (4) In order to reduce potential risks as far as possible, the appropriateness of the provision of instructions for use in electronic form instead of in paper form should be subject to a specific risk assessment by the manufacturer.
- (5) To ensure unconditional access to the instructions for use in electronic form and to facilitate the communication of updates, those instructions should be available on the website of the manufacturer in an official language(s) of the Union determined by the Member State in which the device is made available to the user or patient.
- (6) In order to ensure safety and consistency, instructions for use in electronic form which are provided in addition to instructions for use in paper form should be covered by this Regulation as regards limited requirements in relation to their contents and websites.
- (7) The possibility of providing instructions for use in electronic form should be without prejudice to obligations related to the provision of implant cards in accordance with Article 18 of Regulation (EU) 2017/745.

⁽¹⁾ OJ L 117, 5.5.2017, p. 1.

⁽²⁾ Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).

⁽³⁾ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

⁽⁴⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

- (8) As the protection of the right to privacy of natural persons with respect to the processing of personal data should be ensured by both manufacturers and notified bodies, it is appropriate to provide that websites containing instructions for use of a medical device fulfil the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽³⁾.
- (9) In order to ensure that the rules as regards electronic instructions for use are adapted to the new requirements of Regulation (EU) 2017/745, Commission Regulation (EU) No 207/2012 should be therefore repealed. It should however continue to apply to devices placed on the market or put into service during the transitional period set out in Article 120(3) of Regulation (EU) 2017/745.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Committee on medical devices,

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation establishes the conditions under which information in the instructions for use, as defined by Article 2(14) of Regulation (EU) 2017/745 and detailed in Annex I, Chapter III, point 23.4 to Regulation (EU) 2017/745 may be provided by manufacturers in electronic form, as referred to in Annex I, Chapter III, point 23.1(f), to Regulation (EU) 2017/745.

It also establishes certain requirements concerning contents of and websites for instructions for use that are provided in electronic form in addition to instructions for use in paper form.

This Regulation does not cover products listed in Annex XVI to Regulation (EU) 2017/745.

Article 2

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'instructions for use in electronic form' means instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or made available through a software or a website;
- (2) 'professional users' means persons using the medical device in the course of their work in the framework of a professional healthcare activity;
- (3) 'fixed installed medical devices' means devices and their accessories which are intended to be installed, fastened or otherwise secured at a specific location in a health institution so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare institution.

Article 3

(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices:

- (a) implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745;
- (b) fixed installed medical devices and their accessories covered by Regulation (EU) 2017/745;
- (c) medical devices and their accessories covered by Regulation (EU) 2017/745 and fitted with a built-in system visually displaying the instructions for use.

⁽³⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

(2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:

- (a) the devices and accessories are intended for exclusive use by professional users; and
- (b) the use by other persons is not reasonably foreseeable.

(3) For software covered by Regulation (EU) 2017/745, manufacturers may provide instructions for use in electronic form by means of the software itself instead of in paper form.

Article 4

(1) Manufacturers of devices referred to in Article 3, paragraphs 1 and 3, that provide instructions for use in electronic form to users instead of in paper form shall undertake a documented risk assessment which shall cover at least the following elements:

- (a) knowledge and experience of the intended users in particular regarding the use of the device and user needs;
- (b) characteristics of the environment in which the device will be used;
- (c) knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form;
- (d) access of the user to the reasonably foreseeable electronic resources needed at the time of use;
- (e) performance of safeguards to ensure that the electronic data and content are protected from tampering;
- (f) safety and back-up mechanisms in the event of a hardware or software fault, particularly if the instructions for use in electronic form are integrated within the device;
- (g) foreseeable medical emergency situations requiring the provision of information in paper form;
- (h) impact caused by the temporary unavailability of the specific website or of the internet in general, or of their access in the healthcare institution as well as the safety measures available to cope with such a situation;
- (i) evaluation of the period within which the instructions for use shall be provided in paper form at the user's request;
- (j) assessment of the website's compatibility displaying the electronic instructions for use with different devices which could be used to display those instructions;
- (k) management of different versions of the instructions for use, where applicable in accordance with Article 5(8).

(2) The risk assessment for the provision of the instructions for use in electronic form shall be updated in view of the experience gained in the post-marketing phase.

Article 5

Manufacturers of devices referred to in Article 3, paragraphs 1 and 3, may provide instructions for use to users in electronic form instead of in paper form under the following conditions:

- (1) the risk assessment referred to in Article 4 shall demonstrate that providing instructions for use in electronic form maintains or improves the level of safety obtained by providing the instructions for use in paper form;
- (2) they shall provide instructions for use in electronic form in all Member States where the product is made available or put into service unless duly justified in the risk assessment referred to in Article 4;
- (3) they shall have a system in place to provide the instructions for use in paper form at no additional cost for the user, within the time period set out in the risk assessment referred to in Article 4 and at the latest within 7 calendar days of receiving a request from the user or at the time of delivery of the device if so requested at the time of order;

- (4) they shall provide, on the device or a leaflet, information on foreseeable medical emergency situations and, for devices fitted with a built-in system visually displaying the instructions for use, information on how to start the device;
- (5) they shall ensure the proper design and functioning of the instructions for use in electronic form and provide verification and validation evidence to this effect;
- (6) for medical devices fitted with a built-in system visually displaying the instructions for use, they shall ensure that displaying the instructions for use does not impede the safe use of the device, in particular, life-monitoring or life-supporting functions;
- (7) they shall provide, in their catalogue or other appropriate device information support, information on software and hardware requirements needed to display the instructions for use;
- (8) they shall have a system in place to clearly indicate when the instructions for use have been revised and to inform each user of the device thereof if the revision was necessary for safety reasons;
- (9) for devices with a defined expiry date, except implantable devices, they shall keep the instructions for use available for users in electronic form for 10 years after the last device has been placed on the market and at least 2 years after the end of the expiry date of the last produced device;
- (10) for devices without a defined expiry date and implantable devices, they shall keep the instructions for use available for the users in electronic form for 15 years after the last device has been placed on the market;
- (11) the instructions for use shall be available on their website in an official language of the Union determined by the Member State in which the device is made available to the user or patient;
- (12) effective systems and procedures shall be in place to ensure that device users having downloaded instructions for use from the website can be informed in case of updates or corrective actions with regards to those instructions for use;
- (13) all issued historical electronic versions of the instructions for use shall be available on the website.

Article 6

- (1) Manufacturers shall clearly indicate on the label that the instructions for use of the device are supplied in electronic form instead of in paper form.

That information shall be provided on the packaging for each unit or, where appropriate, on the sales packaging. In the case of fixed installed medical devices, that information shall also be provided on the device itself.

In the case of software, the information shall be provided at the location from where access to the software is granted.

- (2) Manufacturers shall provide information on how to access the instructions for use in electronic form.

That information shall be provided as set out in the second subparagraph of paragraph 1 or, if not practicable, in a paper document supplied with each device.

- (3) The information on how to access the instructions for use in electronic form shall also contain the following:
 - (a) any information needed to view the instructions for use;
 - (b) the Basic UDI-DI and/or the UDI-DI of the device, as respectively referred to in Article 27(6) and Article 27(1), point (a) (i), of Regulation (EU) 2017/745, and any additional information allowing the identification of the device, including its name and if applicable the model;

- (c) relevant manufacturer contact details e.g. manufacturer's name, address, email address or other means of online communication and website;
 - (d) where and how instructions for use in paper form can be requested and within which time they shall be obtained at no additional cost in conformity with Article 5, point (3).
- (4) Where, for devices and accessories referred to in Article 3(1), point (a), a part of the instructions for use is intended to be provided to the patient, that part shall not be provided in electronic form.
- (5) The instructions for use in electronic form shall be available entirely as text, which may contain symbols and graphics, with at least the same information as the instructions for use in paper form. Video or audio files may be provided in addition to the text.

Article 7

- (1) Where manufacturers provide the instructions for use in electronic form on an electronic storage medium together with the device, or where the device itself is fitted with a built-in system visually displaying the instructions for use, the instructions for use in electronic form shall also be made accessible to the users through a website.
- (2) Any website containing instructions for use of a device which are provided in electronic form instead of in paper form shall comply with the following requirements:
- (a) the instructions for use shall be provided in a commonly used format that can be read with freely available software;
 - (b) it shall be protected against unauthorised access and tampering of content in accordance with Article 4(1), point (e);
 - (c) it shall be provided in such a way that the server downtime and display errors are reduced as far as possible;
 - (d) it shall fulfil the requirements of Regulation (EU) 2016/679;
 - (e) the internet address as displayed in accordance with Article 6(2) shall be stable and directly accessible during the periods set out in Article 5, points (9) and (10);
 - (f) all previous versions of the instructions for use issued in electronic form as referred to in Article 5, point (13), and their date of publication shall be available on the website.

Article 8

Where applicable, the fulfilment of the obligations laid down in Articles 4 to 7 of this Regulation shall be reviewed by a notified body during the procedure applicable for conformity assessment as referred to in Article 52 of Regulation (EU) 2017/745.

Article 9

Instructions for use in electronic form, which are provided in addition to complete instructions for use in paper form, shall be consistent with the content of the instructions for use in paper form.

Where such instructions for use are provided through a website, this website shall fulfil the requirements set out in Article 7(2), points (b), (d), (e) and (f).

Article 10

Commission Regulation (EU) No 207/2012 is repealed.

However, it shall continue to apply to devices placed on the market or put into service in accordance with Article 120(3) of Regulation (EU) 2017/745 until 26 May 2024.

References to Regulation (EU) No 207/2012 shall be construed as references to this Regulation and read in accordance with the correlation table in the Annex.

Article 11

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

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

Done at Brussels, 14 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Correlation table

Commission Regulation (EU) No 207/2012	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3(1)	Article 3(1)
Article 3(2)	Article 3(2)
-	Article 3(3)
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	Article 9
-	Article 10
Article 10	Article 11

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2227**of 14 December 2021****amending Regulation (EU) No 1178/2011 as regards the requirements for all-weather operations and for instrument and type rating training in helicopters****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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 ⁽¹⁾, and in particular Articles 23(1) and 27(1) thereof,

Whereas:

- (1) Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011 ⁽²⁾ lays down the training, testing and checking requirements for pilot licences, including requirements for obtaining privileges to fly approaches in accordance with instrument flight rules (IFR) down to decision heights of less than 200 feet, and for instrument and type rating training in helicopters.
- (2) Commission Regulation (EU) No 965/2012 ⁽³⁾ lays down detailed rules for air operations, including requirements for operators to provide to their crew regular training and checking. That Regulation is being amended to reflect the latest International Civil Aviation Organization (ICAO) standards regarding all-weather operations. The amendments to Regulation (EU) No 965/2012 are designed to constitute a comprehensive framework for low-visibility IFR approaches, including for aspects related to pilot training. Therefore, the corresponding requirements for low-visibility IFR approaches in Regulation (EU) No 1178/2011 should be deleted or, where necessary, replaced by references to Regulation (EU) No 965/2012.
- (3) Due to the fact that single-engine helicopters are now being certified also for operation under IFR, the requirements for the helicopter instrument rating should be revised in order to be more relevant for the new types of helicopters and provide more flexibility as regards their use. The helicopter instrument rating and the related training should be designed to cover instrument flight in both single-engine and multi-engine helicopters, so that additional training to convert from a single-engine helicopter instrument rating to a multi-engine helicopter instrument rating would no longer be needed.
- (4) Today the more demanding Part-FCL provisions for pilot training for multi-pilot helicopters apply also to multi-pilot operation in helicopters certified for single-pilot operation. As a result of that additional burden, almost all helicopter operations in such single-pilot certified helicopters are carried out in single-pilot operation, unless multi-pilot operation is mandated by operational requirements. Consequently, the safety benefit of flying with a co-pilot is lost. To avoid this outcome, the requirements and privileges for multi-pilot operation in helicopters should be revised in order to provide more flexibility. Appropriate requirements should be put in place to allow for safe multi-pilot operation in single-pilot helicopters.

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).

⁽³⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

- (5) Since, until now only multi-engine helicopters have been used for helicopter flights under IFR, the existing helicopter instrument ratings have been obtained in multi-engine helicopters. For this reason, and considering the future use of single-engine helicopters under IFR, transitional provisions should be put in place to ensure that pilots currently holding helicopter instrument ratings can use the associated privilege in both single-engine and multi-engine helicopters.
- (6) Training organisations should be given sufficient time to adapt their training programmes.
- (7) Regulation (EU) No 1178/2011 should also be amended to correct certain outdated or incorrect cross-references, as well as provide clarification for certain provisions.
- (8) The European Union Aviation Safety Agency has prepared draft implementing rules and submitted them to the Commission with Opinion No 02/2021 ⁽⁴⁾ in accordance with points (b) and (c) of Article 75(2) and with Article 76(1) of Regulation (EU) 2018/1139.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the committee established in accordance with Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1178/2011 is amended as follows:

(1) Article 4c is amended as follows:

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

‘(b) continue to be entitled to receive revalidation or renewal of their EIR, in accordance with point FCL.825(g) of Annex I (Part-FCL);’;

(b) in paragraph 1, point (c) is replaced by the following:

‘(c) be entitled to receive full credit towards the training requirements in point FCL.835(c)(2)(i) and (iii) of Annex I (Part-FCL), when applying for the issue of a basic instrument rating (BIR) in accordance with point FCL.835 of Annex I (Part-FCL); and’;

(c) in paragraph 1, point (d) is replaced by the following:

‘(d) continue to be entitled to receive full credit as established for EIR holders in Annex I (Part- FCL).’;

(2) the following Article 4d is inserted:

‘Article 4d

Transitional measures for single-engine instrument rating privileges for helicopters

Without prejudice to point FCL.630.H of Annex I (Part-FCL) to this Regulation, all of the following shall apply:

1. instrument ratings for helicopters (IR(H)) issued in accordance with Annex I (Part-FCL) to this Regulation before 30 October 2022 shall be deemed as IR(H) for both single-engine and multi-engine helicopters and shall be reissued as such IR(H), when reissuing a helicopter pilot licence for administrative reasons.

2. Applicants who before 30 October 2022 commenced training for an IR(H) for either single-engine or multi-engine helicopters shall be allowed to complete that training and, in such a case, be issued with an IR(H) for both single-engine and multi-engine helicopters.’;

⁽⁴⁾ <https://www.easa.europa.eu/document-library/opinions>

(3) the following Article 4e is inserted:

'Article 4e

Transitional measures for training, testing and checking related to multi-pilot operations in single-pilot helicopters

1. Member States may decide to issue specific privileges for conducting training, skill tests and proficiency checks in multi-pilot operation in single-pilot helicopters to applicants who meet all of the following conditions:

- (a) hold an instructor or examiner certificate, as applicable, issued in accordance with Annex I (Part-FCL) to this Regulation, including the privileges to instruct or to examine, as applicable, in the relevant type of helicopter;
- (b) have completed the training specified in point FCL.735.H of Part-FCL;
- (c) have experience in multi-pilot operation in helicopters at a level that is acceptable to the competent authority of that Member State.

2. The privileges issued in accordance with paragraph 1 shall be valid until 30 October 2025. In order to revalidate the privileges, applicants shall comply with the experience requirements for instructor and examiner privileges related to multi-pilot operation in single-pilot helicopters as set out in Part-FCL.;

(4) in Article 10a, the following paragraph (6) is added:

'6. Pilot training organisations that provide training for the IR(H) shall adapt their training programme to be compliant with Annex I by 30 October 2023.;

(5) Annex I is amended in accordance with the Annex 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 30 October 2022. However, point (1) of Article 1 shall apply as of the date of entry into force.

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

Done at Brussels, 14 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex I (Part-FCL) to Regulation (EU) No 1178/2011 is amended as follows:

- (1) point FCL.010 is amended as follows:
 - (a) the definition of 'Multi-pilot operation' is replaced by the following:

'Multi-pilot operation' means an operation requiring at least two pilots using multi-crew cooperation in either a multi-pilot or a single-pilot aircraft.';
 - (b) the definition of 'Multi-pilot aircraft' is replaced by the following:

'Multi-pilot aircraft':

 - for aeroplanes, it means aeroplanes certificated for operation with a minimum crew of at least two pilots,
 - for helicopters, airships and powered-lift aircraft, it means an aircraft which is certificated for operation with a minimum crew of at least two pilots or which is required to be operated with at least two pilots in accordance with Regulation (EU) No 965/2012.';
 - (c) the definition of 'Single-pilot aircraft' is replaced by the following:

'Single-pilot aircraft':

 - for aeroplanes, it means an aircraft certificated for operation by one pilot,
 - for helicopters, airships and powered lift aircraft, it means an aircraft which is certificated for operation by one pilot and which is not required to be operated with at least two pilots by Regulation (EU) No 965/2012.';
- (2) in point FCL.060(b), point (1) is replaced by the following:

'(1) as PIC or co-pilot unless he or she has carried out, in the preceding 90 days, at least 3 take-offs, approaches and landings as a pilot flying in an aircraft of the same type or class or an FFS representing that type or class. The 3 take-offs and landings shall be performed in either multi-pilot or single-pilot operations, depending on the privileges held by the pilot; and';
- (3) point FCL.510.H is replaced by the following:

FCL.510.H ATPL(H) – Prerequisites, experience and crediting

Applicants for an ATPL(H) shall:

- (a) hold a CPL(H);
- (b) have received instruction in MCC in accordance with point FCL.735.H;
- (c) have completed as a pilot of helicopters a minimum of 1 000 hours of flight time including at least:
 - (1) 350 hours in multi-pilot operations in helicopters;
 - (2) (i) 250 hours as PIC; or
(ii) 100 hours as PIC and 150 hours as PIC under supervision; or
(iii) 250 hours as PIC under supervision in multi-pilot helicopters. In this case, the ATPL(H) privileges shall be limited to multi-pilot operations only, until 100 hours as PIC have been completed;
 - (3) 200 hours of cross-country flight time of which at least 100 hours shall be as PIC or as PIC under supervision;
 - (4) 30 hours of instrument time of which not more than 10 hours may be instrument ground time; and
 - (5) 100 hours of night flight as PIC or as co-pilot.

Of the 1 000 hours, a maximum of 100 hours may have been completed in an FSTD, of which not more than 25 hours may be completed in an FNPT;

- (d) flight time in aeroplanes shall be credited up to 50 % against the flight time requirements of point (c);
 - (e) the experience required in point (c) shall be completed before the skill test for the ATPL(H) is taken;
 - (f) applicants for an ATPL(H) shall receive a full credit for the requirement in point (b) when they comply with point FCL.720.H(a)(2)(ii) and, additionally, have received training at an ATO to meet the necessary standard for the successful completion of the course as per point FCL.735.H.;
- (4) point FCL.605 is replaced by the following:

FCL.605 IR – Privileges and conditions

(a) Privileges

The privileges of holders of an IR are to fly aircraft under IFR, including PBN operations, with a minimum decision height of:

- (1) no less than 200 ft (60 m);
- (2) less than 200 ft (60 m), provided that they are authorised to do so in accordance with Annex V (Part-SPA) to Regulation (EU) No 965/2012.

(b) Conditions

- (1) Holders of an IR shall exercise their privileges in accordance with the conditions established in Appendix 8 to this Annex.
- (2) To exercise privileges as PIC under IFR in multi-pilot operation in helicopters, holders of an IR(H) shall have at least 70 hours of instrument time, of which up to 30 hours may be instrument ground time.;

- (5) point FCL.620 IR is replaced by the following:

FCL.620 IR – Skill test

Applicants for an IR shall pass a skill test in accordance with Appendix 7 to this Annex to demonstrate their ability to perform the relevant procedures and manoeuvres with a degree of competency appropriate to the privileges granted.;

- (6) after the heading 'SECTION 2 – Specific requirements for the aeroplane category', the following point FCL.620.A is inserted:

FCL.620.A IR(A) – Skill test

- (a) For a multi-engine IR(A), the skill test shall be taken in a multi-engine aeroplane. For a single-engine IR(A), the test shall be taken in a single-engine aeroplane. A multi-engine centreline thrust aeroplane shall be considered a single-engine aeroplane for the purposes of this point.
 - (b) Applicants who have completed a skill test for a multi-engine IR(A) in a single-pilot multi-engine aeroplane for which a class rating is required shall also be issued with a single-engine IR(A) for the single-engine aeroplane class or type ratings that they hold.;
- (7) point FCL.630.H is replaced by the following:

FCL.630.H IR(H) – Extension of the privileges of an IR(H) to further helicopter types

Unless specified otherwise in the operational suitability data established in accordance with Annex I (Part 21) to Commission Regulation (EU) No 748/2012, holders of an IR(H) who wish to extend their IR(H) privileges to further helicopter types shall, in addition to the relevant type rating training course, complete at an ATO 2 hours of flight training on the relevant type by sole reference to instruments according to IFR which may be conducted in an FFS or an FTD which appropriately represents the relevant type for IFR operation.;

- (8) after the heading ‘SECTION 4 – Specific requirements for the airship category’, the following point FCL.620.As is inserted:

‘FCL.620.As IR(As) – Skill test

For a multi-engine IR(As), the skill test shall be taken in a multi-engine airship. For a single-engine IR(As), the test shall be taken in a single-engine airship.’;

- (9) in point FCL.725, point (d) is replaced by the following:

‘(d) Single-pilot and multi-pilot operation

- (1) A pilot who already holds a type rating for an aircraft type, with the privilege for either single-pilot or multi-pilot operations, shall be considered to have already fulfilled the theoretical requirements when applying to add the privilege for the other form of operation on the same aircraft type.
- (2) Such a pilot shall complete additional flight training for the other form of operation in the relevant type in accordance with Appendix 9 to this Annex, unless specified otherwise in the operational suitability data established in accordance with Annex I (Part 21) to Commission Regulation (EU) No 748/2012. This training shall be completed at either of the following:
 - (i) an ATO;
 - (ii) an organisation to which Annex III (Part-ORO) to Regulation (EU) No 965/2012 applies and that is entitled to provide such training on the basis of either an approval or, in the case of single-pilot helicopters, a declaration.
- (3) Except for single-pilot helicopters, the form of operation shall be entered in the licence.
- (4) In the case of single-pilot helicopters, all of the following shall apply:
 - (i) In the case where a skill test or a proficiency check for a non-complex single-pilot helicopter type rating was completed in multi-pilot operations only, a restriction to multi-pilot operation shall be endorsed with the type rating in the licence. This endorsement shall be removed when the applicant completes a proficiency check that included the necessary elements for single-pilot operation as specified in Appendix 9 to this Annex.
 - (ii) In all other cases, the form of operation shall not be entered in the licence. The pilot is entitled to exercise the privileges of the type rating:
 - (A) in single-pilot operation, provided that the skill test or proficiency check either:
 - (1) was completed in single-pilot operation; or
 - (2) was completed in multi-pilot operation and contained additional elements for single-pilot operation, as specified in Appendix 9 to this Annex.
 - (B) in multi-pilot operation under all of the following conditions:
 - (1) the pilot complies with point FCL.720.H(a)(2);
 - (2) the privileges are exercised in accordance with Annex III (Part-ORO) to Regulation (EU) No 965/2012 only;
 - (3) the skill test or proficiency check was completed in multi-pilot operation.’;

- (10) point FCL.720.H is amended as follows:

- (a) the introductory phrase is replaced by the following:

‘Unless otherwise determined in the operational suitability data established in accordance with Annex I (Part 21) to Commission Regulation (EU) No 748/2012, an applicant for the issue of the first helicopter type rating shall comply with the following experience requirements and prerequisites for the issue of the relevant rating.’;

(b) point (a) is amended as follows:

(1) the introductory phrase is replaced by the following:

‘(a) Multi-pilot helicopters. An applicant for a type rating for a multi-pilot helicopter type shall, before starting the type rating training course:’;

(2) in point (2), point (ii) is replaced by the following:

‘(ii) have completed at least 500 hours of flight time as a pilot in multi-pilot operations in any aircraft category.’;

(3) in point (2), point (iii) is deleted;

(c) in point (b), the introductory phrase is replaced by the following:

‘A graduate from an ATP(H)/IR, ATP(H), CPL(H)/IR or CPL(H) integrated course who does not comply with the requirement of point (a)(1), shall be entitled to undergo the type rating training course for a multi-pilot helicopter type rating and shall have the type rating issued with the privileges limited to exercising functions as co-pilot only. The limitation shall be removed once the pilot has complied with all of the following:’;

(d) in point (c), the introductory phrase is replaced by the following:

‘Multi-engine helicopters. An applicant for the issue of a first type rating for a multi-engine helicopter shall:’;

(11) in point FCL.905.TRI, point (a)(5) is amended as follows:

(a) point (ii) is replaced by the following:

‘(ii) MCC training, provided that he or she has completed 350 hours of flight time as a pilot in multi-pilot operations in any aircraft category.’

(b) point (iii) is deleted;

(12) in point FCL.910.TRI, point (c) is amended as follows:

(a) point (2) is replaced by the following:

‘(2) In order to extend the privileges of a TRI(H) to multi-pilot operations in the same type of single-pilot helicopters, the holder shall have at least 350 hours of flight time as a pilot in multi-pilot operations in any aircraft category or have at least 100 hours of flight time as a pilot in multi-pilot operations on the specific type within the last 2 years.’;

(b) a new point (3) is added as follows:

‘(3) Before the privileges of a TRI(H) are extended from single-pilot helicopters to multi-pilot helicopters, the holder shall comply with point FCL.915.TRI(d)(3).’;

(13) in point FCL.915.TRI, point (d) is replaced by the following:

‘(d) for TRI(H):

(1) for a TRI(H) certificate for single-pilot single-engine helicopters, either:

- (i) have completed 250 hours as a pilot on helicopters; or
- (ii) hold an FI(H) certificate.

(2) for a TRI(H) certificate for single-pilot multi-engine helicopters, either:

- (i) have completed 500 hours as pilot of helicopters, including 100 hours as PIC in single-pilot multi-engine helicopters; or
- (ii) hold an FI(H) certificate and have completed 100 hours of flight time as a pilot in multi-engine helicopters.

(3) for a TRI(H) certificate for multi-pilot helicopters, have completed 1 000 hours of flight time as a pilot on helicopters, and have either 350 hours in multi-pilot operations on any aircraft category or 100 hours of flight time as a pilot in multi-pilot operations on the type for which the TRI(H) certificate is sought;’;

(14) in point FCL.915.IRI, point (b) (3) is replaced by the following:

‘(3) when seeking privileges to provide training in multi-engine helicopters, meet the requirements of points FCL.910.TRI(c)(1) and FCL.915.TRI(d)(2);’;

(15) in point FCL.905.SFI, point (d) (2) is replaced by the following:

‘(2) MCC training, provided that they have at least 350 hours as a pilot in multi-pilot operations in any aircraft category.’;

(16) in point FCL.915.SFI, point (e) is amended as follows:

(a) point (2) is replaced by the following:

‘(2) in the case of multi-pilot helicopters, at least 1 000 hours of flying experience as a pilot in helicopters, including at least 350 hours in multi-pilot operations in any aircraft category.’;

(b) point (4) is replaced by the following:

‘(4) in the case of single-pilot single-engine helicopters, completed 250 hours as a pilot on helicopters.’;

(c) a new point (5) is added as follows:

‘(5) in the case of single-pilot helicopters in multi-pilot operations, completed at least 350 hours in multi-pilot operations in any aircraft category.’;

(17) in point FCL.915.MCCI, point (b) is replaced by the following:

‘(b) have at least:

- (1) in the case of aeroplanes, airships and powered-lift aircraft, 1 500 hours of flying experience as a pilot in multi-pilot operations, of which at least 350 hours in the appropriate aircraft category;
- (2) in the case of helicopters, 1 000 hours of flying experience as a pilot in multi-pilot operations, of which at least 350 hours in helicopters.’;

(18) in point FCL.1005.TRE, point (b)(2) is replaced by the following:

‘(2) proficiency checks for the revalidation or renewal of IRs, provided the TRE(H) holds a valid IR(H);’;

(19) in point FCL.1010.TRE, point (b)(6) is replaced by the following:

‘(6) Before the privileges of a TRE(H) are extended from single-pilot operations to multi-pilot operations on the same type of helicopter, the holder shall have either:

- (i) at least 100 hours in multi-pilot operations on this type; or
- (ii) at least 350 hours in multi-pilot operations in any aircraft category.’;

(20) in point FCL.1010.SFE, point (b) is amended as follows:

(a) points (3) and (4) are replaced by the following:

‘(3) in the case of multi-pilot helicopters, have at least 1 000 hours of flight time as pilots of multi-pilot helicopters;

(4) in the case of single-pilot helicopters in multi-pilot operations, have completed at least 350 hours in multi-pilot operations in any aircraft category.’;

(b) a new point (5) is added as follows:

‘(5) for the initial issue of an SFE certificate, have completed at least 50 hours of synthetic flight instruction as a TRI(H) or an SFI(H) on the applicable type.’;

(21) in Section I of Appendix 3, paragraph 9 is replaced by the following:

‘9. Upon completion of the related flying training, the applicant shall take the CPL(H) skill test on either a multi-engine or a single-engine helicopter and the IR skill test on an IFR-certificated helicopter.’;

(22) Section B of Appendix 6 is amended as follows:

(a) paragraph 7 is replaced by the following:

‘7. An IR(H) course shall comprise at least 55 hours instrument time under instruction, of which:

- (a) up to 20 hours may be instrument ground time in an FNPT I (H) or (A). These 20 hours instruction time in FNPT I (H) or (A) may be substituted by 20 hours instruction time for IR(H) in an aeroplane, approved for this course; or
- (b) up to 40 hours may be instrument ground time in a helicopter FTD 2/3, FNPT II/III or FFS.

The instrument flight instruction shall include at least 10 hours in an IFR-certificated helicopter.’;

(b) paragraph 8 is deleted;

(c) paragraph 9.1 is renumbered as ‘8.1.’;

(d) paragraph 9.2 is renumbered as ‘8.2.’;

(e) paragraph 9.3 is renumbered as ‘8.3.’;

(f) paragraph 10 is renumbered as ‘9.’, and its paragraph (b) is replaced by the following:

‘(b) procedure and manoeuvres for IFR operation under normal, abnormal and emergency conditions covering at least:

- transition from visual to instrument flight on take-off,
- standard instrument departures and arrivals,
- en-route IFR procedures,
- holding procedures,
- instrument approaches to specified minima,
- missed approach procedures,
- landings from instrument approaches, including circling.’;

(23) In Appendix 8, Section B is replaced by the following:

‘B. Helicopters

Credits shall be granted only if holders are revalidating or renewing IR privileges for single-pilot helicopters, as appropriate.

If a skill test or a proficiency check, including IR, is performed and the holders have a valid:	Credit is valid towards the IR part in a proficiency check for:
Multi-pilot helicopter (MPH) type rating	Single-pilot helicopter (SPH) of the same type, including privileges for single-pilot operations (*)
Single-pilot helicopter (SPH) type rating, in multi-pilot operations	Privileges for single-pilot operations in the same type (*)

(*) Provided that within the preceding 12 months at least three IFR departures and approaches exercising PBN privileges, including one RNP APCH approach (which may be a Point in Space (PinS) approach), have been performed on a SP type of helicopter in SP operations.’;

(24) Appendix 9 is amended as follows:

(a) Section A is amended as follows:

(1) the heading before paragraph (13) and paragraph (13) are replaced by the following:

‘SPECIFIC REQUIREMENTS FOR THE SKILL TEST/PROFICIENCY CHECK FOR TYPE RATINGS FOR MULTI-PILOT AIRCRAFT, FOR SINGLE-PILOT AIRCRAFT WHEN OPERATED IN MULTI-PILOT OPERATIONS, FOR MPL AND FOR ATPL

13. The skill test for a multi-pilot aircraft or a single-pilot aircraft when operated in multi-pilot operations shall be performed in a multi-crew environment. Another applicant or another type rated qualified pilot may function as the second pilot. If an aircraft is used, the second pilot shall be the examiner or an instructor.’;

(2) the introductory phrase of paragraph 15 is replaced by the following:

‘15. The following matters shall be specifically checked by the examiner for applicants for the ATPL or a type rating for multi-pilot aircraft or for multi-pilot operations in a single-pilot aircraft extending to the duties of a PIC, irrespective of whether the applicants act as PF or PM.’;

(b) Section B is amended as follows:

(1) paragraph 2 is replaced by the following:

‘2. In the case of multi-pilot and single-pilot high-performance complex aeroplanes, applicants shall pass all sections of the skill test or proficiency check. Failure in more than five items will require applicants to take the entire test or check again. Applicants failing five or fewer items shall take the failed items again. Failure in any item on the retest or recheck, including those items that have been passed on a previous attempt, will require applicants to repeat the entire check or test again.’;

(2) in paragraph 6, in the table following paragraph (j), the words ‘*General remarks:* Special requirements for the extension of a type rating for instrument approaches down to a decision height of less than 200 ft (60 m), i. e. CAT II/III operations.’ before the headline ‘Section 6’, the subsequent Section 6 and the words ‘NOTE: CAT II/III operations shall be performed in accordance with the applicable air operations requirements.’ following Section 6 are deleted.

(c) in Section C, the following heading and paragraph (13) are added after paragraph (12):

‘SINGLE-PILOT HELICOPTERS

13. Applicants for the issue, revalidation or renewal of a single-pilot helicopter type rating shall:

- (a) if privileges for single-pilot operation are sought, complete the skill test or proficiency check in single-pilot operation;
- (b) if privileges for multi-pilot operation are sought, complete the skill test or proficiency check in multi-pilot operation;
- (c) if privileges for both single-pilot and multi-pilot privileges are sought, complete the skill test or proficiency check in multi-pilot operation and, additionally, the following manoeuvres and procedures in single-pilot operation:
 - (1) for single-engine helicopters: 2.1 take-off and 2.6 and 2.6.1 autorotative descent and autorotative landing;
 - (2) for multi-engine helicopters: 2.1 take-off and 2.4 and 2.4.1 engine failures shortly before and shortly after reaching TDP;
 - (3) for IR privileges, in addition to point (1) or (2), as applicable, one approach of Section 5, unless the criteria of Appendix 8 to this Annex are met;

- (d) in order to remove a restriction to multi-pilot operation from a non-complex single-pilot helicopter type rating, complete a proficiency check that includes the manoeuvres and procedures referred to in point (c) (1) or (c)(2), as applicable.;
- (d) Section D is amended as follows:
- (1) in paragraph 6, points (a), (b) and (c) are deleted;
- (2) after paragraph 6, the following paragraph (6a) is inserted as follows:
- ‘(6a) The starred items (*) shall be flown solely by reference to instruments. If this condition is not met during the skill test or proficiency check, the type rating will be restricted to VFR only.’;
- (3) in the table following paragraph 8, Section 6 is deleted, and Section 7 is replaced by the following:

‘SECTION 6 – Optional equipment							
6	Use of optional equipment		P	→	→’		

- (e) Section E is amended as follows:
- (1) in paragraph 6, points (a), (b) and (c) are deleted.
- (2) after paragraph 6, the following paragraph (6a) is inserted:
- ‘(6a) The starred items (*) shall be flown solely by reference to instruments. If this condition is not met during the skill test or proficiency check, the type rating will be restricted to VFR only.’;
- (3) in the table following paragraph 8, Section 6 is deleted, and Section 7 is replaced by the following:

‘SECTION 6 – Optional equipment							
6	Use of optional equipment		P	→’.			

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2228**of 14 December 2021****setting the weighted average of maximum mobile termination rates across the Union and repealing
Implementing Regulation (EU) 2020/2082**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 531/2012 of the European Parliament and of the Council of 13 June 2012 on roaming on public mobile communications networks within the Union ⁽¹⁾, and in particular Article 6e(2) thereof,

Whereas:

- (1) Pursuant to Article 6a of Regulation (EU) No 531/2012, from 15 June 2017 domestic providers should not levy any surcharge in addition to the domestic retail price on roaming customers in any Member State for any regulated roaming calls received, where those calls are within the limits allowed by the fair use policy.
- (2) Regulation (EU) No 531/2012 provides for an authorisation to apply a surcharge, however limits any such surcharge applied for receiving regulated roaming calls, to the weighted average of maximum mobile termination rates across the Union.
- (3) Commission Implementing Regulation (EU) 2020/2082 ⁽²⁾ sets out the weighted average of maximum mobile termination rates across the Union, to be applied in 2021 on the basis of the data values as of 1 July 2020.
- (4) The Body of European Regulators for Electronic Communications has provided the Commission with updated information from Member States' national regulatory authorities on the maximum level of mobile termination rates imposed, in accordance with Articles 32, 67 and 74 of Directive (EU) 2018/1972 of the European Parliament and of the Council ⁽³⁾ in each national market for wholesale voice call termination on individual mobile networks and on the total number of subscribers in the Member States.
- (5) Pursuant to Regulation (EU) No 531/2012, the Commission has calculated the weighted average of the maximum mobile termination rates across the Union by multiplying the maximum mobile termination rate permitted in a given Member State by the total number of subscribers in that Member State, summing that product over all Member States and then dividing the total obtained by the total number of subscribers in all Member States, on the basis of the data values as of 30 June 2021. For Member States whose currency is not the euro, the relevant exchange rate is the average for the second quarter of 2021 obtained from the European Central Bank's database.
- (6) The value of the weighted average of maximum mobile termination rates across the Union therefore needs to be updated.
- (7) Implementing Regulation (EU) 2020/2082 should therefore be repealed.
- (8) Under Regulation (EU) No 531/2012, the Commission should annually review the weighted average of maximum mobile termination rates across the Union as set by this Implementing Regulation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Communications Committee,

⁽¹⁾ OJ L 172, 30.6.2012, p 10.

⁽²⁾ Commission Implementing Regulation (EU) 2020/2082 of 14 December 2020 setting the weighted average of maximum mobile termination rates across the Union and repealing Implementing Regulation (EU) 2019/2116 (OJ L 423, 15.12.2020, p. 18).

⁽³⁾ Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code (OJ L 321, 17.12.2018, p. 36).

HAS ADOPTED THIS REGULATION:

Article 1

The weighted average of maximum mobile termination rates across the Union shall be EUR 0,0072 per minute.

Article 2

Implementing Regulation (EU) 2020/2082 is repealed.

Article 3

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 January 2022.

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

Done at Brussels, 14 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2229**of 14 December 2021**

initiating an investigation concerning possible circumvention of the countervailing measures imposed by Implementing Regulation (EU) 2020/776 on imports of certain woven and/or stitched glass fibre fabrics originating in People's Republic of China and Egypt by imports of certain woven and/or stitched glass fibre fabrics consigned from Turkey, whether declared as originating in Turkey or not, and making such imports subject to registration

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union ⁽¹⁾ ('the basic Regulation') and in particular Articles 23(4) and 24(5) thereof,

After having informed the Member States,

Whereas:

A. REQUEST

- (1) The European Commission ('the Commission') has received a request pursuant to Articles 23(4) and 24(5) of Regulation (EU) 2016/1037, to investigate the possible circumvention of the countervailing measures imposed on imports of certain woven and/or stitched glass fibre fabrics originating in People's Republic of China and Egypt and to make imports of certain woven and/or stitched glass fibre fabrics consigned from Turkey, whether declared as originating in Turkey or not, subject to registration.
- (2) The request was lodged on 3 November 2021 by TECH-FAB Europe e.V.

B. PRODUCT

- (3) The product concerned by the possible circumvention is fabrics of woven, and/or stitched continuous filament glass fibre rovings and/or yarns with or without other elements, excluding products which are impregnated or pre-impregnated (pre-preg), and excluding open mesh fabrics with cells with a size of more than 1,8 mm in both length and width and weighing more than 35 g/m² classified on the date of entry into force of Commission Implementing Regulation (EU) 2020/776 ⁽²⁾ under CN codes ex 7019 39 00, ex 7019 40 00, ex 7019 59 00 and ex 7019 90 00 (TARIC codes 7019 39 00 80, 7019 40 00 80, 7019 59 00 80 and 7019 90 00 80) and originating in People's Republic of China and Egypt ('the product concerned'). This is the product to which the measures that are currently in force apply.
- (4) The product under investigation is the same as that defined in the previous recital, currently falling under CN codes ex 7019 39 00, ex 7019 40 00, ex 7019 59 00 and ex 7019 90 00, but consigned from Turkey, whether declared as originating in Turkey or not (TARIC codes 7019 39 00 83, 7019 40 00 83, 7019 59 00 83 and 7019 90 00 83) ('the product under investigation').

C. EXISTING MEASURES

- (5) The measures currently in force and possibly being circumvented are countervailing measures imposed by Implementing Regulation (EU) 2020/776 imposing definitive countervailing duties on imports of certain woven and/or stitched glass fibre fabrics originating in the People's Republic of China and Egypt and amending Commission Implementing Regulation (EU) 2020/492 imposing definitive anti-dumping duties on imports of certain woven and/or stitched glass fibre fabrics originating in the People's Republic of China and Egypt ('the existing measures').

⁽¹⁾ OJ L 176, 30.6.2016, p. 55.

⁽²⁾ Commission Implementing Regulation (EU) 2020/776 of 12 June 2020 imposing definitive countervailing duties on imports of certain woven and/or stitched glass fibre fabrics originating in the People's Republic of China and Egypt and amending Commission Implementing Regulation (EU) 2020/492 imposing definitive anti-dumping duties on imports of certain woven and/or stitched glass fibre fabrics originating in the People's Republic of China and Egypt (OJ L 189, 15.6.2020, p. 1).

D. GROUNDS

- (6) The request contains sufficient evidence that the existing countervailing measures on imports of the product concerned are being circumvented by imports of the product under investigation. In particular, the evidence available to the Commission shows the following.
- (7) A change in the pattern of trade involving exports from the People's Republic of China and Egypt and Turkey to the Union has taken place following the imposition of measures on the product concerned.
- (8) This change appears to stem from a practice for which there is insufficient due cause or economic justification other than the imposition of the duty, namely the consignment of the product concerned via Turkey to the Union with or without having undergone some assembly or completion operation in Turkey.
- (9) Furthermore, the evidence tends to show that the practice described above undermines the remedial effects of the existing countervailing measures on the product concerned both in terms of quantity and prices. Significant volumes of imports of the product under investigation appear to have entered the EU market. In addition, there is sufficient evidence that imports of the product under investigation are made at injurious prices.
- (10) Finally, the evidence tends to show that the product under investigation and/or parts thereof still benefit from the subsidy. Indeed, the product under investigation and the parts thereof are produced by and exported to Turkey by companies in China and Egypt that were found to receive countervailable subsidies for the production and sale of the product under investigation under the existing measures.
- (11) If the investigation would identify other circumvention practices covered by Article 23 of the basic Regulation than the ones mentioned above, then the investigation may also cover these practices.

E. PROCEDURE

- (12) In light of the above, the Commission has concluded that sufficient evidence exists to justify the initiation of an investigation pursuant to Article 23(4) of the basic Regulation and to make imports of the product under investigation subject to registration, in accordance with Article 24(5) of the basic Regulation.
- (13) In order to obtain the information necessary for this investigation, all interested parties should contact the Commission forthwith, but not later than the time-limit set in Article 3(2) of this Regulation. The time-limit set in Article 3(2) of this Regulation applies to all interested parties. If appropriate, information may also be sought from the Union industry.
- (14) The authorities of Turkey, the People's Republic of China and Egypt will be notified of the initiation of the investigation.

(a) Instructions for making written submissions and sending completed questionnaires and correspondence

- (15) Information submitted to the Commission for the purpose of trade defence investigations shall be free from copyrights. Interested parties, before submitting to the Commission information and/or data which is subject to third party copyrights, must request specific permission to the copyright holder explicitly allowing a) the Commission to use the information and data for the purpose of this trade defence proceeding and b) to provide the information and/or data to interested parties to this investigation in a form that allows them to exercise their right of defence.

- (16) All written submissions, including the information requested in this Regulation, completed questionnaires and correspondence provided by interested parties for which confidential treatment is requested shall be labelled 'Sensitive' ⁽³⁾. Parties submitting information in the course of this investigation are invited to reason their request for confidential treatment.
- (17) Parties providing 'Sensitive' information are required to furnish non-confidential summaries of it pursuant to Article 29(2) of Regulation (EU) 2016/1037, which will be labelled 'For inspection by interested parties'. These summaries should be sufficiently detailed to permit a reasonable understanding of the substance of the information submitted in confidence.
- (18) If a party providing confidential information fails to show good cause for a confidential treatment request or does not furnish a non-confidential summary of it in the requested format and quality, the Commission may disregard such information unless it can be satisfactorily demonstrated from appropriate sources that the information is correct.
- (19) Interested parties are invited to make all submissions and requests via TRON.tdi (<https://webgate.ec.europa.eu/tron/> TDI) including scanned powers of attorney and certification sheets.

In order to have access to TRON.tdi, interested parties need an EU Login account. Full instructions on how to register and use TRON.tdi are available on <https://webgate.ec.europa.eu/tron/resources/documents/gettingStarted.pdf>.

By using TRON.tdi or email, interested parties express their agreement with the rules applicable to electronic submissions contained in the document 'CORRESPONDENCE WITH THE EUROPEAN COMMISSION IN TRADE DEFENCE CASES' published on the website of the Directorate-General for Trade: http://trade.ec.europa.eu/doclib/docs/2011/june/tradoc_148003.pdf.

The interested parties must indicate their name, address, telephone and a valid email address and they should ensure that the provided email address is a functioning official business email which is checked on a daily basis. Once contact details are provided, the Commission will communicate with interested parties by email only, unless they explicitly request to receive all documents from the Commission by another means of communication or unless the nature of the document to be sent requires the use of a registered mail. For further rules and information concerning correspondence with the Commission including principles that apply to submissions by email, interested parties should consult the communication instructions with interested parties referred to above.

Commission address for correspondence:

European Commission
Directorate-General for Trade
Directorate G
Office: CHAR 04/039
1049 Brussels
BELGIUM

TRON.tdi: <https://webgate.ec.europa.eu/tron/tdi>

Email: TRADE-GFFTU-AC@ec.europa.eu

(b) Collection of information and holding of hearings

- (20) All interested parties including the Union industry, importers and any relevant associations are invited to make their views known in writing and to provide supporting evidence provided that such submissions are made within the deadline provided for in Article 3(2). Furthermore, the Commission may hear interested parties, provided that they make a request in writing and show that there are particular reasons why they should be heard.

⁽³⁾ A 'Sensitive' document is a document which is considered confidential pursuant to Article 29 of the basic Regulation and Article 12 of the WTO Agreement on Subsidies and Countervailing Measures (SCM Agreement). It is also a document protected pursuant to Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council (OJ L 145, 31.5.2001, p. 43).

(c) Requests for exemptions

- (21) In accordance with Article 23(5) of the basic Regulation, imports of the product under investigation may be exempted from measures if the importation does not constitute circumvention.
- (22) Since the possible circumvention takes place outside the Union, exemptions may be granted, in accordance with Article 23(6) of the basic Regulation, to producers of the product under investigation in Turkey who can show that they are not engaged in circumvention practices as defined in Articles 23(3) of the basic Regulation. Producers, if any, wishing to obtain an exemption should make themselves known within the time-limit indicated in Article 3(1) of this Regulation. Copies of the questionnaire for exporting producers in People's Republic of China and Egypt, the exemption claim form questionnaire for exporting producers in Turkey and questionnaires for importers in the EU are available in the file for inspection by interested parties and on DG Trade's website: https://trade.ec.europa.eu/tdi/case_details.cfm?id=2572. The questionnaires have to be submitted within the time-limit indicated in Article 3(2) of this Regulation.

F. REGISTRATION

- (23) Pursuant to Article 24(5) of the basic Regulation, imports of the product under investigation shall be made subject to registration in order to ensure that, should the investigation result in findings of circumvention, countervailing duties of an appropriate amount, not exceeding the duty for 'all other companies' imposed by Implementing Regulation (EU) 2020/776 respectively for the People's Republic of China and Egypt, can be levied from the date on which registration of such imports was imposed.

G. TIME-LIMITS

- (24) In the interest of sound administration, time-limits should be stated within which:
- interested parties may make themselves known to the Commission, submit questionnaires, present their views in writing or any other information to be taken into account during the investigation,
 - producers in Turkey may request exemptions from measures,
 - interested parties may make a written request to be heard by the Commission.
- (25) Attention is drawn to the fact that the exercise of procedural rights set out in the basic Regulation therefore depends on parties making themselves known within the time-limits laid down in Article 3 of this Regulation.

H. NON-COOPERATION

- (26) If any interested party refuses access to or does not provide the necessary information within the time-limits, or significantly impedes the investigation, findings, affirmative or negative, may be made on the basis of facts available in accordance with Article 28 of the basic Regulation.
- (27) Where it is found that any interested party has supplied false or misleading information, the information shall be disregarded and use may be made of facts available in accordance with Article 28 of the basic Regulation.
- (28) If an interested party does not cooperate or cooperates only partially and findings are therefore based on the facts available in accordance with Article 28 of the basic Regulation, the result may be less favourable to that party than if it had cooperated.

I. SCHEDULE OF THE INVESTIGATION

- (29) The investigation will be concluded, pursuant to Article 23(4) of the basic Regulation, within 9 months of the date of entry into force of this Regulation.

J. PROCESSING OF PERSONAL DATA

- (30) It is noted that any personal data collected in this investigation will be treated in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽⁴⁾.
- (31) A data protection notice that informs all individuals of the processing of personal data in the framework of Commission's trade defence activities is available on DG Trade's website: <http://ec.europa.eu/trade/policy/accessing-markets/trade-defence/>.

K. HEARING OFFICER

- (32) Interested parties may request the intervention of the Hearing Officer for trade proceedings. The Hearing Officer reviews requests for access to the file, disputes regarding the confidentiality of documents, requests for extension of time limits and any other request concerning the rights of defence of interested parties and third parties as may arise during the proceeding.
- (33) The Hearing Officer may organise hearings and mediate between the interested party/-ies and Commission services to ensure that the interested parties' rights of defence are being fully exercised. A request for a hearing with the Hearing Officer should be made in writing and should specify the reasons for the request. The Hearing Officer will examine the reasons for the requests. These hearings should only take place if the issues have not been settled with the Commission services in the due course.
- (34) Any request must be submitted in good time and expeditiously so as not to jeopardise the orderly conduct of proceedings. To that effect, interested parties should request the intervention of the Hearing Officer at the earliest possible time following the occurrence of the event justifying such intervention. Where hearing requests are submitted outside the relevant timeframes, the Hearing Officer will also examine the reasons for such late requests, the nature of the issues raised and the impact of those issues on the rights of defence, having due regard to the interests of good administration and the timely completion of the investigation.
- (35) For further information and contact details interested parties may consult the Hearing Officer's web pages on DG TRADE's website: <http://ec.europa.eu/trade/trade-policy-and-you/contacts/hearing-officer/>,

HAS ADOPTED THIS REGULATION:

Article 1

An investigation is initiated pursuant to Article 23(4) of Regulation (EU) 2016/1037, in order to determine if imports of fabrics of woven, and/or stitched continuous filament glass fibre rovings and/or yarns with or without other elements, excluding products which are impregnated or pre-impregnated (pre-preg), and excluding open mesh fabrics with cells with a size of more than 1,8 mm in both length and width and weighing more than 35 g/m², currently classified under CN codes ex 7019 39 00, ex 7019 40 00, ex 7019 59 00 and ex 7019 90 00 consigned from Turkey, whether declared as originating in Turkey or not, (TARIC codes 7019 39 00 83, 7019 40 00 83, 7019 59 00 83 and 7019 90 00 83) are circumventing the measures imposed by Implementing Regulation (EU) 2020/776.

Article 2

1. The customs authorities of the Member States shall, pursuant to Articles 23(4) and 24(5) of Regulation (EU) 2016/1037, take the appropriate steps to register the imports identified in Article 1 of this Regulation.
2. Registration shall expire 9 months following the date of entry into force of this Regulation.

⁽⁴⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Article 3

1. Interested parties must make themselves known by contacting the Commission within 15 days from the date of entry into force of this Regulation.
2. Interested parties, if their representations are to be taken into account during the investigation, must present their views in writing and submit questionnaire replies, requests for exemptions, or any other information within 37 days from the date of the publication of this Regulation in the *Official Journal of the European Union*, unless otherwise specified.
3. Interested parties may also apply to be heard by the Commission within the same 37-day time limit. For hearings pertaining to the initiation stage of the investigation the request must be submitted within 15 days of the date of entry into force of this Regulation. Any request to be heard must be made in writing and must specify the reasons for the request.

Article 4

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

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

Done at Brussels, 14 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2230**of 14 December 2021**

initiating an investigation concerning possible circumvention of the anti-dumping measures imposed by Commission Implementing Regulation (EU) 2020/492 on imports of certain woven and/or stitched glass fibre fabrics originating in People's Republic of China and Egypt by imports of certain woven and/or stitched glass fibre fabrics consigned from Turkey, whether declared as originating in Turkey or not, and making such imports subject to registration

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ⁽¹⁾ ('the basic Regulation') and in particular Articles 13(3) and 14(5) thereof,

After having informed the Member States,

Whereas:

A. REQUEST

- (1) The European Commission ('the Commission') has received a request pursuant to Articles 13(3) and 14(5) of Regulation (EU) 2016/1036, to investigate the possible circumvention of the anti-dumping measures imposed on imports of certain woven and/or stitched glass fibre fabrics originating in People's Republic of China and Egypt and to make imports of certain woven and/or stitched glass fibre fabrics consigned from Turkey, whether declared as originating in Turkey or not, subject to registration.
- (2) The request was lodged on 3 November 2021 by TECH-FAB Europe e.V.

B. PRODUCT

- (3) The product concerned by the possible circumvention is fabrics of woven, and/or stitched continuous filament glass fibre rovings and/or yarns with or without other elements, excluding products which are impregnated or pre-impregnated (pre-preg), and excluding open mesh fabrics with cells with a size of more than 1,8 mm in both length and width and weighing more than 35 g/m², classified on the date of entry into force of Commission Implementing Regulation (EU) 2020/492 ⁽²⁾ under CN codes ex 7019 39 00, ex 7019 40 00, ex 7019 59 00 and ex 7019 90 00 (TARIC codes 7019 39 00 80, 7019 40 00 80, 7019 59 00 80 and 7019 90 00 80) and originating in People's Republic of China and Egypt ('the product concerned'). This is the product to which the measures that are currently in force apply.
- (4) The product under investigation is the same as that defined in the previous recital, currently falling under CN codes ex 7019 39 00, ex 7019 40 00, ex 7019 59 00 and ex 7019 90 00, but consigned from Turkey, whether declared as originating in Turkey or not (TARIC codes 7019 39 00 83, 7019 40 00 83, 7019 59 00 83 and 7019 90 00 83) ('the product under investigation').

C. EXISTING MEASURES

- (5) The measures currently in force and possibly being circumvented are anti-dumping measures imposed by Implementing Regulation (EU) 2020/492 imposing definitive anti-dumping duties on imports of certain woven and/or stitched glass fibre fabrics originating in the People's Republic of China and Egypt ('the existing measures') ⁽³⁾.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

⁽²⁾ Commission Implementing Regulation (EU) 2020/492 of 1 April 2020 imposing definitive anti-dumping duties on imports of certain woven and/or stitched glass fibre fabrics originating in the People's Republic of China and Egypt (OJ L 108, 6.4.2020, p. 1).

⁽³⁾ OJ L 108, 6.4.2020, p. 1.

D. GROUNDS

- (6) The request contains sufficient evidence that the existing anti-dumping measures on imports of the product concerned are being circumvented by imports of the product under investigation.
- (7) The evidence in the request shows the following:
- (8) A change in the pattern of trade involving exports from the People's Republic of China and Egypt and Turkey to the Union has taken place following the imposition of measures on the product concerned.
- (9) This change appears to stem from the consignment of the product concerned via Turkey to the Union after having undergone assembly operations in Turkey. The evidence shows that such assembly operations constitute circumvention as the operations started or substantially increased since, or just prior to, the initiation of the anti-dumping investigation. Moreover, the request contains sufficient evidence showing that the parts from the People's Republic of China and Egypt constitute 60 % or more of the total value of the assembled product and the value added brought in to the parts during the assembly or completion operation is lower than 25 % of the manufacturing cost.
- (10) Furthermore, the evidence tends to show that the practice described above undermines the remedial effects of the existing anti-dumping measures on the product concerned both in terms of quantity and prices. Significant volumes of imports of the product under investigation appear to have entered the EU market. In addition, there is sufficient evidence that imports of the product under investigation are made at injurious prices.
- (11) Finally, the evidence tends to show that the product under investigation is made at dumped prices in relation to the normal value previously established for the product concerned.
- (12) If the investigation would identify other circumvention practices covered by Article 13 of the basic Regulation than the ones mentioned above, then the investigation may also cover these practices.

E. PROCEDURE

- (13) In light of the above, the Commission has concluded that sufficient evidence exists to justify the initiation of an investigation pursuant to Article 13(3) of the basic Regulation and to make imports of the product under investigation subject to registration, in accordance with Article 14(5) of the basic Regulation.
- (14) In order to obtain the information necessary for this investigation, all interested parties should contact the Commission forthwith, but not later than the time-limit set in Article 3(2) of this Regulation. The time-limit set in Article 3(2) of this Regulation applies to all interested parties. If appropriate, information may also be sought from the Union industry.
- (15) The authorities of Turkey, the People's Republic of China and Egypt will be notified of the initiation of the investigation.

(a) Instructions for making written submissions and sending completed questionnaires and correspondence

- (16) Information submitted to the Commission for the purpose of trade defence investigations shall be free from copyrights. Interested parties, before submitting to the Commission information and/or data which is subject to third party copyrights, must request specific permission to the copyright holder explicitly allowing a) the Commission to use the information and data for the purpose of this trade defence proceeding and b) to provide the information and/or data to interested parties to this investigation in a form that allows them to exercise their right of defence.

- (17) All written submissions, including the information requested in this Regulation, completed questionnaires and correspondence provided by interested parties for which confidential treatment is requested shall be labelled 'Sensitive' ⁽⁴⁾. Parties submitting information in the course of this investigation are invited to reason their request for confidential treatment.
- (18) Parties providing 'Sensitive' information are required to furnish non-confidential summaries of it pursuant to Article 19(2) of Regulation (EU) 2016/1036, which will be labelled 'For inspection by interested parties'. These summaries should be sufficiently detailed to permit a reasonable understanding of the substance of the information submitted in confidence.
- (19) If a party providing confidential information fails to show good cause for a confidential treatment request or does not furnish a non-confidential summary of it in the requested format and quality, the Commission may disregard such information unless it can be satisfactorily demonstrated from appropriate sources that the information is correct.
- (20) Interested parties are invited to make all submissions and requests via TRON.tdi (<https://webgate.ec.europa.eu/tron/> TDI) including scanned powers of attorney and certification sheets.

In order to have access to TRON.tdi, interested parties need an EU Login account. Full instructions on how to register and use TRON.tdi are available on <https://webgate.ec.europa.eu/tron/resources/documents/gettingStarted.pdf>.

By using TRON.tdi or email, interested parties express their agreement with the rules applicable to electronic submissions contained in the document 'CORRESPONDENCE WITH THE EUROPEAN COMMISSION IN TRADE DEFENCE CASES' published on the website of the Directorate-General for Trade: http://trade.ec.europa.eu/doclib/docs/2011/june/tradoc_148003.pdf.

The interested parties must indicate their name, address, telephone and a valid email address and they should ensure that the provided email address is a functioning official business email which is checked on a daily basis. Once contact details are provided, the Commission will communicate with interested parties by email only, unless they explicitly request to receive all documents from the Commission by another means of communication or unless the nature of the document to be sent requires the use of a registered mail. For further rules and information concerning correspondence with the Commission including principles that apply to submissions by email, interested parties should consult the communication instructions with interested parties referred to above.

Commission address for correspondence:

European Commission
Directorate-General for Trade
Directorate G
Office: CHAR 04/039
1049 Brussels
BELGIUM

TRON.tdi: <https://webgate.ec.europa.eu/tron/tdi>

Email: TRADE-GFFTU-AC@ec.europa.eu

(b) Collection of information and holding of hearings

- (21) All interested parties including the Union industry, importers and any relevant associations are invited to make their views known in writing and to provide supporting evidence provided that such submissions are made within the deadline provided for in Article 3(2). Furthermore, the Commission may hear interested parties, provided that they make a request in writing and show that there are particular reasons why they should be heard.

⁽⁴⁾ A 'Sensitive' document is a document which is considered confidential pursuant to Article 19 of the basic Regulation and Article 6 of the WTO Agreement on Implementation of Article VI of the GATT 1994 (Anti-Dumping Agreement). It is also a document protected pursuant to Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council (OJ L 145, 31.5.2001, p. 43).

(c) Requests for exemptions

- (22) In accordance with Article 13(4) of the basic Regulation, imports of the product under investigation may be exempted from measures if the importation does not constitute circumvention.
- (23) Since the possible circumvention takes place outside the Union, exemptions may be granted, in accordance with Article 13(4) of the basic Regulation, to producers of the product under investigation in Turkey who can show that they are not engaged in circumvention practices as defined in Articles 13(1) and 13(2) of the basic Regulation. Producers, if any, wishing to obtain an exemption should make themselves known within the time-limit indicated in Article 3(1) of this Regulation. Copies of the questionnaire for exporting producers in the People's Republic of China and Egypt, the exemption claim form questionnaire for exporting producers in Turkey and questionnaires for importers in the EU are available in the file for inspection by interested parties and on DG Trade's website: https://trade.ec.europa.eu/tdi/case_details.cfm?id=2571. The questionnaires have to be submitted within the time-limit indicated in Article 3(2) of this Regulation.

F. REGISTRATION

- (24) Pursuant to Article 14(5) of the basic Regulation, imports of the product under investigation shall be made subject to registration in order to ensure that, should the investigation result in findings of circumvention, anti-dumping duties of an appropriate amount, not exceeding the duty for 'all other companies' imposed by Implementing Regulation (EU) 2020/492 respectively for the People's Republic of China and Egypt, can be levied from the date on which registration of such imports was imposed.

G. TIME-LIMITS

- (25) In the interest of sound administration, time-limits should be stated within which:
- interested parties may make themselves known to the Commission, submit questionnaires, present their views in writing or any other information to be taken into account during the investigation,
 - producers in Turkey may request exemptions from measures,
 - interested parties may make a written request to be heard by the Commission.
- (26) Attention is drawn to the fact that the exercise of procedural rights set out in the basic Regulation therefore depends on parties making themselves known within the time-limits laid down in Article 3 of this Regulation.

H. NON-COOPERATION

- (27) If any interested party refuses access to or does not provide the necessary information within the time-limits, or significantly impedes the investigation, findings, affirmative or negative, may be made on the basis of facts available in accordance with Article 18 of the basic Regulation.
- (28) Where it is found that any interested party has supplied false or misleading information, the information shall be disregarded and use may be made of facts available in accordance with Article 18 of the basic Regulation.
- (29) If an interested party does not cooperate or cooperates only partially and findings are therefore based on the facts available in accordance with Article 18 of the basic Regulation, the result may be less favourable to that party than if it had cooperated.

I. SCHEDULE OF THE INVESTIGATION

- (30) The investigation will be concluded, pursuant to Article 13(3) of the basic Regulation, within 9 months of the date of entry into force of this Regulation.

J. PROCESSING OF PERSONAL DATA

- (31) It is noted that any personal data collected in this investigation will be treated in accordance with Regulation (EU) 2018/1725 ⁽³⁾.
- (32) A data protection notice that informs all individuals of the processing of personal data in the framework of Commission's trade defence activities is available on DG Trade's website: <http://ec.europa.eu/trade/policy/accessing-markets/trade-defence/>.

K. HEARING OFFICER

- (33) Interested parties may request the intervention of the Hearing Officer for trade proceedings. The Hearing Officer reviews requests for access to the file, disputes regarding the confidentiality of documents, requests for extension of time limits and any other request concerning the rights of defence of interested parties and third parties as may arise during the proceeding.
- (34) The Hearing Officer may organise hearings and mediate between the interested party/-ies and Commission services to ensure that the interested parties' rights of defence are being fully exercised. A request for a hearing with the Hearing Officer should be made in writing and should specify the reasons for the request. The Hearing Officer will examine the reasons for the requests. These hearings should only take place if the issues have not been settled with the Commission services in the due course.
- (35) Any request must be submitted in good time and expeditiously so as not to jeopardise the orderly conduct of proceedings. To that effect, interested parties should request the intervention of the Hearing Officer at the earliest possible time following the occurrence of the event justifying such intervention. Where hearing requests are submitted outside the relevant timeframes, the Hearing Officer will also examine the reasons for such late requests, the nature of the issues raised and the impact of those issues on the rights of defence, having due regard to the interests of good administration and the timely completion of the investigation.
- (36) For further information and contact details interested parties may consult the Hearing Officer's web pages on DG TRADE's website: <http://ec.europa.eu/trade/trade-policy-and-you/contacts/hearing-officer/>,

HAS ADOPTED THIS REGULATION:

Article 1

An investigation is initiated pursuant to Article 13(3) of Regulation (EU) 2016/1036, in order to determine if imports of fabrics of woven, and/or stitched continuous filament glass fibre rovings and/or yarns with or without other elements, excluding products which are impregnated or pre-impregnated (pre-preg), and excluding open mesh fabrics with cells with a size of more than 1,8 mm in both length and width and weighing more than 35 g/m², currently classified under CN codes ex 7019 39 00, ex 7019 40 00, ex 7019 59 00 and ex 7019 90 00, consigned from Turkey, whether declared as originating in Turkey or not (TARIC codes 7019 39 00 83, 7019 40 00 83, 7019 59 00 83 and 7019 90 00 83) are circumventing the measures imposed by Implementing Regulation (EU) 2020/492.

Article 2

1. The customs authorities of the Member States shall, pursuant to Article 13(3) and Article 14(5) of Regulation (EU) 2016/1036, take the appropriate steps to register the imports identified in Article 1 of this Regulation.
2. Registration shall expire 9 months following the date of entry into force of this Regulation.

⁽³⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Article 3

1. Interested parties must make themselves known by contacting the Commission within 15 days from the date of entry into force of this Regulation.
2. Interested parties, if their representations are to be taken into account during the investigation, must present their views in writing and submit questionnaire replies, requests for exemptions, or any other information within 37 days from the date of the publication of this Regulation in the *Official Journal of the European Union*, unless otherwise specified.
3. Interested parties may also apply to be heard by the Commission within the same 37-day time limit. For hearings pertaining to the initiation stage of the investigation the request must be submitted within 15 days of the date of entry into force of this Regulation. Any request to be heard must be made in writing and must specify the reasons for the request.

Article 4

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

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

Done at Brussels, 14 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COUNCIL DECISION (EU) 2021/2231

of 9 December 2021

on the position to be taken on behalf of the European Union within the Regional Steering Committee of the Transport Community as regards the adoption of the budget of the Transport Community for 2022

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 and Article 100(2), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Treaty establishing the Transport Community ('TCT') was concluded by the Union by means of Council Decision (EU) 2019/392 ⁽¹⁾ and entered into force on 1 May 2019.
- (2) Pursuant to Article 35 TCT, the Regional Steering Committee of the Transport Community ('the Steering Committee') is to adopt the budget of the Transport Community every year. Article 35 TCT also empowers the Steering Committee to adopt decisions specifying the procedure for the implementation of the budget.
- (3) The Steering Committee is to adopt a decision on the budget of the Transport Community for 2022 during its meeting in December 2021.
- (4) The proposed budget of the Transport Community for 2022 is needed for the proper functioning of the bodies of the Transport Community. It covers the costs for human resources, travel, IT equipment and software, as well as operational expenditure such as studies, technical assistance and the organisation of conferences and meetings.
- (5) It is appropriate to establish the position to be taken on the Union's behalf within the Steering Committee, as such a decision is necessary for the functioning of the Permanent Secretariat of the Transport Community, and will be binding upon the Union,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on behalf of the Union within the Regional Steering Committee of the Transport Community as regards the budget of the Transport Community for the year 2022 shall be based on the draft decision of the Regional Steering Committee ⁽²⁾.

Article 2

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

⁽¹⁾ Council Decision (EU) 2019/392 of 4 March 2019 on the conclusion, on behalf of the European Union, of the Treaty establishing the Transport Community (OJ L 71, 13.3.2019, p. 1).

⁽²⁾ See document ST 14006/21 at <http://register.consilium.europa.eu>

Done at Brussels, 9 December 2021.

For the Council
The President
A. HOJS

COUNCIL DECISION (EU) 2021/2232**of 14 December 2021****appointing the members of the panel provided for in Article 255 of the Treaty on the Functioning of the European Union**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the second paragraph of Article 255 thereof,

Having regard to the initiative by the President of the Court of Justice on 26 October 2021,

Whereas:

- (1) Pursuant to the first paragraph of Article 255 of the Treaty on the Functioning of the European Union, a panel has been set up in order to give an opinion on candidates' suitability to perform the duties of Judge and Advocate-General of the Court of Justice and the General Court before the Governments of the Member States make the appointments (the 'panel').
- (2) The panel is comprised of seven persons chosen from among former members of the Court of Justice and the General Court, members of national supreme courts and jurists of recognised competence, one of whom is proposed by the European Parliament.
- (3) Account should be taken of a balanced membership of the panel, in particular as regards geographical coverage and as regards representation of the legal systems of the Member States.
- (4) The members of the panel and its President should therefore be appointed,

HAS ADOPTED THIS DECISION:

Article 1

For a period of four years from 1 March 2022, the following shall be appointed as members of the panel provided for in Article 255 of the Treaty on the Functioning of the European Union:

Mr Allan ROSAS, President

Mr Frank CLARKE

Ms Julia LAFFRANQUE

Ms Maria Eugénia MARTINS DE NAZARÉ RIBEIRO

Ms Barbara POŘÍZKOVÁ

Ms Silvana SCIARRA

Mr Vassilios SKOURIS

Article 2

This Decision shall enter into force on 1 March 2022.

Done at Brussels, 14 December 2021.

For the Council
The President
G. DOVŽAN

COMMISSION DECISION (EU) 2021/2233**of 14 December 2021****approving, on behalf of the European Union, amendments to Annexes 10-A and 10-B to the Free Trade Agreement between the European Union and the Republic of Singapore***(notified under document C(2021) 8893)*

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision (EU) 2019/1875 of 8 November 2019 on the conclusion of the Free Trade Agreement between the European Union and the Republic of Singapore ⁽¹⁾, and in particular Article 3 thereof,

Whereas:

- (1) The Free Trade Agreement between the European Union and the Republic of Singapore ('the Agreement') entered into force on 21 November 2019.
- (2) Article 16.1 of the Agreement establishes a Trade Committee, which, inter alia, may consider amendments to the Agreement, or amend provisions of the Agreement in cases specifically provided for in the Agreement.
- (3) Article 10.17.3 of the Agreement provides that the Trade Committee is to adopt a decision regarding the listing in Annex 10-B (Protected Geographical Indications) to the Agreement of the names from Annex 10-A (List of names to be applied for protection as Geographical Indications in the territory of the Parties) to the Agreement as soon as practicable after the procedures for protection of geographical indications have been concluded.
- (4) Article 10.18 of the Agreement provides that the Parties agree on the possibility of amending the list of geographical indications for wines, spirits, agricultural products and foodstuffs listed in Annex 10-B to be protected by each Party.
- (5) The Republic of Singapore has completed the procedure for protection in its territory of two names ('Bardolino Superiore', 'Tiroler Speck') that were listed in Annex 10-A to the Agreement and were applied for protection as geographical indications of the Union.
- (6) The Republic of Singapore has completed the procedure for protection in its territory of one name ('Saint-Emilion Grand Cru') that was not listed in Annex 10-A to the Agreement and was applied for protection as geographical indication of the Union.
- (7) Following the withdrawal of the United Kingdom from the Union as from 1 January 2021, the name 'Scotch Whisky' should be removed from the names listed in Annex 10-B to the Agreement in accordance with Article 10.18 to that Agreement.
- (8) The name 'Polish Cherry' is no longer protected in the Union and should be removed from Annex 10-A to the Agreement.
- (9) Consequently, Annexes 10-A and 10-B to the Agreement should be amended by listing those additional three names as protected geographical indications of the Union in Annex 10-B and removing two of those names from Annex 10-A. The names 'Scotch Whisky' and 'Polish Cherry' should also be removed respectively from Annex 10-B and Annex 10-A, as set out in the attached draft Decision of the Trade Committee and the amendments should be approved on behalf of the Union.
- (10) In order to fulfill as soon as practicable the obligations set out in Articles 10.17.3 and 10.18 of the Agreement, it is appropriate that this decision should enter into force on the day following that of its publication,

⁽¹⁾ Council Decision (EU) 2019/1875 of 8 November 2019 on the conclusion of the Trade Agreement between the European Union and the Republic of Singapore (OJ L 294, 14.11.2019, p. 1).

HAS DECIDED AS FOLLOWS:

Article 1

The amendments to Annexes 10-A and 10-B to the Free Trade Agreement between the European Union and the Republic of Singapore as set out in the draft Decision of the Trade Committee are hereby approved on behalf of the European Union.

The draft Decision of the Trade Committee is set out in the Annex to this Decision.

The position to be taken on the Union's behalf in the first meeting of the Trade Committee shall be based on this draft Decision. Minor changes to the draft Decision of the Trade Committee may be agreed by the representatives of the European Union in the Trade Committee without further decision of the Commission.

Article 2

The representatives of the European Union in the Trade Committee are authorised to adopt the decision of that Committee on behalf of the European Union.

Article 3

This Decision shall be published in the *Official Journal of the European Union*.

After its adoption, the Decision of the Trade Committee shall be published in the *Official Journal of the European Union*.

Done at Brussels, 14 December 2021.

For the Commission

Janusz WOJCIECHOWSKI

Member of the Commission

ANNEX

DRAFT DECISION No X/2021 OF THE EU-SINGAPORE TRADE COMMITTEE
of [date]
amending Annexes 10-A and 10-B to the Free Trade Agreement between the European Union and the
Republic of Singapore

THE TRADE COMMITTEE,

Having regard to the Free Trade Agreement between the European Union and the Republic of Singapore, and in particular Articles 10.17.3 and 10.18 thereof,

Whereas:

- (1) The Free Trade Agreement between the European Union and the Republic of Singapore ('the Agreement') entered into force on 21 November 2019.
- (2) Article 10.17.3 of the Agreement provides that the Trade Committee adopts a decision regarding the listing in Annex 10-B (Protected Geographical Indications) to the Agreement of the names from Annex 10-A (List of names to be applied for protection as Geographical Indications in the territory of the Parties) to the Agreement as soon as practicable after the procedures for protection of geographical indications have been concluded.
- (3) Article 10.18 of the Agreement provides that the Parties agree on the possibility of amending the list of geographical indications for wines, spirits, agricultural products and foodstuffs listed in Annex 10-B to be protected by each Party.
- (4) The Republic of Singapore completed the procedure for protection in its territory of two names ('Bardolino Superiore', 'Tiroler Speck') that were listed in Annex 10-A to the Agreement and were applied for protection as geographical indications of the Union.
- (5) The Republic of Singapore completed the procedure for protection in its territory of one name ('Saint-Emilion Grand Cru') that was not listed in Annex 10-A to the Agreement and was applied for protection as geographical indications of the Union.
- (6) According to Article 10.18 of the Agreement, and following the withdrawal of the United Kingdom from the Union as from 1 January 2021, the name 'Scotch Whisky' should be removed from the names listed in Annex 10-B of the Agreement.
- (7) The name 'Polish Cherry' is no longer protected in the Union and should be removed from Annex 10-A to the Agreement.
- (8) Consequently, Annexes 10-A and 10-B to the Agreement should be amended by listing those additional three names as protected geographical indications of the Union in Annex 10-B and removing two of those names from Annex 10-A. The names 'Scotch Whisky' and 'Polish Cherry' should also be removed respectively from Annex 10-B and Annex 10-A.

HAS ADOPTED THIS DECISION:

Article 1

Annexes 10-A and 10-B to the Free Trade Agreement between the European Union and the Republic of Singapore are replaced by the text in the Annex to this Decision.

Article 2

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

ANNEX

ANNEX 10-A

LIST OF NAMES TO BE APPLIED FOR PROTECTION AS GEOGRAPHICAL INDICATIONS IN THE TERRITORY OF THE PARTIES

SECTION A

Geographical Indications of the Union

	Member State	Geographical Indication	Product Description or Product Class ⁽¹⁾
1.	Czech Republic	Budějovické pivo	Beers
2.	Czech Republic	Budějovický měšťanský var	Beers
3.	Germany	Mittelrhein	Wine
4.	Germany	Rheinhessen	Wine
5.	Germany	Rheingau	Wine
6.	Germany	Mosel	Wine
7.	Germany	Franken	Wine
8.	Germany	Bayerisches Bier	Beers
9.	Germany	Hopfen aus der Hallertau	Other products of Annex I of the Treaty (spices etc.) – Hops
10.	Germany	Schwarzwälder Schinken	Meat products (cooked, salted, smoked, etc.)
11.	Germany	Bremer Klaben	Bread, pastry, cakes, confectionery, biscuits and other baker's wares
12.	Greece	Ρετσίνα Αττικής (Retsina of Attiki)	Wine
13.	Greece	Σάμος (Samos)	Wine
14.	Spain	Utiel-requena	Wine
15.	Spain	Pacharán Navarro	Spirit
16.	Spain	Sierra Mágina	Oils and fats (butter, margarine, oil, etc.) Olive oil
17.	Spain	Aceite del Baix Ebre-Montsía / Oli del Baix Ebre-Montsía	Oils and fats (butter, margarine, oil, etc.) Olive oil
18.	Spain	Aceite del Bajo Aragón	Oils and fats (butter, margarine, oil, etc.) Olive oil
19.	Spain	Antequera	Oils and fats (butter, margarine, oil, etc.) Olive oil
20.	Spain	Priego de Córdoba	Oils and fats (butter, margarine, oil, etc.) Olive oil
21.	Spain	Sierra de Cádiz	Oils and fats (butter, margarine, oil, etc.) Olive oil
22.	Spain	Sierra de Segura	Oils and fats (butter, margarine, oil, etc.) Olive oil
23.	Spain	Sierra de Cazorla	Oils and fats (butter, margarine, oil, etc.) Olive oil

	Member State	Geographical Indication	Product Description or Product Class ⁽¹⁾
24.	Spain	Siurana	Oils and fats (butter, margarine, oil, etc.) Olive oil
25.	Spain	Aceite de Terra Alta / Oli de Terra Alta	Oils and fats (butter, margarine, oil, etc.) Olive oil
26.	Spain	Estepa	Oils and fats (butter, margarine, oil, etc.) Olive oil
27.	Spain	Guijuelo	Meat products (cooked, salted, smoked, etc.) – Hams
28.	Spain	Jamón de Teruel	Meat products (cooked, salted, smoked, etc.) – Hams
29.	Spain	Salchichón de Vic / Llonganissa de Vic	Meat products (cooked, salted, smoked, etc.) – Sausages
30.	Spain	Mahón-Menorca	Cheese
31.	Spain	Cítricos Valencianos / Cítrics Valencians	Fruit, vegetables and cereals fresh or processed – Citrus
32.	Spain	Jijona	Bread, pastry, cakes, confectionery, biscuits and other baker's wares - Nougat
33.	Spain	Turrón de Alicante	Bread, pastry, cakes, confectionery, biscuits and other baker's wares
34.	Spain	Azafrán de la Mancha	Other products of Annex I of the Treaty (spices etc.) – Saffron
35.	France	Moselle	Wine
36.	France	Alsace	Wine
37.	Italy	Pecorino Sardo	Cheese
38.	Italy	Cappero di Pantelleria	Fruit, vegetables and cereals fresh or processed
39.	Italy	Kiwi Latina	Fruit, vegetables and cereals fresh or processed
40.	Italy	Lenticchia di Castelluccio di Norcia	Fruit, vegetables and cereals fresh or processed
41.	Italy	Pesca e nettarina di Romagna	Fruit, vegetables and cereals fresh or processed
42.	Italy	Pomodoro di Pachino	Fruit, vegetables and cereals fresh or processed
43.	Italy	Dolcetto d'Alba	Wine
44.	Italy	Campania	Wine
45.	Italy	Veneto	Wine
46.	Austria	Steirischer Kren	Fruit, vegetables and cereals fresh or processed
47.	Poland	Wódka ziołowa z Niziny Północnopodlaskiej aromatyzowana ekstraktem z trawy żubrowej / Herbal vodka from the North Podlasie Lowland aromatised with an extract of bison grass	Spirit

	Member State	Geographical Indication	Product Description or Product Class ⁽¹⁾
48.	Portugal	Bairrada	Wine
49.	Portugal	Alentejo	Wine
50.	Romania	Cotnari	Wine
51.	Romania	Cotești	Wine
52.	Romania	Panciu	Wine
53.	Romania	Recaș	Wine
54.	Romania	Odobesti	Wine
55.	Slovakia	Vinohradnícka oblasť Tokaj	Wine

(¹) According to the classification of Geographical Indications covered by Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs as set out in Annex XI of Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs.

SECTION B

Geographical indications of Singapore

ANNEX 10-B

PROTECTED GEOGRAPHICAL INDICATIONS

SECTION A

Geographical Indications of the Union

	Member State	Geographical Indication	Product Description or Product Class ⁽¹⁾
1.	Cyprus	Κουμανδάρια	Wine
2.	Cyprus	Ζιβανία/Τζιβανία/ Ζιβάνα/Zivania	Spirit
3.	Czech Republic	České pivo	Beers
4.	Czech Republic	Českobudějovické pivo	Beers
5.	Czech Republic	Žatecký chmel	Other products of Annex I of the Treaty (spices etc.) – Hops
6.	Germany	Korn / Kornbrand ⁽²⁾	Spirit
7.	Germany	Münchener Bier	Beers
8.	Germany	Nürnberger Bratwürste / Nürnberger Rostbratwürste	Meat products (cooked, salted, smoked, etc.) – Sausages
9.	Germany	Aachener Printen	Bread, pastry, cakes, confectionery, biscuits and other baker's wares
10.	Germany	Nürnberger Lebkuchen	Bread, pastry, cakes, confectionery, biscuits and other baker's wares
11.	Germany	Lübecker Marzipan	Bread, pastry, cakes, confectionery, biscuits and other baker's wares

	Member State	Geographical Indication	Product Description or Product Class ⁽¹⁾
12.	Denmark	Danablu	Cheese
13.	Ireland	Irish Whiskey / Uisce Beatha Eireannach / Irish Whisky	Spirit
14.	Ireland	Irish cream	Spirit
15.	Greece	Ούζο / Ouzo ⁽²⁾	Spirit
16.	Greece	Ελιά Καλαμάτας / Elia Kalamatas	Fruit, vegetables and cereals fresh or processed – Table olives
17.	Greece	Μαστίχα Χίου / Masticha Chiou	Natural gums and resins - Chewing gum
18.	Greece	Φέτα / Feta	Cheese
19.	Spain	Málaga	Wine
20.	Spain	Rioja	Wine
21.	Spain	Jerez / Xérès / Sherry / Jerez-Xérès-Sherry	Wine
22.	Spain	Manzanilla - Sanlúcar de Barrameda / Manzanilla	Wine
23.	Spain	La Mancha	Wine
24.	Spain	Cava	Wine
25.	Spain	Navarra	Wine
26.	Spain	Valencia	Wine
27.	Spain	Somontano	Wine
28.	Spain	Ribera del Duero	Wine
29.	Spain	Penedès	Wine
30.	Spain	Bierzo	Wine
31.	Spain	Empordà	Wine
32.	Spain	Priorat	Wine
33.	Spain	Rueda	Wine
34.	Spain	Rías Baixas	Wine
35.	Spain	Jumilla	Wine
36.	Spain	Toro	Wine
37.	Spain	Valdepeñas	Wine
38.	Spain	Cataluña / Catalunya	Wine
39.	Spain	Alicante	Wine
40.	Spain	Brandy de Jerez	Spirit
41.	Spain	Baena	Oils and fats (butter, margarine, oil, etc.) Olive oil
42.	Spain	Les Garrigues	Oils and fats (butter, margarine, oil, etc.) Olive oil

	Member State	Geographical Indication	Product Description or Product Class (1)
43.	Spain	Jabugo	Meat products (cooked, salted, smoked, etc.) – Hams
44.	Spain	Queso Manchego	Cheese
45.	France	Beaujolais	Wine
46.	France	Bordeaux	Wine
47.	France	Bourgogne	Wine
48.	France	Chablis	Wine
49.	France	Champagne	Wine
50.	France	Graves	Wine
51.	France	Médoc	Wine
52.	France	Saint-Emilion	Wine
53.	France	Sauternes	Wine
54.	France	Haut-Médoc	Wine
55.	France	Côtes du Rhône	Wine
56.	France	Languedoc / Coteaux du Languedoc	Wine
57.	France	Côtes du Roussillon	Wine
58.	France	Châteauneuf-du-Pape	Wine
59.	France	Côtes de Provence	Wine
60.	France	Margaux	Wine
61.	France	Touraine	Wine
62.	France	Anjou	Wine
63.	France	Pays d'Oc	Wine
64.	France	Val de Loire	Wine
65.	France	Cognac	Spirit
66.	France	Armagnac	Spirit
67.	France	Calvados	Spirit
68.	France	Comté	Cheese
69.	France	Reblochon / Reblochon de Savoie	Cheese
70.	France	Roquefort	Cheese
71.	France	Camembert de Normandie	Cheese
72.	France	Brie de Meaux	Cheese
73.	France	Emmental de Savoie	Cheese
74.	France	Pruneaux d'Agen	Fruit, vegetables and cereals fresh or processed – Dried cooked plums
75.	France	Huîtres de Marennes Oléron	Fresh fish, molluscs, and crustaceans and products derived there from - Oyster

	Member State	Geographical Indication	Product Description or Product Class (*)
76.	France	Canards à foie gras du Sud-Ouest (Chalosse, Gascogne, Gers, Landes, Périgord, Quercy)	Meat products (cooked, salted, smoked, etc.) – Ducks
77.	France	Jambon de Bayonne	Meat products (cooked, salted, smoked, etc.) – Hams
78.	France	Huile d'olive de Haute-Provence	Oils and fats (butter, margarine, oil, etc.) Olive oil
79.	France	Huile essentielle de lavande de Haute-Provence / Essence de lavande de Haute-Provence	Essential oil -Lavender
80.	France	Saint-Emilion Grand Cru	Wine
81.	Italy	Aceto balsamico tradizionale di Modena	Other products of Annex I of the Treaty (spices etc.) – Sauces
82.	Italy	Aceto Balsamico di Modena	Other products of Annex I of the Treaty (spices etc.) – Sauces
83.	Italy	Cotechino Modena	Meat products (cooked, salted, smoked, etc.)
84.	Italy	Zampone Modena	Meat products (cooked, salted, smoked, etc.)
85.	Italy	Bresaola della Valtellina	Meat products (cooked, salted, smoked, etc.)
86.	Italy	Mortadella Bologna	Meat products (cooked, salted, smoked, etc.)
87.	Italy	Prosciutto di Parma	Meat products (cooked, salted, smoked, etc.) – Hams
88.	Italy	Prosciutto di San Daniele	Meat products (cooked, salted, smoked, etc.) – Hams
89.	Italy	Prosciutto Toscano	Meat products (cooked, salted, smoked, etc.) – Hams
90.	Italy	Provolone Valpadana	Cheese
91.	Italy	Taleggio	Cheese
92.	Italy	Asiago	Cheese
93.	Italy	Fontina	Cheese
94.	Italy	Gorgonzola	Cheese
95.	Italy	Grana Padano	Cheese
96.	Italy	Mozzarella di Bufala Campana	Cheese
97.	Italy	Parmigiano Reggiano	Cheese
98.	Italy	Pecorino Romano	Cheese
99.	Italy	Pecorino Toscano	Cheese
100.	Italy	Arancia Rossa di Sicilia	Fruit, vegetables and cereals fresh or processed

	Member State	Geographical Indication	Product Description or Product Class (*)
101.	Italy	Mela Alto Adige / Südtiroler Apfel	Fruit, vegetables and cereals fresh or processed
102.	Italy	Grappa	Spirit
103.	Italy	Chianti	Wine
104.	Italy	Marsala	Wine
105.	Italy	Asti	Wine
106.	Italy	Barbaresco	Wine
107.	Italy	Barolo	Wine
108.	Italy	Acqui / Brachetto d'Acqui	Wine
109.	Italy	Brunello di Montalcino	Wine
110.	Italy	Vino nobile di Montepulciano	Wine
111.	Italy	Bolgheri Sassicaia	Wine
112.	Italy	Franciacorta	Wine
113.	Italy	Lambrusco di Sorbara	Wine
114.	Italy	Lambrusco Grasparossa di Castelvetro	Wine
115.	Italy	Montepulciano d'Abruzzo	Wine
116.	Italy	Soave	Wine
117.	Italy	Sicilia	Wine
118.	Italy	Toscano / Toscana	Wine
119.	Italy	Conegliano – Prosecco / Conegliano Valdobbiadene – Prosecco / Valdobbiadene – Prosecco	Wine
120.	Italy	Bardolino Superiore	Wine
121.	Austria	Tiroler Speck	Meat products (cooked, salted, smoked, etc.) – Hams
122.	Hungary	Tokaj/Tokaji	Wine
123.	Hungary	Törkölypálinka	Spirit
124.	Hungary	Pálinka	Spirit
125.	Hungary	Szegedi téliszalámi / Szegedi szalámi	Meat products (cooked, salted, smoked, etc.)
126.	Austria	Jägertee / Jagertee / Jagatee	Spirit
127.	Austria	Inländerrum	Spirit
128.	Poland	Polska Wódka/Polish Vodka	Spirit
129.	Portugal	Queijo S. Jorge	Cheese

	Member State	Geographical Indication	Product Description or Product Class ⁽¹⁾
130.	Portugal	Madeira / Vinho da Madeira / Madère / Vin de Madère / Madeira Wine / Madeira Wein / Madera / Vino di Madera / Madeira Wijn	Wine
131.	Portugal	Porto / vinho do Porto / Port / Port Wine / vin de Porto / Oporto / Portvin / Portwein / Portwijn	Wine
132.	Portugal	Douro	Wine
133.	Portugal	Dão	Wine
134.	Portugal	Vinho Verde	Wine
135.	Romania	Dealul Mare	Wine
136.	Romania	Murfatlar	Wine
137.	Romania	Târnave	Wine
138.	Finland	Suomalainen Vodka/ Finsk Vodka / Vodka of Finland	Spirit
139.	Finland	Suomalainen Marjalikööri /Suomalainen Hedelmälikööri / Finsk Bärlikör / Finsk Frutlikör / Finnish berry liqueur / Finnish fruit liqueur	Spirit
140.	Sweden	Svensk Vodka/ Swedish Vodka	Spirit

⁽¹⁾ According to the classification of Geographical Indications covered by Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs as set out in Annex XI of Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs.

⁽²⁾ Product of Germany, Austria, Belgium (German-speaking Community).

⁽³⁾ Product of Greece or Cyprus.

SECTION B

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